FEDERAL REGISTER

Vol. 81 Thursday,

No. 213 November 3, 2016

Pages 76493–76842

OFFICE OF THE FEDERAL REGISTER

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Presidential Documents

Title 3—

The President

Executive Order 13745 of October 31, 2016

Delegation of Function to the Director of the Office of Personnel Management

By virtue of the authority vested in me as President by the Constitution and the laws of the United States, including section 301 of title 3, United States Code, it is hereby ordered as follows:

Section 1. (a) The Director of the Office of Personnel Management (OPM) is hereby authorized to exercise the function vested in the President by section 6391 of title 5, United States Code, of directing OPM to establish an emergency leave transfer program. The Director of OPM shall exercise this authority in consultation with the Director of the Office of Management and Budget.

(b) The Director of OPM shall notify the President of the establishment of any emergency leave transfer program pursuant to the authority in subsection (a).

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.

THE WHITE HOUSE,
October 31, 2016.

[FR Doc. 2016–26753
Filed 11–2–16; 8:45 am]
Billing code 3295–F7–P

Rules and Regulations

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Thursday, November 3, 2016

NATIONAL CREDIT UNION ADMINISTRATION

12 CFR Parts 708a, 708b, and 790

RIN 3133–AE65

Office Name Change

AGENCY: National Credit Union Administration (NCUA).

ACTION: Final rule.

SUMMARY: The NCUA Board (''Board'') is issuing a final rule to rename its Office of Consumer Protection to provide additional clarity about the function and role of the office. The new name will be the Office of Consumer Financial Protection and Access.

DATES: This rule is effective November 3, 2016.

FOR FURTHER INFORMATION CONTACT: Gail W. Laster, Director, Office of Consumer Financial Protection and Access or Elizabeth Wirick, Senior Staff Attorney, Office of General Counsel, 1775 Duke Street, Alexandria, VA 22314 or telephone (703) 518–6540.

SUPPLEMENTARY INFORMATION:

I. Background

In 2009, the Board established the Office of Consumer Protection (OCP) to ensure that NCUA applies all relevant consumer protections, promotes helpful tools for consumers such as financial education and encourages credit unions to serve all eligible consumers. In creating OCP, the Board recognized the need for greater focus on both providing consumer financial protection and increasing access to credit union services.

The new name for the office will better encapsulate its scope and duties. Adding the word ''financial'' to the title of the office clarifies that its focus is on consumer financial protection, rather than other types of consumer protection issues. Adding the word ''access'' to the title of the office emphasizes the office's role in increasing member access to responsible financial services and products, addressing the financial needs of the unbanked and under-banked, and improving the financial conditions of distressed communities. The office's role of handling new charter applications, field of membership expansions and low income designation requests is unique among federal financial regulators and also enhances NCUA's consumer financial protection efforts. Providing additional clarity about the office's mission, namely consumer financial protection and access to financial services, will benefit consumers, their communities and credit unions.

II. Regulatory Procedures

1. Final Rule Under the Administrative Procedure Act (APA)

Generally, the APA requires a federal agency to provide the public with notice and an opportunity to comment on agency rulemakings.[1] This rule is exempt from the APA's notice and comment requirement because it addresses NCUA's organization and structure.[2]

2. Effective Date

The APA also generally requires publication in the **Federal Register** at least 30 days before the effective date of a rule. Agencies can dispense with the 30-day requirement for good cause.[3] NCUA finds good cause to dispense with the 30-day effective date requirement, as this rule is technical rather than substantive. The rule will, therefore, be effective immediately upon publication.

3. Small Business Regulatory Enforcement Fairness Act

The Small Business Regulatory Enforcement Fairness Act of 1996[4] (SBREFA) provides generally for congressional review of agency rules. A reporting requirement is triggered in instances where NCUA issues a final rule as defined by Section 551 of the APA.[5] As required by SBREFA, NCUA has submitted this rule to the Office of Management and Budget for it to determine if the final rule is a ''major rule'' for purposes of SBREFA. NCUA does not believe the rule is major.

4. Regulatory Flexibility Act

The Regulatory Flexibility Act requires NCUA to prepare an analysis of any significant economic impact a regulation may have on a substantial number of small entities (primarily those under $100 million in assets).[6] This final rule will have no economic impact on small credit unions as it addresses only the name of one NCUA office. Accordingly, NCUA certifies the rule will not have a significant economic impact on a substantial number of small credit unions.

5. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (PRA) applies to rulemakings in which an agency by rule creates a new paperwork burden on regulated entities or increases an existing burden.[7] For purposes of the PRA, a paperwork burden may take the form of a reporting or recordkeeping requirement, both referred to as information collections. As the final rule is simply a name change for one of NCUA's offices, NCUA has determined it does not increase paperwork requirements under the PRA.

6. Executive Order 13132

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

7. Assessment of Federal Regulations and Policies on Families

NCUA has determined that this rule will not affect family well-being within

[1] 5 U.S.C. 553(b).
[2] *Id.* (b)(A).
[3] *Id.* 553(d)(3).
[4] Public Law 104–121.
[5] 5 U.S.C. 551.
[6] 5 U.S.C. 603(a).
[7] 44 U.S.C. 3507(d); 5 CFR part 1320.

the meaning of section 654 of the Treasury and General Government Appropriations Act, 1999, Public Law 105–277, 112 Stat. 2681 (1998).

List of Subjects

12 CFR Part 708a

Credit unions, Charter conversions.

12 CFR Part 708b

Credit unions, Mergers of credit unions.

12 CFR Part 790

Organization and functions (Government agencies).

By the National Credit Union Administration Board, on October 27, 2016.

Gerard Poliquin,

Secretary of the Board.

For the reasons discussed above, the National Credit Union Administration amends 12 CFR parts 708a, 708b, and 790 as follows:

PART 708a—BANK CONVERSIONS AND MERGERS

■ 1. The authority citation for part 708a continues to read as follows:

Authority: 12 U.S.C. 1766, 1785(b), and 1785(c).

■ 2. Revise the first sentence of the definition of ''Regional Director'' in § 708a.101 to read as follows:

§ 708a.101 Definitions.

* * * * *

Regional Director means either the director for the NCUA Regional Office for the region where a natural person credit union's main office is located or the director of the NCUA's Office of Consumer Financial Protection and Access. * * *

* * * * *

PART 708b—MERGERS OF FEDERALLY-INSURED CREDIT UNIONS; VOLUNTARY TERMINATION OR CONVERSION OF INSURED STATUS

■ 3. The authority citation for part 708b continues to read as follows:

Authority: 12 U.S.C. 1752(7), 1766, 1785, 1786, and 1789.

■ 4. Revise the first sentence of the definition of ''Regional Director'' in § 708b.2 to read as follows:

§ 708b.2 Definitions.

* * * * *

Regional Director means either the director for the NCUA Regional Office for the region where a natural person credit union's main office is located or the director of the NCUA's Office of Consumer Financial Protection and Access. * * *

* * * * *

PART 790—DESCRIPTION OF NCUA; REQUESTS FOR AGENCY ACTION

■ 5. The authority citation for part 790 continues to read as follows:

Authority: 12 U.S.C. 1766, 1789, 1795f.

■ 6. Revise paragraphs (b)(15)(i) introductory text and (b)(15)(ii) of § 790.2 to read as follows:

§ 790.2 Central and field office organization.

* * * * *

(b) * * *

(15) *Office of Consumer Financial Protection and Access.* (i) The Office of Consumer Financial Protection and Access contains four divisions:

* * * * *

(ii) The Office provides consumer services, including consumer education and complaint resolution; establishes, consolidates, and coordinates consumer financial protections within the agency; acts as the central liaison on consumer financial protection with other federal agencies; and nationalizes field of membership processing and chartering activities.

* * * * *

[FR Doc. 2016–26495 Filed 11–2–16; 8:45 am]

BILLING CODE 7535–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9786]

RIN 1545–BC70

Credit for Increasing Research Activities; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Correcting amendment.

SUMMARY: This document contains corrections to final regulations (TD 9786) that were published in the **Federal Register** on Tuesday, October 4, 2016 (81 FR 68299). The final regulations provided guidance regarding the application of the credit for increasing research activities.

DATES: This correction is effective November 3, 2016 and is applicable on or after October 4, 2016.

FOR FURTHER INFORMATION CONTACT: Martha Garcia or Jennifer Records of the Office of Associate Chief Counsel (Passthroughs and Special Industries) at (202) 317–6853 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The final regulations (TD 9786) that are the subject of this correction are under section 41 of the Internal Revenue Code.

Need for Correction

As published, the final regulations (TD 9786) contain errors that may prove to be misleading and are in need of clarification.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Correction of Publication

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

PART 1—INCOME TAXES

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

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

■ **Par. 2.** Section 1.41–4(c)(6)(viii) is amended by:

■ a. Revising the fifth sentence of *Example 14* paragraph (ii).

■ b. Revising the fifth sentence of *Example 17* paragraph (i).

The revisions read as follows:

§ 1.41–4 Qualified research for expenditures paid or incurred in taxable years ending on or after December 31, 2003.

* * * * *

(c) * * *

(6) * * *

(viii) * * *

Example 14. * * *

(ii) * * * If X's research activities related to the development or improvement of Subset B constitute qualified research under section 41(d), without regard to section 41(d)(4)(E), and the allocable expenditures are qualified research expenditures under section 41(b), X may include $6,250 (25% × $25,000) of the software research expenditures of Subset B in computing the amount of X's credit, pursuant to paragraph (c)(6)(vi)(C) of this section.

* * * * *

Example 17. * * *

(i) * * * The ability to use the idle employees' computers would save X significant costs because X would not have

to buy new hardware to expand the computing power. * * *

* * * * *

Martin V. Franks,

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

[FR Doc. 2016–26522 Filed 10–31–16; 4:15 pm]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9792]

RIN 1545–BJ48

United States Property Held by Controlled Foreign Corporations in Transactions Involving Partnerships; Rents and Royalties Derived in the Active Conduct of a Trade or Business

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations and removal of temporary regulations.

SUMMARY: This document contains final regulations that provide rules regarding the treatment as United States property of property held by a controlled foreign corporation (CFC) in connection with certain transactions involving partnerships. In addition, the final regulations provide rules for determining whether a CFC is considered to derive rents and royalties in the active conduct of a trade or business for purposes of determining foreign personal holding company income (FPHCI), as well as rules for determining whether a CFC holds United States property as a result of certain related party factoring transactions. This document finalizes proposed regulations, and withdraws temporary regulations, published on September 2, 2015. It also finalizes proposed regulations, and withdraws temporary regulations, published on June 14, 1988. The final regulations affect United States shareholders of CFCs.

DATES:

Effective Date: These regulations are effective on November 3, 2016.

Applicability Dates: For dates of applicability, see §§ 1.954–2(i), 1.956–1(g), 1.956–2(h), 1.956–3(d), and 1.956–4(f).

FOR FURTHER INFORMATION CONTACT: Rose E. Jenkins, (202) 317–6934 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

On September 2, 2015, the Department of the Treasury (Treasury Department) and the IRS published final and temporary regulations under sections 954 and 956 (TD 9733) (the 2015 temporary regulations) in the **Federal Register** (80 FR 52976, as corrected at 80 FR 66415 and 80 FR 66416). On the same date, the Treasury Department and the IRS published a notice of proposed rulemaking (REG–155164–09) (the 2015 proposed regulations) in the **Federal Register** (80 FR 53058, as corrected at 80 FR 66485) cross-referencing the temporary regulations and proposing additional regulations under section 956 regarding the treatment as United States property of property held by a CFC in connection with certain transactions involving partnerships. No public hearing was requested or held. Formal written comments were received with respect to the 2015 proposed regulations under section 956 and are available at *www.regulations.gov* or upon request. No comments were received with respect to the 2015 proposed regulations under section 954. This Treasury decision adopts the 2015 proposed regulations, with the changes described in the Summary of Comments and Explanation of Revisions section of this preamble, as final regulations and removes the corresponding temporary regulations. No changes are made to the regulations under section 954.

Additionally, on June 14, 1988, the Treasury Department and the IRS published temporary regulations under sections 304, 864, and 956 (TD 8209) in the **Federal Register** (53 FR 22163), which included guidance under section 956(c)(3) treating as United States property certain trade or service receivables acquired by a CFC from a related United States person in certain factoring transactions (the 1988 temporary regulations). On the same date, the Treasury Department and the IRS published a notice of proposed rulemaking (INTL–49–86, subsequently converted to REG–209001–86) (the 1988 proposed regulations) in the **Federal Register** (53 FR 22186) cross-referencing the 1988 temporary regulations. Although formal written comments were received on the 1988 proposed regulations, none relate to the specific issues addressed in these final regulations. This Treasury decision adopts § 1.956–3 of the 1988 proposed regulations without substantive change as a final regulation (together with the 2015 proposed regulations adopted as final regulations, these final regulations) and removes the corresponding temporary regulations. This preamble does not discuss the formal written comments concerning other rules in the 1988 proposed regulations, which are beyond the scope of these final regulations. The other portions of the 1988 proposed regulations remain in proposed form, except to the extent withdrawn in the partial withdrawal of the notice of proposed rulemaking published in the Proposed Rules section of this issue of the **Federal Register** (REG–122387–16).

The Treasury Department and the IRS published Revenue Ruling 90–112 (1990–2 CB 186) (see § 601.601(d)(2)(ii)(*b*)), on December 31, 1990, before promulgating the rule in § 1.956–2(a)(3) that, prior to modification by this document, addressed the application of section 956 when a CFC is a partner in a partnership that holds property that would be United States property if owned directly by the CFC. This Treasury decision withdraws Revenue Ruling 90–112.

Summary of Comments and Explanation of Revisions

Section 956 determines the amount that a United States shareholder (as defined in section 951(b)) of a CFC must include in gross income with respect to the CFC under section 951(a)(1)(B). This amount is determined, in part, based on the average of the amounts of United States property held, directly or indirectly, by the CFC at the close of each quarter during its taxable year. For this purpose, in general, the amount taken into account with respect to any United States property is the adjusted basis of the property, reduced by any liability to which the property is subject. See section 956(a) and § 1.956–1(e). Section 956(e) grants the Secretary authority to prescribe such regulations as may be necessary to carry out the purposes of section 956, including regulations to prevent the avoidance of section 956 through reorganizations or otherwise.

These final regulations retain the basic approach and structure of the 2015 proposed regulations and the portion of the 1988 proposed regulations that relates to § 1.956–3, with certain revisions, as discussed in this Summary of Comments and Explanation of Revisions.

1. Changes to § 1.956–1 To Conform to the Current Statute

These final regulations take into account certain statutory changes in section 13232(a) of the Revenue Reconciliation Act of 1993 (Pub. L. 103–66, 107 Stat. 312) (the 1993 Act) regarding the methodology for

calculating the amount determined under section 956 with respect to a United States shareholder of a CFC. As enacted in section 12 of the Revenue Act of 1962 (Pub. L. 87–834, 76 Stat. 960) (the 1962 Act), and prior to the modification made by the 1993 Act, section 951(a)(1)(B) required a United States shareholder to include an amount in income based on its pro rata share of the CFC's ''increase in earnings invested in United States property'' for the relevant taxable year. Section 956 (as then in effect), in turn, defined the amount of earnings of a CFC invested in United States property at the close of a taxable year and set forth rules for determining a United States shareholder's pro rata share of the CFC's increase in earnings for a taxable year.

The 1993 Act revised the structure and operating rules for determining amounts included in income under sections 951(a)(1)(B) and 956. In general, as revised in 1993, the amount determined under section 956 is based on a United States shareholder's pro rata share of the average amount of United States property held by the CFC as of the close of each quarter of the relevant taxable year. The amendments made by the 1993 Act are effective for tax years of CFCs beginning after September 30, 1993, and for tax years of United States shareholders in which or with which such tax years of CFCs end.

On February 20, 1964, the Treasury Department and the IRS published § 1.956–1 (TD 6704 (29 FR 2599), which was amended by TD 6795 (30 FR 933) in 1965, TD 7712 (45 FR 52373) in 1980, and TD 8209 (53 FR 22163) in 1988) when the section 956 amount was still determined based on the increase of a CFC's earnings invested in United States property during the relevant tax year. Amendments to § 1.956–1 made after 1993 (TD 9402 (73 FR 35580) and TD 9530 (76 FR 36993, corrected at 76 FR 43891)) did not revise the regulation to reflect the changes to section 956(a) made by the 1993 Act. The Treasury Department and the IRS are aware that some taxpayers have attempted to apply parts of § 1.956–1 to tax years for which those parts were superseded by the 1993 Act. In order to avoid confusion, these final regulations revise the section heading of § 1.956–1 (as well as the parallel heading of § 1.956–1T), and the general rules in § 1.956–1(a), to reflect changes made in the 1993 Act. In addition, these final regulations remove the text in paragraphs (b)(1) through (3), (c), and (d) of § 1.956–1 in order to conform § 1.956–1 to the Code and reserve paragraphs (c) and (d). As a result, proposed § 1.956–1(b)(4) is redesignated as § 1.956–1(b) in these final regulations.

2. Section 1.956–1(b) Anti-Avoidance Rule

Prior to the 2015 temporary regulations, § 1.956–1T(b)(4) provided that a CFC would be considered to hold indirectly investments in United States property acquired by any other foreign corporation that is controlled by the foreign corporation if one of the principal purposes for creating, organizing, or funding (thorugh capital contributions or debt) such other foreign corporation is to avoid the application of section 956 with respect to the CFC. The 2015 temporary regulations modified the anti-avoidance rule in § 1.956–1T(b)(4) so that the rule can also apply when a foreign corporation controlled by a CFC is funded other than through capital contributions or debt and expanded the rule to apply to transactions involving partnerships that are controlled by a CFC.

A. Definition of Funding

In response to the additional guidance on the term funding, a comment suggested that the modification gives rise to uncertainty concerning the application of the anti-avoidance rule and requested that the anti-avoidance rule be revised in these final regulations in one of three alternative ways in order to clarify the application of the rule: (i) Reverting to the language in § 1.956–1T(b)(4) in effect prior to the 2015 temporary regulations; (ii) defining the term funding as either a related CFC contributing capital to or holding debt of the funded entity, or an unrelated person contributing capital to or holding debt of the funded entity, provided that the contribution or loan would not have been made or maintained on the same terms but for the funding CFC contributing capital to or holding debt of the unrelated person; or (iii) clarifying the scope of the term funding with examples that depict when the rule applies and illustrating that common business transactions conducted on arm's-length terms and certain other transactions would not be considered a funding for purposes of the rule.

The Treasury Department and the IRS continue to be concerned about tax planning that is inconsistent with the policy underlying section 956. The policy concerns addressed by the anti-avoidance rule are not limited to fundings by debt or equity; rather, the anti-avoidance rule should apply to all fundings with a principal purpose of avoiding the purposes of section 956, regardless of the form of the funding. The Treasury Department and the IRS have concluded that reverting to the prior formulation of the rule, which applied when there was a ''funding (through capital contributions or debt),'' or adopting the narrow definition of funding proposed in the comment could allow taxpayers to engage in planning that would inappropriately avoid the application of section 956.

In addition, the Treasury Department and the IRS disagree with the view expressed in the comment that the expanded scope of fundings could result in common business transactions being subject to the anti-avoidance rule. Whether a transaction is a ''funding'' does not alone determine whether the transaction is subject to the anti-avoidance rule because the rule applies only when a principal purpose of the funding is to avoid section 956 with respect to the funding CFC. Thus, although the 2015 temporary regulations broaden the funding standard, the ''avoidance'' requirement ensures that ordinary course transactions are not subject to the anti-avoidance rule.

The Treasury Department and the IRS agree, however, that examples illustrating that the anti-avoidance rule should not apply to certain common transactions would be helpful. Accordingly, these final regulations add new examples that address common transactions highlighted by the comment to further illustrate the distinction between funding transactions that are subject to the anti-avoidance rule and common business transactions to which the anti-avoidance rule does not apply. See *Example 4* through *Example 6* of § 1.956–1(b)(4). For example, *Example 5* and *Example 6* illustrate a sale of property for cash in the ordinary course of business and a repayment of a loan, respectively, to which the anti-avoidance rule does not apply. However, *Example 4* illustrates that, consistent with the holding in situation 3 in Revenue Ruling 87–89 (1987–2 CB 195), a CFC may be treated as holding United States property as a result of a deposit with an unrelated bank if the unrelated bank would not have made a loan to another person on the same terms absent the CFC's deposit.

B. Application To Acquisitions of Property by a Partnership Controlled by a CFC

Section 1.956–1(b)(4) of the 2015 proposed regulations expands the anti-avoidance rule to include transactions involving partnerships that are controlled by a CFC that provides funding to the partnership. Proposed § 1.956–1(b)(4)(iii) contains a coordination rule that provides that this

new partnership rule applies only to the extent that the amount of United States property that a CFC would be treated as holding under the rule exceeds the amount that it would be treated as holding under proposed § 1.956–4(b). The coordination rule prevents a CFC from being treated as holding duplicative amounts of United States property as a result of a single partnership interest pursuant to the application of proposed §§ 1.956–1(b)(4) and 1.956–4(b). This rule is illustrated by *Example 4* in proposed § 1.956–1(b)(4)(iv), which is included as *Example 7* in § 1.956–1(b)(4) of these final regulations.

A comment recommended that the anti-avoidance rule should not apply in the case of a partnership in which the funding CFC is a partner, as in *Example 4* in proposed § 1.956–1(b)(4)(iv). Noting that proposed § 1.956–4(b) would treat a funding CFC that is a partner in the funded partnership as owning a share of any United States property acquired by the partnership using the funding, the comment asserted that the inclusion resulting from proposed § 1.956–4(b) is sufficient and there is no need for the anti-avoidance rule to apply to create a disproportionate inclusion that would deter taxpayers from entering into transactions in order to avoid the application of section 956. The Treasury Department and the IRS, however, do not agree with the premise of this comment that the anti-avoidance rule results in a disproportionate inclusion in this case. Rather, the Treasury Department and the IRS consider that, in the circumstances in which the anti-avoidance rule would apply, the funded entity, which is controlled by the CFC, essentially serves as a surrogate for the funding CFC with respect to the investment in United States property. Accordingly, the Treasury Department and the IRS have determined that, when a partnership acts as a surrogate for a CFC partner's investment in United States property, the CFC partner's interest in the United States property should not be limited to the CFC's attributable share of the property as determined under § 1.956–4(b). For these reasons, the comment is not adopted.

With respect to the coordination rule in proposed § 1.956–1(b)(4)(iii), another comment noted that a CFC also could be treated as holding duplicative amounts of United States property as a result of a single partnership obligation pursuant to the application of proposed §§ 1.956–1(b)(4) and 1.956–4(c). For example, suppose a domestic corporation (P) wholly owns two controlled foreign corporations (FS1 and FS2), and P is a 40% partner in a foreign partnership (FPRS), while FS1 is a 60% partner. Suppose further that FS2 loans $100x to FPRS, which FPRS uses to acquire $100x of United States property. In these circumstances, FS2 would be treated as holding $40x of United States property under proposed § 1.956–4(c) and existing § 1.956–2(a) (and would not be treated as holding any United States property under proposed § 1.956–4(b)) and could be treated under proposed § 1.956–1(b)(4) and existing § 1.956–2(a) as holding the $100x of United States property acquired by the partnership with its funding. The Treasury Department and the IRS have determined that it is appropriate to limit the amount of United States property that FS2 is treated as holding in the example to $100x, consistent with the result that would apply if FS2 had not funded FPRS's acquisition of United States property and instead had acquired the United States property itself. (Note that, in a case where proposed § 1.956–1(b)(4) would apply, FPRS should not be treated as holding the United States property that would be treated under that rule as held by FS2, and accordingly, FS1 should not be treated as holding United States property under proposed § 1.956–4(b) in this example.) Accordingly, the coordination rule in proposed § 1.956–1(b)(4)(iii) is expanded in final § 1.956–1(b)(3) to prevent a CFC from being treated as holding duplicative amounts of United States property under the anti-avoidance rule as a result of a partnership obligation, and an additional example is added to illustrate this rule. See § 1.956–1(b)(4), *Example 8*.

Further, as noted in the preamble to the 2015 proposed regulations, the references to § 1.956–2(a)(3) in proposed § 1.956–1(b)(4)(iii) and in the examples in proposed § 1.956–1(b)(4)(iv) that illustrate the application of proposed § 1.956–1(b)(4)(i)(C) are supplanted in these final regulations with references to § 1.956–4(b), which replaces § 1.956–2(a)(3) in these final regulations as the applicable rule concerning United States property held indirectly by a controlled foreign corporation through a partnership.

3. Factoring Rules

As noted in the Background section of this preamble, in 1988, the Treasury Department and the IRS proposed § 1.956–3 to address the application of section 956 to property acquired by a CFC in certain related party factoring transactions. No comments were received on these proposed rules. The 2015 proposed regulations proposed revisions to these proposed rules in § 1.956–3(b)(2)(ii) with respect to the application of section 956 to acquisitions of receivables indirectly through a nominee, pass-through entity, or related foreign corporation, and no comments were received on these proposed revisions. These final regulations adopt these portions of the 2015 proposed regulations without change, and also adopt the remainder of the rules in proposed § 1.956–3 that were proposed in the 1988 proposed regulations, with minor revisions to improve clarity and conform to existing regulations.

4. Partnership Property Indirectly Held by a CFC Partner

Under proposed § 1.956–4(b)(1), a CFC partner in a partnership is treated as holding its attributable share of property held by the partnership. In addition, proposed § 1.956–4(b)(1) provides that, for purposes of section 956, a partner's adjusted basis in the property of the partnership equals the partner's attributable share of the partnership's adjusted basis in the property.

Under proposed § 1.956–4(b)(2), a CFC partner's attributable share of partnership property is determined in accordance with the CFC partner's liquidation value percentage with respect to the partnership, unless the partnership agreement contains a special allocation of income (or, where appropriate, gain) with respect to a particular item or items of partnership property that differs from the partner's liquidation value percentage in a particular taxable year. In that case, the partner's attributable share of the property is determined solely by reference to the partner's special allocation with respect to the property, provided the special allocation does not have a principal purpose of avoiding the purposes of section 956.

A. Revenue Ruling 90–112's Outside Basis Limitation

As noted in the Background section of this Preamble, in 1990, the Treasury Department and the IRS published Revenue Ruling 90–112, which addressed the treatment under section 956 of United States property held by a CFC indirectly through a partnership. The holding in the revenue ruling generally is consistent with § 1.956–2(a)(3) (added by TD 9008, 67 FR 58020, in 2002), as well as proposed § 1.956–4(b), in that a CFC that is a partner in a partnership is treated as indirectly holding property held by the partnership when the property would be United States property if the CFC held

it directly. However, the revenue ruling includes a limitation on the measurement of United States property that is not included in the final or proposed regulations. Specifically, the revenue ruling provides that the amount of United States property taken into account for purposes of section 956 when a CFC partner indirectly owns property through a partnership is limited by the CFC's adjusted basis in the partnership.

The outside basis limitation in Revenue Ruling 90–112 has resulted in a lack of clarity concerning the determination of the amount of United States property held by a CFC partner through a partnership because neither § 1.956–2(a)(3) nor proposed § 1.956–4(b) include the limitation. A comment requested that proposed § 1.956–4(b)(1) be revised to add the outside basis limitation because the limitation is reflective of the underlying economics and consistent with the policy underlying section 956.

After consideration of the comment, the Treasury Department and the IRS have concluded that the outside basis limitation is not warranted. The rule in proposed § 1.956–4(b)(1) is based on an aggregate approach to partnerships and measures the amount of United States property indirectly held by a CFC partner on a property-by-property basis. An overall limitation on the amount of United States property a CFC partner is considered to indirectly hold through a partnership is inconsistent with this property-by-property aggregate approach to United States property held by the partnership. Additionally, a limitation determined by reference to a CFC partner's basis in its partnership interest is less consistent with section 956(a), which provides that the amount of United States property directly or indirectly held by a CFC is determined by reference to the adjusted basis of the United States property itself. Moreover, the Treasury Department and the IRS are concerned that, under the rules of subchapter K, adjustments may be made to outside basis through the allocation of liabilities pursuant to the regulations under section 752 that are inconsistent with the policy of section 956. Accordingly, the Treasury Department and the IRS have determined that an outside basis limitation should not be incorporated into the rule in proposed § 1.956–4(b)(1). Because proposed § 1.956–4(b)(1) indicates that, for purposes of section 956, a partner's adjusted basis in the property of the partnership equals the partners' attributable share of the partnership's adjusted basis in the property, no revision to the rule is necessary to clarify that there is no outside basis limitation.

Revenue Ruling 90–112 is obsoleted in the Effect on Other Documents section of this preamble. For tax years ending prior to the obsolescence of the revenue ruling, taxpayers may rely on the outside basis limitation provided in the revenue ruling.

B. Consistent Use of Liquidation Value Percentage Method for Purposes of Both § 1.956–4(b) and (c)

In contrast to the rule provided in proposed § 1.956–4(b) providing that a CFC partner's attributable share of partnership property is determined in accordance with the CFC partner's liquidation value percentage, proposed § 1.956–4(c) provided that a partner's share of a partnership obligation is determined in accordance with the partner's interest in partnership profits. The preamble to the 2015 proposed regulations requested comments as to whether a single method should be used as the general rule for determining both a partner's share of partnership assets under proposed § 1.956–4(b) and a partner's share of a partnership obligation under proposed § 1.956–4(c), and, if so, whether the appropriate measure would be a partner's interest in partnership profits, liquidation value percentage, or an alternative measure. Comments suggested that a liquidation value percentage method should be used for purposes of both sets of rules. In accordance with these comments, these final regulations retain the liquidation value percentage method set forth in proposed § 1.956–4(b), and, as discussed in Part 5.B of this Summary of Comments and Explanation of Revisions, revise the general rule in proposed § 1.956–4(c) to implement the liquidation value percentage method.

C. Time for Determining the Liquidation Value Percentage

A comment recommended that the liquidation value percentage of partners in a partnership should be determined on an annual basis, rather than upon formation and upon the occurrence of events described in § 1.704–1(b)(2)(iv)(*f*)(*5*) or § 1.704–1(b)(2)(iv)(*s*)(*1*) (revaluation events) as provided in proposed § 1.956–4(b)(2)(i). The comment noted that partnerships do not necessarily book up (or adjust) partnership capital accounts in connection with revaluation events and suggested that requiring a redetermination of liquidation value percentage regardless of whether a book-up occurs would impose a burden on such partnerships. The comment also noted that partners' relative economic interests in the partnership may change for reasons unrelated to revaluation events, such as when a partnership agreement provides for different profit sharing percentages that apply based on different hurdles.

The Treasury Department and the IRS continue to consider it appropriate for liquidation value percentage to be redetermined upon a revaluation event, which may result in a significant change in the partners' relative economic interests in a partnership. Accordingly, upon a revaluation event, a partnership is required to determine the partnership's capital accounts resulting from a hypothetical book up at such point in time even if the partnership did not actually book up capital accounts in connection with such an event. However, in light of the comment's observation that partners' relative economic interests in the partnership may change significantly as a result of allocations of income or other items under the partnership agreement even in the absence of a revaluation event, § 1.956–4(b)(2)(i) of these final regulations provides that a partner's liquidation value percentage must be redetermined in certain additional circumstances. Specifically, if the liquidation value percentage determined for any partner on the first day of the partnership's taxable year would differ from the most recently determined liquidation value percentage of that partner by more than 10 percentage points, then the liquidation value percentage must be redetermined on that day even in the absence of a revaluation event. For example, if the liquidation value percentage of a partner was determined upon a revaluation event to be 40 percent and, on the first day of a subsequent year before the occurrence of another revaluation event, would be less than 30 percent or more than 50 percent if redetermined on that day, then the liquidation value percentage must be redetermined on that day.

D. Special Allocations

Proposed § 1.956–4(b)(2)(ii) defines a special allocation as an allocation of income (or, where appropriate, gain) from partnership property to a partner under a partnership agreement that differs from the partner's liquidation value percentage in a particular taxable year. In this regard, questions have arisen as to whether allocations pursuant to section 704(c) and the regulations thereunder constitute special allocations. Although a partnership agreement may reference section 704(c) or provide for the adoption of a particular section 704(c)

method, allocations under section 704(c) are tax allocations required by operation of the Code and regulations. In response to these questions, the Treasury Department and the IRS have revised the definition of special allocations in final § 1.956–4(b)(2)(ii) to clarify that a special allocation is an allocation of book income or gain, rather than a tax allocation such as the allocations required under section 704(c).

Questions also have arisen as to whether certain allocations of income with respect to all of the property of a partnership, as opposed to allocations of income from a specific item or subset of partnership property, constitute special allocations described in proposed § 1.956–4(b)(2)(i). These final regulations clarify that, for purposes of these regulations, a special allocation means only an allocation of income (or, where appropriate, gain) from a subset of the property of the partnership to a partner other than in accordance with the partner's liquidation value percentage in a particular taxable year.

As noted in this Part 4 of this Summary of Comments and Explanation of Revisions, proposed § 1.956–4(b)(2)(ii) states that a partner's attributable share of an item of partnership property is not determined by reference to a special allocation with respect to the property if the special allocation has a principal purpose of avoiding the purposes of section 956. A comment requested that these final regulations provide guidance on the circumstances in which special allocations are treated as having a principal purpose of avoiding section 956. Specifically, the comment suggested that proposed § 1.956–4(b) be revised to include a presumption that a transaction does not have a principal purpose of avoiding section 956 when the allocation is respected under section 704(b) and is reasonable taking into account the facts and circumstances relating to the economic arrangement of the partners and the characteristics of the property at issue.

The determination of whether a special allocation has a principal purpose of avoiding the purposes of section 956 must take into account all of the relevant facts and circumstances, which include the factors set forth in the comment. However, an allocation adopted with a principal purpose of avoiding the purposes of section 956 could nonetheless be respected under section 704(b), which is not based on, and does not take into account, section 956 policy considerations. In addition, it is not clear what additional clarity would be added by the reasonableness requirement, which itself is necessarily a facts-and-circumstances determination. After consideration of the comment, the Treasury Department and the IRS have determined that the presumption requested by the comment is not appropriate, and the comment is not adopted.

A comment noted that determining a partner's attributable share of an item of property by reference to a special allocation of income or gain with respect to that property could produce results that are inconsistent with the liquidation value percentage approach because of the forward-looking nature of special allocations. The comment described, but did not explicitly recommend, an alternative approach that would limit the effect of a special allocation to the portion of the liquidation value that represents actual appreciation, as opposed to initial book value. The Treasury Department and the IRS recognize the conceptual issue highlighted by the comment but have determined that the alternative approach described by the comment would entail substantial administrative complexity. Additionally, the Treasury Department and the IRS continue to consider it appropriate, in cases in which special allocations are economically meaningful, to determine a partner's attributable share of property in accordance with such special allocations, since such allocations replicate the effect of owning, outside of the partnership, an interest in the property that is proportional to the special allocation.

However, the Treasury Department and the IRS have determined that special allocations with respect to a partnership controlled by a U.S. multinational group (a controlled partnership) and its CFCs are unlikely to have economic significance for the group as a whole and can facilitate inappropriate tax planning. Accordingly, the Treasury Department and the IRS are proposing a new rule in a notice of proposed rulemaking in the Proposed Rules section of this issue of the **Federal Register** (REG–114734–16) under which a partner's attributable share of property of a controlled partnership is determined solely in accordance with the partner's liquidation value percentage, without regard to any special allocations.

5. Obligations of Foreign Partnerships

A. Use of an Aggregate Approach as the General Rule

Pursuant to section 956(c), United States property includes an obligation of a United States person. In addition, under section 956(d) and § 1.956–2(c), a CFC is treated as holding an obligation of a United States person if the CFC is a pledgor or guarantor of the obligation. Therefore, if a CFC makes or guarantees a loan to a United States person, an income inclusion may be required with respect to the CFC under sections 951(a)(1)(B) and 956. Under the general rule in proposed § 1.956–4(c)(1), an obligation of a foreign partnership would be treated as an obligation of its partners in proportion to the partners' interest in partnership profits, unless the exception in proposed § 1.956–4(c)(2) (for obligations of partnerships in which neither the lending CFC nor any person related to the lending CFC is a partner) or the special rule in proposed § 1.956–4(c)(3) (regarding certain partnership distributions) applies. Thus, the general rule adopts an aggregate approach that would treat an obligation of a foreign partnership as an obligation of its partners.

A comment asserted that taking the aggregate approach to a foreign partnership for this purpose is overly broad and inconsistent with the policy underlying section 956. The comment states that a CFC loan to a foreign partnership results in a repatriation of CFC earnings to the United States partners in the partnership only when the loan proceeds either are used to acquire United States property or are distributed to the partners, which, according to the comment, are adequately addressed in § 1.956–1T(b)(4) and (5). Accordingly, the comment requested that the rules in § 1.956–1T(b)(4) and (5) be finalized, but that the general rule in § 1.956–4(c)(1) be removed. Thus, the comment generally advocates for the treatment of a foreign partnership as an entity, with anti-abuse rules to address certain situations. In contrast, another comment indicated that the concerns identified in the preamble to the 2015 proposed regulations ''constitute an appropriate basis for the general aggregate approach of [proposed § 1.956–4(c)(1)]''.

After consideration of the comments, the Treasury Department and the IRS have concluded that it is appropriate to retain the aggregate approach of the general rule in proposed § 1.956–4(c). The Treasury Department and the IRS disagree with the assertion that the aggregate approach is not supported by the policy of section 956. As discussed in the preamble to the 2015 proposed regulations, failing to treat an obligation of a foreign partnership as an obligation of its partners could allow for the deferral of U.S. taxation of CFC earnings and profits in a manner that is inconsistent with the purpose of section

956. As discussed in that preamble, the legislative history provides that Congress intended section 956 to apply when deferred CFC earnings are made available to a United States shareholder, which occurs when a United States shareholder conducts operations through a foreign partnership that are funded by deferred CFC earnings, without regard to whether there is any distribution from the partnership to the United States shareholder. In addition, as described in Section C of this Part 5 of this Summary of Comments and Explanation of Revisions, there are exceptions from the treatment of obligations as United States property under § 1.956–4(c) that the Treasury Department and the IRS have determined mitigate some of the concerns about the breadth of the general rule raised by the comment. Accordingly, the final regulations do not adopt the recommendation to abandon the aggregate approach.

B. Liquidation Value Percentage Method

The preamble to the 2015 proposed regulations requested comments on whether the liquidation value percentage method or another method would be a more appropriate basis for determining a partner's share of a foreign partnership's obligation. In addition, as noted in Part 4.B of this Summary of Comments and Explanation of Revisions, the 2015 proposed regulations solicited comments on whether a single method should be used for determining both a partner's share of partnership assets under proposed § 1.956–4(b) and a partner's share of partnership obligations under proposed § 1.956–4(c).

Comments highlighted a number of issues related to applying a rule based on a partner's interest in partnership profits and noted the lack of guidance in the 2015 proposed regulations for applying this standard for purposes of proposed § 1.956–4(c). The comments stated that a partner's interest in partnership profits would be a difficult standard to apply for partnerships other than simple partnerships, because a partner's interest in partnership profits can fluctuate significantly from year to year, as well as during a taxable year. The comments noted that the proposed rule did not address whether the determination would be made based solely on the partnership's profits in the current year or whether the determination would take into account the expected profits over the term of the partnership. Moreover, under section 956(a), the amount of United States property held by a CFC as a result of being treated as holding an obligation of a related United States person under proposed § 1.956–4(c) would be the average of the amounts held by the CFC at the close of each quarter of its taxable year. Thus, under proposed § 1.956–4(c), taxpayers would need to determine a CFC partner's interest in partnership profits on a quarterly basis when a relevant partnership obligation is outstanding throughout a taxable year. As a result, calculating the amount of United States property held by a CFC in a taxable year could be complicated when a partner's interest in partnership profits is not known until the end of the taxable year (such as when there are one or more tiers of allocations of partnership profits based on various internal rate of return hurdles). Furthermore, the requirement to determine a CFC's interest in United States property on a quarterly basis could result in the calculation of a section 956 amount that is inconsistent with the annual profit allocated to the partner from the partnership for that year.

After consideration of these comments, the Treasury Department and the IRS have determined that the liquidation value percentage method should be used to determine a partner's share of a foreign partnership's obligation because of the potential for complexity in calculating a partner's interest in partnership profits for purposes of proposed § 1.956–4(c) as well as the uncertainty inherent in the method. The liquidation value percentage method is a sound indicator of a partner's interest in a partnership. Moreover, the objective rules provided in proposed § 1.956–4(b) for determining the liquidation value percentage provide more certainty than the rule in proposed § 1.956–4(c). In addition, using the same standard for determining a partner's share of partnership property and a partner's share of partnership obligations reduces complexity for taxpayers that must apply both sets of rules for purposes of section 956 with respect to a single partnership. Accordingly, these final regulations provide that an obligation of a foreign partnership is treated as an obligation of its partners in proportion to the partners' liquidation value percentage with respect to the partnership. As described in Part 4.C of this Summary of Comments and Explanation of Revisions, a partner's liquidation value percentage must be determined upon formation of a partnership and any revaluation events and in certain other circumstances in which redetermination of the liquidation value percentage would result in a significant change from the previously determined liquidation value percentage.

C. Exceptions From General Rule of Aggregate Treatment

Proposed § 1.956–4(c)(2) provides an exception from the aggregate treatment of proposed § 1.956–4(c)(1) that applies if neither the CFC that holds the obligation (or is treated as holding the obligation) nor any person related to the CFC (within the meaning of section 954(d)(3)) is a partner in the partnership on the CFC's quarterly measuring date on which the treatment of the obligation as United States property is being determined. A comment suggested an additional exception from the general rule in proposed § 1.956–4(c)(1) providing for aggregate treatment of partnership obligations. The comment requested that an obligation of a foreign partnership not be treated as an obligation of its partners to the extent that the obligation arises from a routine, ordinary course transaction between the lending CFC and the foreign partnership.

The comment highlighted a fact pattern involving an obligation arising from a deposit by a CFC with a foreign partnership that acts as a coordination center for a taxpayer's cash pooling system. In this case, the comment asserted that any United States partners in the partnership should not be considered to have accessed the deferred earnings of the CFC deposited with the partnership and that, accordingly, the aggregate approach to partnership obligations should not apply to treat the CFC as holding an obligation of the United States partners for purposes of section 956. Regarding this fact pattern, the Treasury Department and the IRS observe that the short-term obligation exception in § 1.956–2T(d)(2)(iv), which applies when a CFC holds obligations of a United States person for a limited period of time during a taxable year, generally would prevent an inclusion under section 956 in the fact pattern described in the comment if the CFC had a net deposit with the partnership only for the limited period of time described in that exception. The Treasury Department and the IRS have concluded that there is no reason to provide a more expansive exception from United States property treatment for obligations of a foreign partnership with certain United States persons as partners than would apply with respect to obligations incurred directly by those same United States persons.

Another comment recommended adding a new *de minimis* exception that

would provide that an obligation of a foreign partnership is not treated as an obligation of a United States person that is a partner if the United States person and its related persons own less than a specified percentage, 10% or 20%, of the profits and capital interests in the foreign partnership. The comment noted that a U.S. partner with a relatively small interest in a partnership may lack the ability to cause the partnership to make a distribution to the U.S. partner.

Although a U.S. partner with a relatively small partnership interest may not be able to compel a distribution from the partnership, the potential to directly access partnership assets is not, as the comment acknowledges, the sole or overriding consideration motivating the aggregate approach to partnerships under the proposed regulations and these final regulations. Even if the other partners in a partnership in which a United States shareholder of a CFC is a minority partner are unrelated to the United States shareholder, the United States shareholder would still benefit from the funding of the partnership's business with deferred earnings of the CFC to the extent of its interest in the partnership. Additionally, as noted in the preamble to the 2015 proposed regulations, a standard based on whether the funding CFC or a related person is a partner in the partnership, rather than whether such persons own a certain minimum interest in the partnership, is consistent with the relevant exception adopted by Congress in section 956(c)(2)(L).

Accordingly, the Treasury Department and the IRS have determined that the additional exceptions to aggregate treatment suggested in the comments are not warranted.

D. Special Obligor Rule in the Case of Certain Distributions

The 2015 proposed regulations include a special funded distribution rule that increases the amount of a foreign partnership obligation that is treated as United States property when the following requirements are satisfied: (i) A CFC lends funds (or is a pledgor or guarantor with respect to a loan) to a foreign partnership whose obligation is, in whole or in part, United States property with respect to the CFC pursuant to proposed § 1.956–4(c)(1) and existing § 1.956–2(a); (ii) the partnership distributes an amount of money or property to a partner that is related to the CFC (within the meaning of section 954(d)(3)) and whose obligation would be United States property if held (or treated as held) by the CFC; (iii) the foreign partnership would not have made the distribution but for a funding of the partnership through an obligation held (or treated as held) by the CFC; and (iv) the distribution exceeds the partner's share of the partnership obligation as determined in accordance with the partner's interest in partnership profits. When these requirements are satisfied, proposed § 1.956–4(c)(3) provided that the amount of the partnership obligation that is treated as an obligation of the distributee partner (and thus as United States property held by the CFC) is the lesser of the amount of the distribution that would not have been made but for the funding of the partnership and the amount of the partnership obligation.

Comments suggested that taxpayers might take the position that the ''but for'' requirement in proposed § 1.956–4(c)(3) is not satisfied in certain situations in which CFC earnings are effectively repatriated to a partner that is a related United States person. For example, taxpayers might take the position that a partnership distribution could have been made without the funding by the CFC merely by establishing that a third party would have loaned the funds needed for the partnership to make the distribution. The Treasury Department and the IRS have determined that this position is inconsistent with the purposes of this rule. Accordingly, these final regulations clarify the funded distribution rule by providing with respect to the ''but for'' requirement in proposed § 1.956–4(c)(3) that a foreign partnership will be treated as if it would not have made a distribution of liquid assets but for a funding of the partnership through obligations held (or treated as held) by a CFC to the extent the foreign partnership did not have sufficient liquid assets to make the distribution immediately prior to the distribution, without taking into account the obligations. When a CFC holds (or is treated as holding) multiple obligations of the foreign partnership to which this rule could potentially apply, its applicability is determined first with respect to the obligation acquired (or treated as acquired) closest in time to the distribution, and then successively to other obligations further in time from the distribution until the distribution is fully accounted for.

6. Comments Concerning Multiple Inclusions

Comments were received in response to the request for comments included in the preamble to the 2015 proposed regulations concerning whether the Treasury Department and the IRS should exercise the authority granted under section 956(e) to prescribe regulations concerning situations in which multiple CFCs serve, or are treated, as pledgors or guarantors of a single obligation for purposes of section 956(d) in order to limit the aggregate inclusions of a United States shareholder with respect to a CFC under sections 951(a)(1)(B) and 956 to the unpaid principal amount of the obligation. The Treasury Department and the IRS continue to study the comments concerning multiple inclusions under section 956(d), which do not impact any of the proposed regulations adopted by this Treasury decision.

Effective/Applicability Dates

The rules in § 1.954–2(c)(1)(i) and (d)(1)(i) (regarding the active development test) apply to rents or royalties, as applicable, received or accrued during taxable years of CFCs ending on or after September 1, 2015, and to taxable years of United States shareholders in which or with which such taxable years end, but only with respect to property manufactured, produced, developed, or created, or, in the case of acquired property, property to which substantial value has been added, on or after September 1, 2015. The rules in § 1.954–2(c)(1)(iv), (c)(2)(ii), (d)(1)(ii), and (d)(2)(ii) (regarding the active marketing test), as well as the rules in § 1.954–2(c)(2)(iii)(E), (c)(2)(viii), (d)(2)(iii)(E), and (d)(2)(v) (regarding cost-sharing arrangements), apply to rents or royalties, as applicable, received or accrued during taxable years of CFCs ending on or after September 1, 2015, and to taxable years of United States shareholders in which or with which such taxable years end, to the extent that such rents or royalties are received or accrued on or after September 1, 2015. The section 956 anti-avoidance rules in § 1.956–1(b) apply to taxable years of CFCs ending on or after September 1, 2015, and to taxable years of United States shareholders in which or with which such taxable years end, with respect to property acquired, including property treated as acquired as the result of a deemed exchange of property pursuant to section 1001, on or after September 1, 2015. The rules regarding factoring transactions in § 1.956–3 (other than § 1.956–3(b)(2)(ii)) apply to trade or service receivables acquired (directly or indirectly) after March 1, 1984.

The remaining rules in these final regulations apply to taxable years of CFCs ending on or after November 3, 2016, and taxable years of United States shareholders in which or with which such taxable years end. In general, these remaining rules apply to property

acquired, or pledges or guarantees entered into, on or after September 1, 2015, including property considered acquired, and pledges and guarantees considered entered into, on or after September 1, 2015, as a result of a deemed exchange pursuant to section 1001. See § 1.956–4(c) (dealing with obligations of foreign partnerships); §§ 1.956–2(c), 1.956–4(d), and 1.956–1(e)(2) (dealing with pledges and guarantees, including pledges and guarantees by a partnership and with respect to obligations of a foreign partnership); and § 1.956–3(b)(2)(ii) (dealing with trade and service receivables acquired from related United States persons indirectly through nominees, pass-through entities, or related foreign corporations). Two rules, however, apply to all obligations held on or after November 3, 2016. See §§ 1.956–2(a)(3) and 1.956–4(e) (dealing with obligations of disregarded entities and domestic partnerships, respectively). Finally, § 1.956–4(b) (dealing with partnership property indirectly held by a CFC) applies to property acquired on or after November 3, 2016. No inference is intended as to the application of the provisions amended by these final regulations under prior law, including in transactions involving obligations of foreign partnerships. The IRS may, where appropriate, challenge transactions under the Code, regulatory provisions under prior law, or judicial doctrines.

Effect on Other Documents

Rev. Rul. 90–112 (1990–2 CB 186) is obsolete as of November 3, 2016.

Special Analyses

Certain IRS regulations, including these regulations, are exempt from the requirements of Executive Order 12866, as supplemented and reaffirmed by Executive Order 13563. Therefore, a regulatory assessment is not required. It has also 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 the 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), the notice of proposed rulemaking preceding these regulations was submitted to the Chief Counsel of Advocacy of the Small Business Administration for comment on its impact on small business.

Drafting Information

The principal author of these regulations is Rose E. Jenkins of the Office of Associate Chief Counsel (International). However, other personnel from the Treasury Department and the IRS participated in their development.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Adoption of Amendments to the Regulations

Accordingly, 26 CFR part 1 is amended as follows:

PART 1—INCOME TAXES

■ **Paragraph 1.** The authority citation for part 1 is amended by adding entries in numerical order to read in part as follows:

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

Section 1.956–1 also issued under 26 U.S.C. 956(d) and 956(e).

Section 1.956–2 also issued under 26 U.S.C. 956(d) and 956(e).

Section 1.956–3 also issued under 26 U.S.C. 864(d)(8) and 956(e).

Section 1.956–4 also issued under 26 U.S.C. 956(d) and 956(e).

* * * * *

■ **Par. 2.** Section 1.954–2 is amended by:

■ 1. Revising paragraphs (c)(1)(i), (c)(1)(iv), and (c)(2)(ii).

■ 2. Removing the word ''and'' at the end of paragraph (c)(2)(iii)(C).

■ 3. Removing the period at the end of paragraph (c)(2)(iii)(D) and adding in its place a semicolon and the word ''and''.

■ 4. Revising paragraphs (c)(2)(iii)(E) and (c)(2)(viii).

■ 5. Revising paragraphs (d)(1)(i), (d)(1)(ii), and (d)(2)(ii).

■ 6. Removing the word ''and'' at the end of paragraph (d)(2)(iii)(C).

■ 7. Removing the period at the end of paragraph (d)(2)(iii)(D), and adding in its place a semicolon and the word ''and''.

■ 8. Revising paragraphs (d)(2)(iii)(E) and (d)(2)(v).

■ 9. Revising paragraph (i).

The revisions and additions read as follows:

§ 1.954–2 Foreign personal holding company income.

* * * * *

(c) * * *

(1) * * *

(i) Property that the lessor, through its own officers or staff of employees, has manufactured or produced, or property that the lessor has acquired and, through its own officers or staff of employees, added substantial value to, but only if the lessor, through its officers or staff of employees, is regularly engaged in the manufacture or production of, or in the acquisition and addition of substantial value to, property of such kind;

* * * * *

(iv) Property that is leased as a result of the performance of marketing functions by such lessor through its own officers or staff of employees located in a foreign country or countries, if the lessor, through its officers or staff of employees, maintains and operates an organization either in such country or in such countries (collectively), as applicable, that is regularly engaged in the business of marketing, or of marketing and servicing, the leased property and that is substantial in relation to the amount of rents derived from the leasing of such property.

(2) * * *

(ii) *Substantiality of foreign organization.* For purposes of paragraph (c)(1)(iv) of this section, whether an organization either in a foreign country or in foreign countries (collectively) is substantial in relation to the amount of rents is determined based on all the facts and circumstances. However, such an organization will be considered substantial in relation to the amount of rents if active leasing expenses, as defined in paragraph (c)(2)(iii) of this section, equal or exceed 25 percent of the adjusted leasing profit, as defined in paragraph (c)(2)(iv) of this section. In addition, for purposes of aircraft or vessels leased in foreign commerce, an organization will be considered substantial if active leasing expenses, as defined in paragraph (c)(2)(iii) of this section, equal or exceed 10 percent of the adjusted leasing profit, as defined in paragraph (c)(2)(iv) of this section. For purposes of paragraphs (c)(1)(iv) and (c)(2) of this section and § 1.956–2(b)(1)(vi), the term *aircraft or vessels* includes component parts, such as engines that are leased separately from an aircraft or vessel.

(iii) * * *

(E) Deductions for CST Payments or PCT Payments (as defined in § 1.482–7(b)).

* * * * *

(viii) *Cost sharing arrangements (CSAs).* For purposes of paragraphs (c)(1)(i) and (iv) of this section, CST Payments or PCT Payments (as defined in § 1.482–7(b)(1)) made by the lessor to another controlled participant (as defined in § 1.482–7(j)(1)(i)) pursuant to a CSA (as defined in § 1.482–7(a)) do not cause the activities undertaken by that other controlled participant to be considered to be undertaken by the lessor's own officers or staff of employees.

* * * * *

(d) * * *

(1) * * *

(i) Property that the licensor, through its own officers or staff of employees, has developed, created, or produced, or property that the licensor has acquired and, through its own officers or staff of employees, added substantial value to, but only so long as the licensor, through its officers or staff of employees, is regularly engaged in the development, creation, or production of, or in the acquisition and addition of substantial value to, property of such kind; or

(ii) Property that is licensed as a result of the performance of marketing functions by such licensor through its own officers or staff of employees located in a foreign country or countries, if the licensor, through its officers or staff of employees, maintains and operates an organization either in such foreign country or in such foreign countries (collectively), as applicable, that is regularly engaged in the business of marketing, or of marketing and servicing, the licensed property and that is substantial in relation to the amount of royalties derived from the licensing of such property.

(2) * * *

(ii) *Substantiality of foreign organization.* For purposes of paragraph (d)(1)(ii) of this section, whether an organization either in a foreign country or in foreign countries (collectively) is substantial in relation to the amount of royalties is determined based on all of the facts and circumstances. However, such an organization will be considered substantial in relation to the amount of royalties if active licensing expenses, as defined in paragraph (d)(2)(iii) of this section, equal or exceed 25 percent of the adjusted licensing profit, as defined in paragraph (d)(2)(iv) of this section.

(iii) * * *

(E) Deductions for CST Payments or PCT Payments (as defined in § 1.482–7(b)).

* * * * *

(v) *Cost sharing arrangements (CSAs).* For purposes of paragraphs (d)(1)(i) and (ii) of this section, CST Payments or PCT Payments (as defined in § 1.482–7(b)(1)) made by the licensor to another controlled participant (as defined in § 1.482–7(j)(1)(i)) pursuant to a CSA (as defined in § 1.482–7(a)) do not cause the activities undertaken by that other controlled participant to be considered to be undertaken by the licensor's own officers or staff of employees.

* * * * *

(i) *Effective/applicability dates*—(1) *Paragraphs (c)(2)(v) through (vii).* Paragraphs (c)(2)(v) through (vii) of this section and *Example 6* of paragraph (c)(3) of this section apply to taxable years of controlled foreign corporations beginning on or after May 2, 2006, and for taxable years of United States shareholders with or within which such taxable years of the controlled foreign corporations end. Taxpayers may elect to apply paragraphs (c)(2)(v) through (vii) to taxable years of controlled foreign corporations beginning after December 31, 2004, and for taxable years of United States shareholders with or within which such taxable years of the controlled foreign corporations end. If an election is made to apply § 1.956–2(b)(1)(vi) to taxable years beginning after December 31, 2004, then the election must also be made for paragraphs (c)(2)(v) through (vii) of this section.

(2) *Other paragraphs.* Paragraphs (c)(1)(i) and (d)(1)(i) of this section apply to rents or royalties, as applicable, received or accrued during taxable years of controlled foreign corporations ending on or after September 1, 2015, and to taxable years of United States shareholders in which or with which such taxable years end, but only with respect to property manufactured, produced, developed, or created, or in the case of acquired property, property to which substantial value has been added, on or after September 1, 2015. Paragraphs (c)(1)(iv), (c)(2)(ii), (c)(2)(iii)(E), (c)(2)(viii), (d)(1)(ii), (d)(2)(ii), (d)(2)(iii)(E), and (d)(2)(v) of this section apply to rents or royalties, as applicable, received or accrued during taxable years of controlled foreign corporations ending on or after September 1, 2015, and to taxable years of United States shareholders in which or with which such taxable years end, to the extent that such rents or royalties are received or accrued on or after September 1, 2015. See § 1.954–2(c)(1)(i), (c)(1)(iv), (c)(2)(ii), (c)(2)(iii), (d)(1)(i), (d)(1)(ii), (d)(2)(ii), and (d)(2)(iii), as contained in 26 CFR part 1 revised as of April 1, 2015, for rules applicable to rents or royalties, as applicable, received or accrued before September 1, 2015.

* * * * *

§ 1.954–2T [Removed]

■ **Par. 3.** Section 1.954–2T is removed.

■ **Par. 4.** Section 1.956–1 is amended by:

■ 1. Revising the section heading and paragraphs (a) and (b).

■ 2. Removing and reserving paragraphs (c) and (d).

■ 3. Revising paragraphs (e)(2) and (g).

The revisions read as follows:

§ 1.956–1 Shareholder's pro rata share of the average of the amounts of United States property held by a controlled foreign corporation.

(a) *In general.* Subject to the provisions of section 951(a) and the regulations thereunder, a United States shareholder of a controlled foreign corporation is required to include in gross income the amount determined under section 956 with respect to the shareholder for the taxable year but only to the extent not excluded from gross income under section 959(a)(2) and the regulations thereunder.

(b) *Amount of United States property held indirectly by a controlled foreign corporation*—(1) *General rule.* For purposes of section 956, United States property held indirectly by a controlled foreign corporation includes—

(i) United States property held on behalf of the controlled foreign corporation by a trustee or a nominee;

(ii) United States property acquired by any other foreign corporation that is controlled by the controlled foreign corporation if a principal purpose of creating, organizing, or funding by any means (including through capital contributions or debt) the other foreign corporation is to avoid the application of section 956 with respect to the controlled foreign corporation; and

(iii) Property acquired by a partnership that is controlled by the controlled foreign corporation if the property would be United States property if held directly by the controlled foreign corporation, and a principal purpose of creating, organizing, or funding by any means (including through capital contributions or debt) the partnership is to avoid the application of section 956 with respect to the controlled foreign corporation.

(2) *Control.* For purposes of paragraphs (b)(1)(ii) and (iii) of this section, a controlled foreign corporation controls a foreign corporation or partnership if the controlled foreign corporation and the other foreign corporation or partnership are related within the meaning of section 267(b) or section 707(b). For this purpose, in determining whether two corporations are members of the same controlled group under section 267(b)(3), a person is considered to own stock owned directly by such person, stock owned for the purposes of section 1563(e)(1), and stock owned with the application of section 267(c).

(3) *Coordination rule.* Paragraph (b)(1)(iii) of this section applies only to the extent that the amount of United States property that is treated under that paragraph as held indirectly by a

controlled foreign corporation through the partnership exceeds the sum of—

(i) The amount of United States property described in paragraph (b)(1)(iii) of this section that is treated as held by the controlled foreign corporation as a result of the application of § 1.956–4(b) with respect to the partnership; and

(ii) The amount of United States property that is treated as held by the controlled foreign corporation as a result of the application of § 1.956–4(c) with respect to any portion of an obligation attributable to the funding described in paragraph (b)(1)(iii) of this section of the partnership by the controlled foreign corporation.

(4) *Examples.* The following examples illustrate the rules of this paragraph (b). In each example, P is a domestic corporation that wholly owns two controlled foreign corporations, FS1 and FS2.

Example 1. (i) *Facts.* FS1 sells inventory to FS2 in exchange for trade receivables due in 60 days. Avoiding the application of section 956 with respect to FS1 was not a principal purpose of establishing the trade receivables. FS2 has no earnings and profits, and FS1 has substantial accumulated earnings and profits. FS2 makes a loan to P equal to the amount it owes FS1 under the trade receivables. FS2 pays the trade receivables according to their terms.

(ii) *Result.* FS1 will not be considered to indirectly hold United States property under this paragraph (b) because the funding of FS2 through the sale of inventory in exchange for the establishment of trade receivables was not undertaken with a principal purpose of avoiding the application of section 956 with respect to FS1.

Example 2. (i) *Facts.* The facts are the same as in *Example 1* of this paragraph (b)(4), except that, with a principal purpose of avoiding the application of section 956 with respect to FS1, FS1 and FS2 agree to defer FS2's payment obligation, and FS2 does not timely pay the receivables.

(ii) *Result.* FS1 is considered to hold indirectly United States property under this paragraph (b) and § 1.956–2(a) because there was a funding of FS2, a principal purpose of which was to avoid the application of section 956 with respect to FS1.

Example 3. (i) *Facts.* FS1 has $100x of post-1986 undistributed earnings and profits and $100x post-1986 foreign income taxes, but does not have any cash. FS2 has earnings and profits of at least $100x, no post-1986 foreign income taxes, and substantial cash. Neither FS1 nor FS2 has earnings and profits described in section 959(c)(1) or section 959(c)(2). FS2 loans $100x to FS1. FS1 then loans $100x to P. An income inclusion by P of $100x under sections 951(a)(1)(B) and 956 with respect to FS1 would result in foreign income taxes deemed paid by P under section 960. A principal purpose of funding FS1 through the loan from FS2 is to avoid the application of section 956 with respect to FS2.

(ii) *Result.* Under paragraph (b)(1)(ii) of this section, FS2 is considered to indirectly hold the $100x obligation of P that is held by FS1. As a result, P has an income inclusion of $100x under sections 951(a)(1)(B) and 956 with respect to FS2, and the foreign income taxes deemed paid by P under section 960 is $0. P does not have an income inclusion under sections 951(a)(1)(B) and 956 with respect to FS1 related to the $100x loan from FS1 to P.

Example 4. (i) *Facts.* FS1 deposits $100x with BK, an unrelated foreign financial institution. FS2 subsequently borrows $100x from BK. BK would not have loaned the $100x to FS2 on the same terms absent FS1's deposit. FS2 loans the $100x borrowed from BK to P. FS2 has no earnings and profits, and FS1 has substantial accumulated earnings and profits. A principal purpose for the transactions is to avoid the application of section 956 with respect to FS1.

(ii) *Result.* FS1 is considered to hold indirectly United States property under this paragraph (b) and § 1.956–2(a) because FS1's deposit with BK, which facilitates BK's loan to FS2, is considered a funding by FS1 of FS2, a principal purpose of which was to avoid the application of section 956 with respect to FS1.

Example 5. (i) *Facts.* FS1 sells inventory to FS2 in exchange for $100x. The sale occurred in the ordinary course of FS1's trade or business and FS2's trade or business, and the terms of the sale are consistent with terms that would be observed among parties dealing at arm's length. FS1 makes a $100x loan to P. FS2 has no earnings and profits, and FS1 has substantial accumulated earnings and profits.

(ii) *Result.* FS2 will not be considered to indirectly hold United States property under this paragraph (b) because a sale in the ordinary course of business for cash on terms that are consistent with those that would be observed among parties dealing at arm's length does not constitute a funding.

Example 6. (i) *Facts.* In Year 1, FS2 loans $100x to FS1 to finance FS1's trade or business. The terms of the loan are consistent with those that would be observed among parties dealing at arm's length. In Year 2, FS1 repays the loan in accordance with the terms of the loan. Immediately after the repayment by FS1, FS2 loans $100x to P. FS2 has no earnings and profits, and FS1 has substantial accumulated earnings and profits.

(ii) *Result.* FS1 will not be considered to indirectly hold United States property under this paragraph (b) because a repayment of a loan that has terms that are consistent with those that would be observed among parties dealing at arm's length and that is repaid consistent with those terms does not constitute a funding.

Example 7. (i) *Facts.* FS1 has substantial earnings and profits. P and FS1 are the only partners in FPRS, a foreign partnership. FS1 contributes $600x cash to FPRS in exchange for a 60% interest in the partnership, and P contributes real estate located outside the United States ($400x value) to FPRS in exchange for a 40% interest in the partnership. There are no special allocations in the FPRS partnership agreement. FPRS lends $100x to P. Under § 1.956–4(b) and § 1.956–2(a), FS1 is treated as holding United States property of $60x (60% x $100x) as a result of the FPRS loan to P. A principal purpose of creating, organizing, or funding FPRS is to avoid the application of section 956 with respect to FS1.

(ii) *Result.* Before taking into account paragraph (b)(3) of this section, because FS1 controls FPRS and a principal purpose of creating, organizing, or funding FPRS was to avoid the application of section 956 with respect to FS1, FS1 is considered under paragraph (b)(1)(iii) of this section to indirectly hold the $100x obligation of P that would be United States property if held directly by FS1. However, under paragraph (b)(3) of this section, FS1 is treated as holding United States property under paragraph (b)(1)(iii) only to the extent the amount held indirectly under paragraph (b)(1)(iii) of this section exceeds the sum of the amount of the United States property that FS1 is treated as holding as a result of the application of § 1.956–4(b) with respect to FPRS. The amount of United States property that FS1 is treated as indirectly holding under paragraph (b)(1)(iii) of this section and § 1.956–2(a) ($100x) exceeds the amount determined under § 1.956–4(b) ($60x) by $40x. Thus, FS1 is considered to hold United States property within the meaning of section 956(c) in the amount of $100x ($60x under § 1.956–4(b) and $40x under paragraphs (b)(1)(iii) and (b)(3) of this section).

Example 8. (i) *Facts.* FS1 and FS2 have substantial earnings and profits. P and FS1 are the only partners in FPRS, a foreign partnership. There are no special allocations in the FPRS partnership agreement. P's liquidation value percentage with respect to FPRS is 40%, and FS1's liquidation value percentage with respect to FPRS is 60%. FS2 lends $100x to FPRS, and FPRS lends $100x to P. Under § 1.956–4(c) and § 1.956–2(a), FS2 is treated as holding United States property of $40x (40% x $100x) as a result of its loan to FPRS. A principal purpose of funding FPRS is to avoid the application of section 956 with respect to FS2.

(ii) *Result.* Before taking into account paragraph (b)(3) of this section, because FS2 controls FPRS and a principal purpose of funding FPRS was to avoid the application of section 956 with respect to FS2, FS2 is considered under paragraph (b)(1)(iii) of this section to indirectly hold the $100x obligation of P that would be United States property if held directly by FS2. However, under paragraph (b)(3) of this section, FS2 is treated as holding United States property under paragraph (b)(1)(iii) only to the extent the amount held indirectly under paragraph (b)(1)(iii) of this section exceeds the amount of United States property that FS2 is treated as holding as a result of the application of § 1.956–4(c) with respect to the obligation with which FS2 funds FPRS. The amount of United States property that FS2 is treated as indirectly holding under paragraph (b)(1)(iii) of this section and § 1.956–2(a) ($100x) exceeds the amount determined under § 1.956–4(c) ($40x) by $60x. Thus, FS2 is considered to hold United States property within the meaning of section 956(c) in the amount of $100x ($40x under § 1.956–4(c) and $60x under paragraphs (b)(1)(iii) and

(b)(3) of this section). P does not have an income inclusion under sections 951(a)(1)(B) and 956 with respect to FS1 related to the P obligation held by FPRS.

(c)–(d) [Reserved]

(e) * * *

(2) *Rule for pledges and guarantees.* For purposes of this section, the amount of an obligation treated as held (before application of § 1.956–4(b)) as a result of a pledge or guarantee described in § 1.956–2(c) is the unpaid principal amount of the obligation on the applicable determination date.

* * * * *

(g) *Effective/applicability date.* (1) Paragraph (a) of this section applies to taxable years of controlled foreign corporations ending on or after November 3, 2016, and to taxable years of United States shareholders in which or with which such taxable years end.

(2) Paragraph (b) of this section applies to taxable years of controlled foreign corporations ending on or after September 1, 2015, and to taxable years of United States shareholders in which or with which such taxable years end, with respect to property acquired on or after September 1, 2015. See paragraph (b)(4) of § 1.956–1T, as contained in 26 CFR part 1 revised as of April 1, 2015, for the rules applicable to taxable years of controlled foreign corporations ending before September 1, 2015, and property acquired before September 1, 2015. For purposes of this paragraph (g)(2), a deemed exchange of property pursuant to section 1001 on or after September 1, 2015 constitutes an acquisition of the property on or after that date.

(3) Paragraph (e)(2) of this section applies to taxable years of controlled foreign corporations ending on or after November 3, 2016, and taxable years of United States shareholders in which or with which such taxable years end, with respect to pledges or guarantees entered into on or after September 1, 2015. For purposes of this paragraph (g)(3), a pledgor or guarantor is treated as entering into a pledge or guarantee when there is a significant modification, within the meaning of § 1.1001–3(e), of an obligation with respect to which it is a pledgor or guarantor on or after September 1, 2015.

* * * * *

■ **Par. 5.** Section 1.956–1T is revised to read as follows:

§ 1.956–1T Shareholder's pro rata share of the average of the amounts of United States property held by a controlled foreign corporation.

(a) through (e)(4) [Reserved]

(5) Exclusion for certain recourse obligations. For purposes of § 1.956–1(e)(1) of the regulations, in the case of an investment in United States property consisting of an obligation of a related person, as defined in section 954(d)(3) and paragraph (f) of § 1.954–1, a liability will not be recognized as a specific charge if the liability representing the charge is with recourse with respect to the general credit or other assets of the investing controlled foreign corporation.

(e)(6) [Reserved]. For further guidance, see § 1.956–1(e)(6).

(f) Effective/applicability date. Paragraph (e)(5) of this section applies to investments made on or after June 14, 1988.

(g)–(h) [Reserved]

■ **Par. 6.** Section 1.956–2 is amended by:

■ 1. Revising paragraphs (a)(3), (c)(1), and (c)(2).

■ 2. Adding *Example 4* to paragraph (c)(3).

■ 3. Adding paragraph (h).

The revisions and addition read as follows:

§ 1.956–2 Definition of United States property.

(a) * * *

(3) *Treatment of disregarded entities.* For purposes of section 956, an obligation of a business entity (as defined in § 301.7701–2(a) of this chapter) that is disregarded as an entity separate from its owner for federal tax purposes under §§ 301.7701–1 through 301.7701–3 of this chapter is treated as an obligation of its owner.

* * * * *

(c) *Treatment of pledges and guarantees*—(1) *General rule.* Except as provided in paragraph (c)(4) of this section, for purposes of section 956, any obligation of a United States person with respect to which a controlled foreign corporation or a partnership is a pledgor or guarantor will be considered to be held by the controlled foreign corporation or the partnership, as the case may be. See § 1.956–1(e)(2) for rules that determine the amount of the obligation treated as held by a pledgor or guarantor under this paragraph (c). For rules that treat an obligation of a foreign partnership as an obligation of the partners in the foreign partnership for purposes of section 956, see § 1.956–4(c).

(2) *Indirect pledge or guarantee.* If the assets of a controlled foreign corporation or a partnership serve at any time, even though indirectly, as security for the performance of an obligation of a United States person, then, for purposes of paragraph (c)(1) of this section, the controlled foreign corporation or partnership will be considered a pledgor or guarantor of that obligation. If a partnership is considered a pledgor or guarantor of an obligation, a controlled foreign corporation that is a partner in the partnership will not also be treated as a pledgor or guarantor of the obligation solely as a result of its ownership of an interest in the partnership. For purposes of this paragraph, a pledge of stock of a controlled foreign corporation representing at least 66⅔ percent of the total combined voting power of all classes of voting stock of such corporation will be considered an indirect pledge of the assets of the controlled foreign corporation if the pledge is accompanied by one or more negative covenants or similar restrictions on the shareholder effectively limiting the corporation's discretion to dispose of assets and/or incur liabilities other than in the ordinary course of business. See § 1.956–4(d) for guidance on the treatment of indirect pledges or guarantees of an obligation of a partnership attributed to its partners under § 1.956–4(c).

(3) * * *

Example 4. (i) *Facts.* USP, a domestic corporation, owns 70% of the stock of FS, a controlled foreign corporation, and a 90% interest in FPRS, a foreign partnership. X, an unrelated foreign person, owns 30% of the stock of FS. Y, an unrelated foreign person, owns a 10% interest in FPRS. There are no special allocations in the FPRS partnership agreement. FPRS borrows $100x from Z, an unrelated person. FS pledges its assets as security for FPRS's performance of its obligation to repay the $100x loan. USP's share of the $100x FPRS obligation, determined in accordance with its liquidation value percentage, is $90x. Under § 1.956–4(c), $90x of the FPRS obligation is treated as an obligation of USP for purposes of section 956.

(ii) *Result.* For purposes of section 956, under paragraph (c)(1) of this section, FS is considered to hold an obligation of USP in the amount of $90x, and thus is treated as holding United States property in the amount of $90x.

* * * * *

(h) *Effective/applicability date.* (1) Paragraph (a)(3) of this section applies to taxable years of controlled foreign corporations ending on or after November 3, 2016, and taxable years of United States shareholders in which or with which such taxable years end, with respect to obligations held on or after November 3, 2016.

(2) Paragraphs (c)(1), (c)(2), and *Example 4* of paragraph (c)(3) of this section apply to taxable years of controlled foreign corporations ending on or after November 3, 2016, and taxable years of United States shareholders in which or with which

such taxable years end, with respect to pledges and guarantees entered into on or after September 1, 2015. For purposes of this paragraph (h)(2), a pledgor or guarantor is treated as entering into a pledge or guarantee when there is a significant modification, within the meaning of § 1.1001–3(e), of an obligation with respect to which it is a pledgor or guarantor on or after September 1, 2015.

* * * * *

■ **Par. 7.** Section § 1.956–3 is added to read as follows:

§ 1.956–3 Certain trade or service receivables acquired from United States persons.

(a) *In general.* For purposes of section 956(a) and § 1.956–1, the term ''United States property'' also includes any trade or service receivable if the trade or service receivable is acquired (directly or indirectly) from a related person who is a United States person (as defined in section 7701(a)(30)) (a *related United States person*) and the obligor under the receivable is a United States person. A trade or service receivable described in this paragraph is considered to be United States property notwithstanding the exceptions (other than subparagraph (H)) contained in section 956(c)(2). The terms ''trade or service receivable'' and ''related person'' have the respective meanings given to the terms by section 864(d) and the regulations thereunder, including § 1.864–8T(b). For purposes of this section, the exception in § 1.956–2T(d)(2)(ii) does not apply to trade or service receivables described in this paragraph.

(b) *Acquisition of a trade or service receivable*—(1) *General rule.* The rules of § 1.864–8T(c)(1) apply to determine whether a controlled foreign corporation has acquired a trade or service receivable.

(2) *Indirect acquisitions*—(i) *Acquisition through unrelated person.* A trade or service receivable is considered acquired from a related person when it is acquired from an unrelated person who acquired (directly or indirectly) the receivable from a person who is a related person to the acquiring person.

(ii) *Acquisition by nominee, pass-through entity, or related foreign corporation.* A controlled foreign corporation is treated as holding a trade or service receivable that is held by a nominee on its behalf, or by a simple trust or other pass-through entity (other than a partnership) to the extent of its direct or indirect ownership or beneficial interest in such simple trust or other pass-through entity. See §§ 1.956–1(b) and 1.956–4(b) for rules that may treat a controlled foreign corporation as indirectly holding a trade or service receivable held by a foreign corporation or partnership. A controlled foreign corporation that is treated as holding a trade or service receivable held by another person (the *direct holder*) (or that would be treated as holding the receivable if the receivable were United States property or would be United States property if held directly by the controlled foreign corporation) is considered to have acquired the receivable from the person from whom the direct holder acquired the receivable. This paragraph (b)(2)(ii) does not limit the application of paragraph (b)(2)(iii) of this section. The following examples illustrate the application of this paragraph (b)(2)(ii):

Example 1. (i) *Facts.* A domestic corporation, P, wholly owns a controlled foreign corporation, FS, with substantial earnings and profits. FS contributes $200x of cash to a partnership, PRS, in exchange for an 80% partnership interest. An unrelated foreign person contributes real estate located in a foreign country with a fair market value of $50x to PRS for the remaining 20% partnership interest. There are no special allocations in the PRS partnership agreement. PRS uses the $200x of cash received from FS to purchase trade receivables from P. The obligors with respect to the trade receivables are United States persons that are not related to any partner in PRS. The liquidation value percentage, as determined under § 1.956–4(b), for FS with respect to PRS is 80%. A principal purpose of funding PRS (through FS's cash contribution) is to avoid the application of section 956 with respect to FS.

(ii) *Result.* Under § 1.956–4(b)(1), FS is treated as holding 80% of the trade receivables acquired by PRS from P, with a basis equal to $160x (80% × $200x, PRS's basis in the trade receivables). However, because FS controls PRS and a principal purpose of FS funding PRS was to avoid the application of section 956 with respect to FS, under § 1.956–1(b), if the trade receivables would be United States property if held directly by FS, FS additionally would be treated as holding the trade receivables to the extent that they exceed the amount of the receivables it holds under § 1.956–4(b), which is $40x ($200x − $160x). Accordingly, under this paragraph (b)(2)(ii), FS is treated as having acquired from P, a related United States person, the trade receivables that it is treated as holding with a basis equal to $200x ($160x + $40x). Thus, FS is treated as holding United States property with a basis of $200x under paragraph (a) of this section.

Example 2. (i) *Facts.* A domestic corporation, P, wholly owns a controlled foreign corporation, FS1, that has earnings and profits of at least $300x. FS1 organizes a foreign corporation, FS2, with a $200x cash contribution. FS2 uses the cash contribution to purchase trade receivables from P. The obligors with respect to the trade receivables are unrelated United States persons. A principal purpose of funding FS2 (through FS1's cash contribution) is to avoid the application of section 956 with respect to FS1.

(ii) *Result.* Under § 1.956–1(b), if the trade receivables held by FS2 were United States property, FS1 would be treated as holding the trade receivables held by FS2 because FS1 controls FS2 and a principal purpose of FS1 funding FS2 was to avoid the application of section 956 with respect to FS1. Accordingly, under this paragraph (b)(2)(ii), FS1 is treated as having acquired from P, a related United States person, the trade receivables that it would be treated as holding with a basis equal to $200x. Thus, FS1 is treated as holding United States property with a basis of $200x under paragraph (a) of this section.

(iii) *Swap or pooling arrangements.* A trade or service receivable of a United States person is considered to be a trade or service receivable acquired from a related United States person and subject to the rules of this section when it is acquired in accordance with an arrangement that involves two or more groups of related persons, if the groups are unrelated to each other and the effect of the arrangement is that one or more persons in each group acquire (directly or indirectly) trade or service receivables from one or more unrelated United States persons who are also parties to the arrangement in exchange for reciprocal purchases of receivables from related United States persons. The following example illustrates the application of this paragraph (b)(2)(iii):

Example. (i) *Facts.* Controlled foreign corporations A, B, C, and D are wholly-owned subsidiaries of domestic corporations M, N, O, and P, respectively. M, N, O, and P are not related persons. According to a prearranged plan, A, B, C, and D each acquire trade or service receivables from M, N, O, and/or P. The obligors under some or all of the receivables acquired by each of A, B, C, and D are United States persons.

(ii) *Result.* The effect of the prearranged plan is that each of A, B, C, and D acquires trade or service receivables of United States persons from one or more unrelated United States persons who are also parties to the arrangement, in exchange for reciprocal purchases of receivables from a related United States person. Accordingly, each of A, B, C, and D is treated as holding a trade or service receivable acquired from a related United States person and is subject to the rules of this section. As a result, each of A, B, C, and D is treated as holding an amount of United States property equal to its adjusted basis in the receivables acquired pursuant to the arrangement with respect to which the obligors are United States persons.

(iv) *Financing arrangements.* If a controlled foreign corporation participates (directly or indirectly) in a lending transaction that results in a loan to a United States person who purchases property described in section 1221(a)(1) (*inventory property*) or services from a related United States person, or to any

person who purchases from a related United States person trade or service receivables under which the obligor is a United States person, or to a person who is a related person with respect to the purchaser, and if the loan would not have been made or maintained on the same terms but for the corresponding purchase, then the controlled foreign corporation is considered to have indirectly acquired a trade or service receivable described in paragraph (a) of this section. For purposes of this paragraph (b)(2)(iv), it is immaterial that the sums lent are not, in fact, the sums used to finance the purchase of the inventory property or services or trade or service receivables from a related United States person. The amount to be taken into account with respect to the United States property treated as held by a controlled foreign corporation as a result of the application of this paragraph (b)(2)(iv) is the lesser of the amount lent pursuant to a lending transaction described in this paragraph (b)(2)(iv) and the purchase price of the inventory property, services, or trade or service receivables. The following examples illustrate the application of this paragraph (b)(2)(iv):

Example 1. (i) *Facts.* P, a domestic corporation, owns all of the outstanding stock of FS1, a controlled foreign corporation. P sells inventory property for $200x to X, an unrelated United States person. FS1 makes a $100x short-term loan to X, which loan would not have been made or maintained on the same terms but for X's purchase of P's inventory property.

(ii) *Result.* FS1 directly participates in a lending transaction described in this paragraph (b)(2)(iv). Thus, FS1 is considered to have acquired a trade or service receivable described in paragraph (a) of this section. That is, FS1 is considered to have acquired a trade or service receivable of a United States person from a related United States person. As a result, FS1 is treated as holding United States property in the amount of $100x.

Example 2. (i) *Facts.* The facts are the same as in *Example 1* of this paragraph (b)(2)(iv), except that instead of loaning money to X directly, FS1 deposits $300x with an unrelated financial institution that loans $200x to X in order for X to purchase P's inventory property. The loan would not have been made or maintained on the same terms but for the corresponding deposit.

(ii) *Result.* FS1 is considered to have acquired a trade or service receivable described in paragraph (a) of this section because FS1 indirectly participates in a lending transaction described in this paragraph (b)(2)(iv). See Rev. Rul. 87–89, 1987–2 CB 195. That is, FS1 is considered to have acquired a trade or service receivable of a United States person from a related United States person. Thus, FS1 is treated as holding United States property in the amount of $200x.

Example 3. (i) *Facts.* P, a domestic corporation, owns all of the outstanding stock of FS1, a controlled foreign corporation. FS1 makes a $300x loan to U, an unrelated foreign corporation, in connection with U's purchase from P of receivables from the sale of inventory property by P to United States obligors for $200x.

(ii) *Result.* FS1 is considered to have acquired a trade or service receivable described in paragraph (a) of this section because FS1 directly participates in a lending transaction described in this paragraph (b)(2)(iv). That is, FS1 is considered to have acquired a trade or service receivable of a United States person from a related United States person. Thus, FS1 is treated as holding United States property in the amount of $200x.

(c) *Substitution of obligor.* For purposes of this section, the substitution of another person for a United States obligor is disregarded, unless it can be demonstrated by the parties to the transaction that the primary purpose for the arrangement was not the avoidance of section 956. The following example illustrates the application of this paragraph (c):

Example. (i) *Facts.* P, a domestic corporation, owns all of the outstanding stock of FS1, a controlled foreign corporation with substantial accumulated earnings and profits. P sells inventory property to X, a domestic corporation unrelated to P. To pay for the inventory property, X arranges for a foreign financing entity to issue a note to P. P then sells the note to FS1. P and X cannot demonstrate that the primary purpose for X's assignment of the payment obligation to the foreign financing entity was not the avoidance of section 956.

(ii) *Result.* The substitution of the foreign financing entity for X is disregarded, and FS1 is treated as holding an obligation of a United States person acquired from a related United States person. Thus, FS1 is treated as holding United States property in the amount of the purchase price of the note.

(d) *Effective/applicability date*—(1) Except as provided in paragraph (d)(2) of this section, this section applies to trade or service receivables acquired (directly or indirectly) after March 1, 1984.

(2) Paragraph (b)(2)(ii) of this section applies to taxable years of controlled foreign corporations ending on or after November 3, 2016, and taxable years of United States shareholders in which or with which such taxable years end, with respect to trade or service receivables acquired on or after September 1, 2015. For purposes of this paragraph (d), a significant modification, within the meaning of § 1.1001–3(e), of a trade or service receivable on or after September 1, 2015, constitutes an acquisition of the trade or service receivable on or after that date.

§ 1.956–3T [Removed]

■ **Par. 8.** Section 1.956–3T is removed.

■ **Par. 9.** Section 1.956–4 is added to read as follows:

§ 1.956–4 Certain rules applicable to partnerships.

(a) *Overview.* This section provides rules concerning the application of section 956 to certain obligations of and property held by a partnership. Paragraph (b) of this section provides rules concerning United States property held indirectly by a controlled foreign corporation through a partnership. Paragraph (c) of this section provides rules that generally treat obligations of a foreign partnership as obligations of the partners in the foreign partnership, as well as a special rule that treats a partner that is a United States person as owing additional amounts of a partnership obligation in certain circumstances. Paragraph (d) of this section sets forth a rule concerning the application of the indirect pledge or guarantee rule to obligations of partnerships. Paragraph (e) of this section provides that obligations of a domestic partnership are obligations of a United States person. Paragraph (f) of this section provides effective and applicability dates. See §§ 1.956–1(b) and 1.956–2(c) for additional rules applicable to partnerships.

(b) *Property held indirectly through a partnership*—(1) *General rule.* For purposes of section 956, a partner in a partnership is treated as holding its attributable share of any property held by the partnership (including an obligation that the partnership is treated as holding as a result of the application of § 1.956–2(c)). A partner's attributable share of partnership property is determined under the rules set forth in paragraph (b)(2) of this section. An upper-tier partnership's attributable share of the property of a lower-tier partnership is treated as property of the upper-tier partnership for purposes of applying this paragraph (b)(1) to the partners of the upper-tier partnership. For purposes of section 956, a partner's adjusted basis in the property of the partnership equals the partner's attributable share of the partnership's adjusted basis in the property, as determined under the rules set forth in paragraph (b)(2) of this section, taking into account any adjustments to basis under section 743(b) (with respect to the partner) or section 734(b) or any similar adjustments to basis. The rules in § 1.956–1(e)(2) apply to determine the amount of an obligation treated as held by a partnership as a result of the application of § 1.956–2(c). See § 1.956–

1(b) for special rules that may treat a controlled foreign corporation as holding a greater amount of United States property held by a partnership than the amount determined under this section.

(2) *Methodology*—(i) *Liquidation value percentage*—(A) *Calculation.* Except as otherwise provided in paragraph (b)(2)(ii) of this section, for purposes of paragraph (b)(1) of this section, a partner's attributable share of partnership property is determined in accordance with the partner's liquidation value percentage. For purposes of this paragraph (b)(2)(i) and paragraph (c)(1) of this section, the liquidation value of a partner's interest in a partnership is the amount of cash the partner would receive with respect to the interest if, on the applicable determination date, as provided in paragraph (b)(2)(i)(B) of this section, the partnership sold all of its assets for cash equal to the fair market value of such assets (taking into account section 7701(g)), satisfied all of its liabilities (other than those described in § 1.752–7), paid an unrelated third party to assume all of its § 1.752–7 liabilities in a fully taxable transaction, and then liquidated. A partner's liquidation value percentage is the ratio (expressed as a percentage) of the liquidation value of the partner's interest in the partnership divided by the aggregate liquidation value of all of the partners' interests in the partnership.

(B) *Determination date.* The *determination date* with respect to a partnership is the most recent of—

(*1*) The formation of the partnership;

(*2*) An event described in § 1.704–1(b)(2)(iv)(*f*)(*5*) or § 1.704–1(b)(2)(iv)(*s*)(*1*) (a *revaluation event*), irrespective of whether the capital accounts of the partners are adjusted in accordance with § 1.704–1(b)(2)(iv)(*f*); or

(*3*) The first day of the partnership's taxable year, as determined under section 706, provided the liquidation value percentage determined for any partner on that day would differ from the most recently determined liquidation value percentage of that partner by more than 10 percentage points.

(ii) *Special allocations.* For purposes of paragraph (b)(1) of this section, if a partnership agreement provides for the allocation of book income (or, where appropriate, book gain) from a subset of the property of the partnership to a partner other than in accordance with the partner's liquidation value percentage in a particular taxable year (a *special allocation*), then the partner's attributable share of that property is determined solely by reference to the partner's special allocation with respect to the property, provided the special allocation does not have a principal purpose of avoiding the purposes of section 956.

(3) *Examples.* The following examples illustrate the rule of this paragraph (b):

Example 1. (i) *Facts.* USP, a domestic corporation, wholly owns FS, a controlled foreign corporation, which, in turn, owns an interest in FPRS, a foreign partnership. The remaining interest in FPRS is owned by an unrelated foreign person. FPRS holds non-depreciable property with an adjusted basis of $100x (the ''FPRS property'') that would be United States property if held by FS directly. At the close of quarter 1 of year 1, the liquidation value percentage, as determined under paragraph (b)(2) of this section, for FS with respect to FPRS is 25%. There are no special allocations in the FPRS partnership agreement.

(ii) *Result.* Under paragraph (b)(1) of this section, for purposes of section 956, FS is treated as holding its attributable share of the property held by FPRS with an adjusted basis equal to its attributable share of FPRS's adjusted basis in such property. Under paragraph (b)(2) of this section, FS's attributable share of property held by FPRS is determined in accordance with FS's liquidation value percentage, which is 25%. Thus, FS's attributable share of the FPRS property is 25%, and its attributable share of FPRS's basis in the FPRS property is $25x. Accordingly, for purposes of determining the amount of United States property held by FS as of the close of quarter 1 of year 1, FS is treated as holding United States property with an adjusted basis of $25x.

Example 2. (i) *Facts.* The facts are the same as in *Example 1* of this paragraph (b)(3), except that the FPRS partnership agreement, which satisfies the requirements of section 704(b), specially allocates 80% of the income with respect to the FPRS property to FS. The special allocation does not have a principal purpose of avoiding the purposes of section 956.

(ii) *Result.* Under paragraph (b)(1) of this section, for purposes of section 956, FS is treated as holding its attributable share of property held by FPRS with an adjusted basis equal to its attributable share of FPRS's adjusted basis in such property. In general, FS's attributable share of property held by FPRS is determined in accordance with FS's liquidation value percentage. However, because the special allocation does not have a principal purpose of avoiding the purposes of section 956, under paragraph (b)(2)(ii) of this section, FS's attributable share of the FPRS property is determined by reference to its special allocation. FS's special allocation percentage for the FPRS property is 80%, and thus FS's attributable share of the FPRS property is 80% and its attributable share of FPRS's basis in the FPRS property is $80x. Accordingly, for purposes of determining the amount of United States property held by FS as of the close of quarter 1 of year 1, FS is treated as holding United States property with an adjusted basis of $80x.

Example 3. (i) *Facts.* USP, a domestic corporation, wholly owns FS, a controlled foreign corporation, which, in turn, owns an interest in FPRS, a foreign partnership. USP owns the remaining interest in FPRS. FPRS holds property (the ''FPRS property'') that would be United States property if held by FS directly. The FPRS property has an adjusted basis of $100x and is anticipated to appreciate in value but generate relatively little income. The FPRS partnership agreement, which satisfies the requirements of section 704(b), specially allocates 80% of the income with respect to the FPRS property to USP and 80% of the gain with respect to the disposition of FPRS property to FS. The special allocation does not have a principal purpose of avoiding the purposes of section 956.

(ii) *Result.* Because the special allocation does not have a principal purpose of avoiding the purposes of section 956, under paragraph (b)(2)(ii) of this section, FS's attributable share of the FPRS property is determined by reference to a special allocation with respect to the FPRS property. Given the income and gain anticipated with respect to the FPRS property, it is appropriate to determine FS's attributable share of the property in accordance with the special allocation of gain. Accordingly, for purposes of determining the amount of United States property held by FS in each year that FPRS holds the FPRS property, FS's attributable share of the FPRS property is 80% and its attributable share of FPRS's basis in the FPRS property is $80x. Thus, FS is treated as holding United States property with an adjusted basis of $80x.

(c) *Obligations of a foreign partnership*—(1) *In general.* Except as provided in paragraphs (c)(2) and (c)(3) of this section, for purposes of section 956, an obligation of a foreign partnership is treated as a separate obligation of each of the partners in the partnership to the extent of each partner's share of the obligation. A partner's share of the partnership's obligation is determined in accordance with the partner's liquidation value percentage, as determined under the rules set forth in paragraph (b)(2)(i) of this section, without regard to the rules set forth in paragraph (b)(2)(ii) of this section. An upper-tier partnership's share of an obligation of a lower-tier partnership is treated as an obligation of the upper-tier partnership for purposes of applying this paragraph (c)(1) to the partners of the upper-tier partnership.

(2) *Exception for obligations of partnerships in which neither the lending controlled foreign corporation nor any person related to the lending controlled foreign corporation is a partner.* For purposes of applying section 956 with respect to a controlled foreign corporation, an obligation of a foreign partnership is treated as an obligation of a foreign partnership, and not as an obligation of its partners, if neither the controlled foreign corporation nor any person related to

the controlled foreign corporation within the meaning of section 954(d)(3) is a partner in the partnership. For purposes of section 956, an obligation treated as an obligation of a foreign partnership pursuant to this paragraph (c)(2) is not an obligation of a United States person.

(3) *Special obligor rule in the case of certain partnership distributions*—(i) *General rule.* For purposes of determining a partner's share of a foreign partnership's obligation under section 956, if the foreign partnership distributes an amount of money or property to a partner that is related to a controlled foreign corporation within the meaning of section 954(d)(3) and whose obligation would be United States property if held (or if treated as held) by the controlled foreign corporation, and the foreign partnership would not have made the distribution but for a funding of the partnership through an obligation held (or treated as held) by a controlled foreign corporation, notwithstanding § 1.956–1(e), the partner's share of the partnership obligation is the greater of—

(A) The partner's share of the partnership obligation as determined under paragraph (c)(1) of this section; and

(B) The lesser of the amount of the distribution to the partner that would not have been made but for the funding of the partnership and the amount of the obligation (as determined under § 1.956–1(e)).

(ii) *Deemed treatment*—(A) For purposes of applying paragraph (c)(3)(i) of this section, in the case of a distribution of liquid assets by a foreign partnership to a partner, the foreign partnership is treated as if it would not have made the distribution of liquid assets to the partner but for the funding of the partnership through an obligation or obligations held (or treated as held) by the controlled foreign corporation to the extent the foreign partnership does not have sufficient liquid assets to make the distribution immediately prior to the distribution, without taking into account the obligation or obligations.

(B) If the controlled foreign corporation holds (or is treated as holding) multiple obligations of the foreign partnership, paragraph (c)(3)(ii)(A) of this section applies to the obligations in reverse chronological order starting with the obligation that was acquired (or the obligation with respect to which a pledge or guarantee was entered into) closest in time to the distribution. Paragraph (c)(3)(ii)(A) of this section applies to an obligation only to the extent that the full amount of the distribution is not otherwise treated, pursuant to paragraph (c)(3)(ii)(A) of this section, as if it would not have been made but for the funding of the partnership through one or more other obligations.

(C) For purposes of paragraph (c)(3)(ii) of this section, a significant modification, within the meaning of § 1.1001–3(e), of an obligation constitutes an acquisition of the obligation on or after that date, and a pledgor or guarantor is treated as entering into a pledge or guarantee when there is a significant modification, within the meaning of § 1.1001–3(e), of an obligation with respect to which it is a pledgor or guarantor.

(D) For purposes of paragraph (c)(3)(ii) of this section, liquid assets means cash or cash equivalents, marketable securities within the meaning of section 453(f)(2), or an obligation owed by a related person (within the meaning of section 954(d)(3)).

(4) *Examples.* The following examples illustrate the rules of this paragraph (c):

Example 1. (i) *Facts.* USP, a domestic corporation, wholly owns FS, a controlled foreign corporation, and owns an interest in FPRS, a foreign partnership. At the close of quarter 1 of year 1, the liquidation value percentage, as determined under paragraph (b)(2)(i) of this section, for USP with respect to FPRS is 90%. X, a foreign person that is unrelated to USP or FS, owns the remaining interest in FPRS. FPRS borrows $100x from FS. FS's basis in the FPRS obligation is $100x.

(ii) *Result.* Under paragraph (c)(1) of this section, for purposes of section 956, the obligation of FPRS is treated as obligations of its partners (USP and X) in proportion to each partner's liquidation value percentage with respect to FPRS. Because USP, a partner in FPRS, is related to FS within the meaning of section 954(d)(3), the exception in paragraph (c)(2) of this section does not apply. Based on its liquidation value percentage, USP's share of the FPRS obligation is $90x. Accordingly, for purposes of section 956, $90x of the FPRS obligation held by FS is treated as an obligation of USP and is United States property within the meaning of section 956(c). Therefore, on the date the loan is made, FS is treated as holding United States property of $90x.

Example 2. (i) *Facts.* The facts are the same as in *Example 1* of this paragraph (c)(4), except that USP owns 40% of the stock of FS and is not a related person (as defined in section 954(d)(3)) with respect to FS. Y, a United States person that is unrelated to USP or X, owns the remaining 60% of the stock of FS.

(ii) *Result.* Because neither FS nor any person related to FS within the meaning of section 954(d)(3) is a partner in FPRS, the exception in paragraph (c)(2) of this section applies to treat the FPRS obligation as an obligation of a foreign partnership and not an obligation of a United States person. Therefore, paragraph (c)(1) of this section does not apply, and FS is not treated as holding United States property.

Example 3. (i) *Facts.* USP, a domestic corporation, wholly owns FS, a controlled foreign corporation. USP and FS own interests in FPRS, a foreign partnership. USP's liquidation value percentage with respect to FPRS is 60%, and FS's liquidation value percentage with respect to FPRS is 30%. U.S.C., a domestic corporation that is unrelated to USP and FS, also owns an interest in FPRS; its liquidation value percentage is 10%. FPRS borrows $100x from an unrelated person. FS guarantees the FPRS obligation.

(ii) *Result.* Under paragraph (c)(1) of this section, for purposes of section 956, the obligation of FPRS is treated as obligations of its partners (USP, FS, and U.S.C.) in proportion to each partner's liquidation value percentage. Because USP, a partner in FPRS, is related to FS within the meaning of section 954(d)(3), and because FS is a partner in FPRS, the exception in paragraph (c)(2) of this section does not apply. Based on their liquidation value percentages, USP's share of the FPRS obligation is $60x, and U.S.C.'s share of the FPRS obligation is $10x. For purposes of section 956, $60x of the FPRS obligation is treated as an obligation of USP, and $10x of the FPRS obligation is treated as an obligation of U.S.C. Under § 1.956–2(c)(1), FS is treated as holding the obligations of USP and U.S.C. that FS guaranteed. All of the exceptions to the definition of United States property contained in section 956 and § 1.956–2 must be considered to determine whether the obligations of USP and U.S.C. that are treated as held by FS constitute United States property. Accordingly, the obligation of U.S.C. is not United States property under section 956(c)(2)(F) and § 1.956–2(b)(1)(viii). The obligation of USP, however, is United States property within the meaning of section 956(c). Therefore, on the date the guarantee is made, FS is treated as holding United States property of $60x.

Example 4. (i) *Facts.* USP, a domestic corporation, wholly owns FS, a controlled foreign corporation. USP owns an interest in FPRS, a foreign partnership; its liquidation value percentage with respect to FPRS is 70%. A domestic corporation that is unrelated to USP and FS owns the remaining interest in FPRS; its liquidation value percentage is 30%. FPRS borrows $100x from FS and makes a distribution of $80x to USP. FPRS would not have made the distribution to USP but for the funding of FPRS by FS.

(ii) *Result.* Because USP, a partner in FPRS, is related to FS within the meaning of section 954(d)(3), the exception in paragraph (c)(2) of this section does not apply. Moreover, an obligation of USP held by FS would be United States property. USP's share of the FPRS obligation as determined under paragraph (c)(1) of this section in accordance with USP's liquidation value percentage is $70x. Under paragraph (c)(3) of this section, USP's share of the FPRS obligation is the greater of (i) USP's attributable share of the obligation, $70x, or (ii) the lesser of the amount of the distribution, $80x, or the amount of the obligation, $100x. For purposes of section 956, therefore, $80x of the FPRS obligation is treated as an

obligation of USP and is United States property within the meaning of section 956(c). Thus, on the date the loan is made, FS is treated as holding United States property of $80x.

(d) *Limitation on a partner's indirect pledge or guarantee.* For purposes of section 956 and § 1.956–2(c), a controlled foreign corporation that is a partner in a partnership is not considered a pledgor or guarantor of the portion of an obligation of the partnership attributed to its partners that are United States persons under paragraph (c) of this section solely as a result of the attribution of a portion of the partnership's assets to the controlled foreign corporation under paragraph (b) of this section.

(e) *Obligations of a domestic partnership.* For purposes of section 956, an obligation of a domestic partnership is an obligation of a United States person. See section 956(c)(2)(L) for an exception from the treatment of such an obligation as United States property.

(f) *Effective/applicability dates.* (1) Paragraph (b) of this section applies to taxable years of controlled foreign corporations ending on or after November 3, 2016, and taxable years of United States shareholders in which or with which such taxable years end, with respect to property acquired on or after November 3, 2016. For purposes of this paragraph (f)(1), a deemed exchange of property pursuant to section 1001 on or after November 3, 2016, constitutes an acquisition of the property on or after that date. See § 1.956–2(a)(3), as contained in 26 CFR part 1 revised as of April 1, 2016, for the rules applicable to taxable years of a controlled foreign corporation beginning on or after July 23, 2002, and ending before November 3, 2016, and with respect to property acquired before November 3, 2016, to taxable years of a controlled foreign corporation beginning on or after July 23, 2002.

(2) Except as otherwise provided in this paragraph (f)(2), paragraph (c) of this section applies to taxable years of controlled foreign corporations ending on or after November 3, 2016, and taxable years of United States shareholders in which or with which such taxable years end, with respect to obligations acquired, or pledges or guarantees entered into, on or after September 1, 2015, and, for purposes of paragraph (c)(3) of this section, in the case of distributions made on or after September 1, 2015. Paragraph (c)(3)(ii) of this section applies to taxable years of controlled foreign corporations ending on or after November 3, 2016, and taxable years of United States shareholders in which or with which such taxable years end, with respect to obligations acquired, or pledges or guarantees entered into, on or after September 1, 2015, and distributions made on or after November 3, 2016. For purposes of this paragraph (f)(2), a significant modification, within the meaning of § 1.1001–3(e), of an obligation on or after September 1, 2015 constitutes an acquisition of the obligation on or after that date. Furthermore, for purposes of this paragraph (f)(2), a pledgor or guarantor is treated as entering into a pledge or guarantee when there is a significant modification, within the meaning of § 1.1001–3(e), of an obligation with respect to which it is a pledgor or guarantor on or after September 1, 2015. See § 1.956–1T(b)(5), as contained in 26 CFR part 1 revised as of April 1, 2016, for rules applicable to taxable years of controlled foreign corporations ending on or after September 1, 2015, and before November 3, 2016, and to taxable years of United States shareholders in which or with which such taxable years end, in the case of distributions made on or after September 1, 2015.

(3) Paragraph (d) of this section applies to taxable years of controlled foreign corporations ending on or after November 3, 2016, and taxable years of United States shareholders in which or with which such taxable years end, with respect to pledges or guarantees entered into on or after September 1, 2015. For purposes of this paragraph (f)(3), a pledgor or guarantor is treated as entering into a pledge or guarantee when there is a significant modification, within the meaning of § 1.1001–3(e), of an obligation with respect to which it is a pledgor or guarantor on or after September 1, 2015.

(4) Paragraph (e) of this section applies to taxable years of controlled foreign corporations ending on or after November 3, 2016, and to taxable years of United States shareholders in which or with which such taxable years end, with respect to obligations held on or after November 3, 2016.

John Dalrymple,

Deputy Commissioner for Services and Enforcement.

Approved: October 17, 2016.

Mark J. Mazur,

Assistant Secretary of the Treasury (Tax Policy).

[FR Doc. 2016–26425 Filed 11–2–16; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2016–0966]

Drawbridge Operation Regulation; Harlem River, New York City, NY

AGENCY: Coast Guard, DHS.

ACTION: Notice of deviation from drawbridge regulation.

SUMMARY: The Coast Guard has issued a temporary deviation from the operating schedule that governs the Spuyten Duyvil Bridge across the Harlem River, mile 7.9, New York City, New York. This deviation is necessary to allow the bridge owner to perform a test of the submarine cables at the bridge.

DATES: This deviation is effective from 10 p.m. on December 9, 2016 to 7 a.m. on December 11, 2016.

ADDRESSES: The docket for this deviation, [USCG–2016–0966] is available at *http://www.regulations.gov.* Type the docket number in the ''SEARCH'' box and click ''SEARCH''. Click on Open Docket Folder on the line associated with this deviation.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary deviation, call or email Judy Leung-Yee, Project Officer, First Coast Guard District, telephone (212) 514–4330, email *judy.k.leung-yee@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Spuyten Duyvil Bridge, mile 7.9, across the Harlem River, has a vertical clearance in the closed position of 5 feet at mean high water and 9 feet at mean low water. The existing bridge operating regulations are found at 33 CFR 117.789(d).

The waterway is transited by commercial vessels.

The bridge owner, National Railroad Passenger Corporation (Amtrak), requested a temporary deviation from the normal operating schedule to perform a test of the submarine cables at the bridge.

Under this temporary deviation, the Spuyten Duyvil Bridge shall remain in the closed position from 10 p.m. on December 9, 2016 to 7 a.m. on December 11, 2016.

Vessels able to pass under the bridge in the closed position may do so at any time. The bridge will be able to open for emergencies and there is an alternate route for vessels to pass.

The Coast Guard will inform the users of the waterways through our Local and Broadcast Notices to Mariners of the

change in operating schedule for the bridge so that vessel operations can arrange their transits to minimize any impact caused by the temporary deviation. The Coast Guard notified known companies of the commercial vessels, NYPD, and FDNY in the area and they have no objections to the temporary deviation.

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

Dated: October 31, 2016.

C.J. Bisignano,

Supervisory Bridge Management Specialist, First Coast Guard District.

[FR Doc. 2016–26531 Filed 11–2–16; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2016–0978]

Drawbridge Operation Regulation; Pass Manchac, Manchac, LA

AGENCY: Coast Guard, DHS.

ACTION: Notice of deviation from drawbridge regulations.

SUMMARY: The Coast Guard has issued a temporary deviation from the operating schedule that governs the Canadian National (CN) Railroad automated bascule span drawbridge across Pass Manchac, mile 6.7 at Manchac, between St. John and Tangipahoa Parishes, Louisiana. The deviation is necessary to accommodate bridge repair work essential for the continued operation of the bridge. This deviation allows the bridge to remain closed-to-navigation for eight hours on three consecutive days, allowing vessels to pass with a one-hour advance notice.

DATES: This deviation is effective from November 15, 2016 through November 17, 2016 from 5 a.m. through 2 p.m.

ADDRESSES: The docket for this deviation, [USCG–2016–0978] is available at *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary deviation, call or email Donna Gagliano, Bridge Administration Branch, Coast Guard, telephone (504) 671–2128, email *Donna.Gagliano@uscg.mil.*

SUPPLEMENTARY INFORMATION: CN Railroad, requested that a one-hour advance notice be given for the passage of vessels on the automated bascule span drawbridge across Pass Manchac, mile 6.7 at Manchac, between St. John and Tangipahoa Parishes, Louisiana. The deviation is necessary to replace the rail, fasteners, and lift joints on the bridge. This work is essential for the continued operation of the bridge.

In accordance with 33 CFR 117.484, the bridge is not tended and is therefore automated. These operations are described in 33 CFR 117.484. Currently, the bridge remains open until the passage of a train at which time it closes to allow the train to pass. This deviation will allow the bridge to remain closed to all marine traffic from 5 a.m. through 2 p.m. on Tuesday, November 15, 2016 through Thursday, November 17, 2016, without a one-hour advance notice.

The bridge will remain operational to vessels with a one-hour advanced notice. A tender will be on site to operate the bridge during the set work schedule and will be monitoring channel 16.

Navigation on the waterway consists of small tugs with and without tows, commercial vessels, and recreational craft, including sailboats. The Coast Guard will also inform the users of the waterways through our Local and Broadcast Notices to Mariners of the change in operating schedule for the bridge to minimize any impact caused by the temporary deviation. The bridge will be unable to open during these repairs and no alternate route is available.

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

Dated: October 31, 2016.

David M. Frank,

Bridge Administrator, Eighth Coast Guard District.

[FR Doc. 2016–26597 Filed 11–2–16; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2016–0992]

RIN 1625–AA00

Safety Zone; Arkansas River, Little Rock, AR

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for all waters of the Arkansas River beginning at mile marker 118.6 and ending at mile marker 119.6. The safety zone is necessary to protect persons, property, and infrastructure from potential damage and safety hazards associated with the demolition of the Broadway Bridge. This rulemaking prohibits persons and vessels from entering the safety zone area during certain operations unless authorized by the Captain of the Port Memphis or a designated representative.

DATES: This rule is effective without actual notice from November 3, 2016 until 10 p.m. on December 1, 2016. For the purposes of enforcement, actual notice will be used from 10 p.m. on October 28, 2016 until November 3, 2016.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov,* type USCG–2016–0992 in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Petty Officer Todd Manow, Sector Lower Mississippi River Prevention Department, U.S. Coast Guard; telephone 901–521–4813, email *Todd.M.Manow@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

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

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary 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. The Coast Guard had previously established a

safety zone for this bridge demolition, [Docket Number USCG–2016–0885], and enforced it from October 1, 2016 until November 1, 2016. The Coast Guard was recently made aware by the contractor that demolition activities would not be completed in the original timeline. Immediate action is needed to respond to potential safety hazards related to a bridge demolition on or over this navigable waterway. It is impracticable and contrary to the public interest to publish an NPRM because we must establish this safety zone by November 1, 2016.

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

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 33 U.S.C. 1231. The COTP has determined that potential hazards associated with a bridge demolition starting November 1, 2016 will be a safety concern for anyone desiring to transit this section of the Arkansas River. This rule is needed to protect personnel, vessels, and infrastructure in the navigable waters within the safety zone while bridge demolition is occurring.

IV. Discussion of the Rule

This rule establishes a safety zone from 10 p.m. on November 1, 2016 through 10 p.m. on December 1, 2016. The safety zone will cover all navigable waters within one half mile on either side of the Broadway Bridge, beginning at mile marker 118.6 and ending at mile marker 119.6. Vessels will be prohibited from entering the safety zone from 30 minutes prior to, until 30 minutes after, any blasting or large-scale removal operation that takes place on the Broadway Bridge; designated representatives will be on-scene to stop or reroute traffic during these evolutions. No vessel or person will be permitted to enter the safety zone without obtaining permission from the COTP or a designated representative. During the entire effective period of this safety zone, regardless of operations, all vessel traffic will be required to maintain slowest speeds for safe navigation; marker buoys will be placed informing waterway users of a no-wake zone. This safety zone is intended to protect personnel, vessels, and infrastructure in these navigable waters while the bridge is being demolished.

V. Regulatory Analyses

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

A. Regulatory Planning and Review

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

This regulatory action determination is based on the size and location of the safety zone, a one-mile section of the Arkansas River in the vicinity of Little Rock, AR. Although in effect from November 1, 2016 until December 1, 2016, traffic will only be excluded from this safety zone from 30 minutes before until 30 minutes after any blasting or large-scale removal operation that takes place on the Broadway Bridge. During periods of non-exclusion, vessel traffic will be allowed to transit at slowest speeds for safe navigation through this safety zone. Moreover, the Coast Guard will issue Broadcast Notice to Mariners via VHF–FM marine channel 16 about the zone and the rule allows vessels to seek permission to enter the zone.

B. Impact on Small Entities

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

While some owners or operators of vessels intending to transit the safety zone may be small entities, for the reasons stated in section V.A above, this rule will not have a significant economic impact on any vessel owner or operator.

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

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

C. Collection of Information

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

D. Federalism and Indian Tribal Governments

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

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

FURTHER INFORMATION CONTACT section above.

E. Unfunded Mandates Reform Act

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

F. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a month-long safety zone limiting vessel speed and intermittently prohibiting entry into a one-mile area of the Arkansas River adjacent to the Broadway Bridge during demolition operations. It is 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.

List of Subjects in 33 CFR Part 165

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

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

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

■ 2. A new temporary § 165.35T08–0992 is added to read as follows:

§ 165.35T08–0992 Safety Zone; Arkansas River; Little Rock, AR.

(a) *Location.* All waters of the Arkansas River beginning at mile marker 118.6 and ending at mile marker 119.6 in the vicinity of Little Rock, AR.

(b) *Periods of enforcement.* This temporary safety zone will be enforced 30 minutes before until 30 minutes after any blasting or large-scale removal operation that takes place on the Broadway Bridge from 10 p.m. on October 28, 2016 through 10 p.m. on December 1, 2016.

(c) *Regulations.* (1) In accordance with the general regulations in § 165.23 of this part, entry into this area during blasting or large-scale removal operations is prohibited unless authorized by the COTP or a designated representative. All persons and vessels permitted to deviate from the safety zone requirements, as well as enter the restricted area must transit at the slowest safe speed and comply with all lawful directions issued by the COTP or a designated representative.

(2) Buoys marked ''No-Wake'' will be placed along the navigation channel while this safety zone is in effect.

(3) Persons or vessels requiring entry into or passage through this safety zone during prohibited entry periods must request permission from the COTP or a designated representative. They may be contacted on VHF Channel 16 or at 1–866–777–2784.

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

(d) *Informational broadcasts.* The COTP Memphis or a designated representative will inform the public through broadcast notices to mariners of the enforcement period for the safety zone, as well as any changes in the dates and times of enforcement.

Dated: October 28, 2016.

T.J. Wendt,

Captain, U.S. Coast Guard, Captain of the Port, Memphis, Tennessee.

[FR Doc. 2016–26529 Filed 11–2–16; 8:45 am]

BILLING CODE 9110–04–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 11

[ET Docket No. 04–296; FCC 16–32]

Amendment of the Emergency Alert System; Independent Spanish Broadcasters Association, the Office of Communication of the United Church of Christ, Inc., and the Minority Media and Telecommunications Council, Petition for Immediate Relief

AGENCY: Federal Communications Commission.

ACTION: Final rule; announcement of effective date.

SUMMARY: In this document, the Commission announces that the Office of Management and Budget (OMB) has approved, until Oct. 31, 2019, the information collection associated with the Commission's Order (*Order*) in ET Docket No. 04–296, FCC 16–32, adopted on March 23, 2016, and released on March 30, 2016, which, among other things, adopted new multilingual alerting reporting rules into its State Emergency Alert System (EAS) Plan reporting requirements. This document is consistent with the *Order,* which stated that the Commission would publish a document in the **Federal Register** announcing the effective date of those rules.

DATES: The amendments to 47 CFR 11.21 published at 81 FR 27342, May 6, 2016, are effective November 3, 2016.

FOR FURTHER INFORMATION CONTACT: Lisa Fowlkes, Deputy Bureau Chief, Public Safety and Homeland Security Bureau, at (202) 418–7452, or by email at *Lisa.Fowlkes@fcc.gov.*

SUPPLEMENTARY INFORMATION: This document announces that, on Oct 12, 2016, OMB approved, until Oct. 31, 2019, the information collection requirements associated with the multilingual reporting requirements adopted in on rules contained in the Commission's *Order,* FCC 16–32, published at 81 FR 27342, May 6, 2016. The OMB Control Number is 3060–0207. The Commission publishes this document as an announcement of the effective date of the rules. If you have any comments on the burden estimates listed below, or how the Commission can improve the collections and reduce any burdens caused thereby, please contact Nicole Ongele, Federal Communications Commission, Room 1–A620, 445 12th Street SW., Washington, DC 20554. Please include the OMB Control Number, 3060–0207, in your correspondence. The Commission will

also accept your comments via email at *PRA@fcc.gov.*

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

Synopsis

As required by the Paperwork Reduction Act of 1995 (44 U.S.C. 3507), the FCC is notifying the public that it received final OMB approval on October 12, 2016, for the information collection requirements contained in the modifications to the Commission's rules in 47 CFR part 11. Under 5 CFR part 1320, an agency may not conduct or sponsor a collection of information unless it displays a current, valid OMB Control Number.

No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act that does not display a current, valid OMB Control Number. The OMB Control Number is 3060–0207.

The foregoing notice is required by the Paperwork Reduction Act of 1995, Public Law 104–13, October 1, 1995, and 44 U.S.C. 3507.

The total annual reporting burdens and costs for the respondents are as follows:

OMB Control Number: 3060–0207.

OMB Approval Date: October 12, 2016.

OMB Expiration Date: October 31, 2019.

Title: Part 11, Emergency Alert System.

Form Number: N/A.

Respondents: Business and not-for-profit entities.

Number of Respondents and Responses: 63,080 respondents; 3,596,546 responses.

Estimated Time per Response: 1 hour (EAS Participants); 20 hours (SECCs).

Frequency of Response: One-time, and on-occasion reporting requirements.

Obligation to Respond: Required if distributing State and local EAS alerts in a given state. The statutory authority for this information collection is contained in sections 1, 2, 4(i), 4(o), 301, 303(r), 303(v), 307, 309, 335, 403, 624(g),706, and 715 of the Communications Act of 1934, as amended, 47 U.S.C. 151, 152, 154(i), 154(o), 301, 303(r), 303(v), 307, 309, 335, 403, 544(g), 606, and 615.

Total Annual Burden: 110,476 hours.

Total Annual Cost: None.

Nature and Extent of Confidentiality: An assurance of confidentiality is not offered because this information collection does not require the collection of personally identifiable information (PII) from individuals.

Privacy Act: No impact(s).

Needs and Uses: Section 11.21 of the Commission's part 11 (EAS) rules, 47 CFR 11.21, requires that State Emergency Communications Committees (SECC) prepare and submit State EAS Plans to the FCC for approval before State and local EAS alerts may be distributed within the state. On March 30, 2016, the Commission released the *Order,* FCC 16–32, published at 81 FR 27342, May 6, 2016, adopting rule amendments to section 11.21, 47 CFR 11.21—containing information collection requirements—designed to promote and better understand the landscape of multilingual alerting across the country. The rule amendments generally require EAS Participants (the broadcasters, cable systems, and other service providers subject to the EAS rules) to prepare and submit to their respective SECCs, a description of their efforts and activities to make available EAS alert message content to persons who communicate in languages other than English. SECCs are required to prepare a summary of such descriptions they receive and include such summary in the State EAS Plan they administer.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. 2016–26555 Filed 11–2–16; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 160126052–6974–02]

RIN 0648–BF72

Fisheries of the Northeastern United States; Atlantic Sea Scallop Fishery; Amendment 19

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

ACTION: Final rule.

SUMMARY: This final rule implements Amendment 19 to the Atlantic Sea Scallop Fishery Management Plan, which the New England Fishery Management Council adopted and submitted to NMFS for approval. Amendment 19 establishes a specifications process outside of the current framework adjustment process and adjusts the start of the scallop fishing year from March 1 to April 1. These changes will help reduce potential economic and biological consequences from late implementation of specifications and reduce the overall administrative burden associated with late implementation. As a result of these changes, NMFS will be able to implement simple specifications actions at the start of the fishing year on a more consistent basis.

DATES: Effective December 5, 2016.

ADDRESSES: The Council developed an environmental assessment (EA) for this action that describes these measures and other considered alternatives and provides a thorough analysis of the impacts of the measures and alternatives. Copies of the Amendment, the EA, and the Regulatory Flexibility Analysis (RFA), are available upon request from Thomas A. Nies, Executive Director, New England Fishery Management Council, 50 Water Street, Newburyport, MA 01950.

Copies of the small entity compliance guide are available from John K. Bullard, Regional Administrator, NMFS, Greater Atlantic Regional Fisheries Office, 55 Great Republic Drive, Gloucester, MA 01930–2298, or available on the Internet at *http://www.greateratlantic.fisheries.noaa.gov/sustainable/species/scallop/.*

FOR FURTHER INFORMATION CONTACT: Travis Ford, Fishery Policy Analyst, 978–281–9233.

SUPPLEMENTARY INFORMATION:

Background

The Council adopted Amendment 19 to the Atlantic Sea Scallop Fishery Management Plan (FMP) at its December 3, 2015, meeting and submitted the amendment to NMFS on June 16, 2016. NMFS published a notice of availability on July 20, 2016 (81 FR 47152), and a proposed rule, including a reference on how to obtain the amendment and the draft final EA, for approving and implementing Amendment 19 on August 16, 2016 (81 FR 54533). The NOA included a 60-day public comment period that closed on September 19, 2016, and the proposed rule included a 30-day public comment period that closed on September 15, 2016. NMFS reviewed and finalized the amendment document to ensure consistency with the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act), the Scallop FMP, and other applicable laws. NMFS approved Amendment 19 in its entirety.

In order to incorporate the most recent available scallop survey information, which has proved essential in setting appropriate access area catch levels, the Council has been taking final action in November or December, and NMFS has typically implemented allocations in May or June. Prior to this action, this would result in allocations for a given fishing year in place 2 to 3 months after the March 1 start of the fishing year.

To address these timing issues while still supporting the current timeline for integrating the best available science in to the management process, Amendment 19 establishes a specifications process so that allocations do not need to be tied to more complex actions like frameworks or amendments that tend to have longer development, review, and implementation timelines; and adjusts the scallop fishing year to April 1 through March 31.

Allowing for Allocations To Be Set Through Specifications Actions

Amendment 19 creates a new specifications process for the Scallop FMP. Adding the ability to adjust allocations through a specifications setting process produces some time savings because the Council will not be required to discuss measures over the course of two Council meetings, as is required under a framework. In addition, measures developed in a specifications action will be limited to those related to allocations and possession limits. This means that some of the more complicated management measures typically contained in frameworks will not be included, thus the development and rulemaking for these actions will be simplified. Although developing a specifications action will save some time in the development of allocations, it would not guarantee allocations will be in place by March 1 of each year. It is more likely that allocations could be implemented on April 1, a month after the current start of the fishing year.

The Council will not be required to set scallop allocations through a specifications action and could utilize a framework to develop more robust management measures, but more complicated actions and more management measures under consideration generally means the action will take longer to develop, review, and implement.

Changing the Start of the Fishing Year to April 1

Because a specifications action would more likely be implemented on April 1, Amendment 19 changes the scallop fishing year to April 1 through March 31. Pushing the fishing year back one month will increase the likelihood that NMFS will be able to implement simple specifications actions at the start of the scallop fishing year on a more consistent basis and not need to implement default measures at all.

To give the industry time to account for this change in their business planning, this measure will not be effective until fishing year 2018. Because the current fishing year began on March 1, 2016, fishing year 2016 will not be affected by this change. Fishing year 2017 will be 13 months long, running from March 1, 2017, through March 31, 2018. The Council intends to prorate allocations appropriately for 2017 to account for this additional month. On April 1, 2018, the scallop fishing year will officially change for fishing year 2018 and beyond.

Amendment 19 also adjusts the scallop permit year so that it continues to match the official fishing year (*i.e.,* scallop permits will need to be renewed by April 1 of each year). This change is also effective beginning in fishing year 2018.

Regulatory Corrections Under Regional Administrator Authority

NMFS removed the annual specifications from the regulatory text and reorganized the layout of the regulations to help streamline the approval of future specifications actions. As a result, this rule includes revisions to the regulatory text that reorganize and condense references to annual scallop allocations and possession limits. These adjustments do not make any substantive changes to the implications of the current regulations and allow future specifications-setting actions to be implemented sooner by avoiding the need to make extensive regulatory changes for each specifications-setting action. These changes are consistent with section 305(d) of the Magnuson-Stevens Act, which provides that the Secretary of Commerce may promulgate regulations necessary to ensure that amendments to an FMP are carried out in accordance with the FMP and the Magnuson-Stevens Act.

To accommodate the specifications process and simplify the scallop regulations, NMFS makes the following changes to regulatory text: Revising the definitions in § 648.2 to remove the unnecessary distinction between Rotational Closed Areas and Scallop Access Areas; consolidating all of the allocations into a single table in § 648.53; condensing the explanations of OFL, ABC, and ACL into § 648.53, which creates a single section dedicated to all of the catch limits (the current regulations have this information repeated again at § 648.55, which NMFS removed); removing §§ 648.57 and 648.58 and integrating them into §§ 648.59 and 648.60 to describe the scallop access area program and remove the unnecessary distinction between Rotational Closed Areas and Scallop Access Areas; and moving access area program requirements currently in § 648.60 to § 648.59 to provide a dedicated section to access area program requirements (§ 648.59) and a dedicated section to listing all of the scallop access areas (§ 648.60).

Under this same section 305(d) authority, this action also makes the following revisions to the regulatory text, unrelated to the addition of a specifications process, to address text that is unnecessary, outdated, unclear, or NMFS could otherwise improve: Revising §§ 648.14(i)(2)(vi)(B) and 648.14(i)(3)(v)(E) to clarify in the prohibitions a requirement currently in § 648.58(e) that vessels cannot transit the Closed Area II Rotational Area, the Closed Area II Extension Rotational Area, or the Elephant Trunk Closed Area unless there is a compelling safety reason for transiting the area; adding back in text, at § 648.53(c), regarding limited access accountability measures that was unintentionally removed during Framework Adjustment 27 to the Scallop FMP (81 FR 26727, May 4, 2016); updating a reference in § 648.54 regarding the state waters exemption program that was unintentionally overlooked in Framework Adjustment 26 to the Scallop FMP (80 FR 22119, April 21, 2015); revising § 648.56(f) to reflect a change that scallop research set-aside (RSA) can be harvested to accommodate the change in fishing year (changing from May 31 to June 30 of the fishing year subsequent to the fishing year in which the set-aside is awarded); and revising § 648.62(c) to clarify that NGOM vessels must declare either a Federal NGOM trip or a state-waters NGOM trip on their VMS units when declaring a scallop trip.

Finally, due to the extensive regulatory changes in this action, NMFS is updating references throughout the scallop regulations that NMFS has changed based on the regulatory adjustments. NMFS has included a summary of all of the regulatory changes in this rule in Table 1.

TABLE 1—SUMMARY OF REGULATORY CHANGES TO 50 CFR PART 648

Section	Current title	Title	Type of changes	Summary of changes
648.2	Definitions	Same	Amendment 19 & Regulatory Streamlining.	Changes address the new scallop fishing year and remove the unnecessary distinction between Rotational Closed Areas and Scallop Access Areas.
648.10	VMS and DAS requirements for vessel owners/operators.	Same	Regulatory Streamlining	Changes update references that will change based on regulatory adjustments to other sections.
648.14	Prohibitions	Same	Regulatory Streamlining & Corrections.	Changes update references that will change based on regulatory adjustments to other sections. Clarification that vessels cannot transit the Closed Area II Rotational Area, the Closed Area II Extension Rotational Area, or the Elephant Trunk Closed Area.
648.51	Gear and crew restrictions.	Same	Regulatory Streamlining	Changes update references that will change based on regulatory adjustments to other sections.
648.52	Possession and landing limits.	Same	Regulatory Streamlining	Changes update references that will change based on regulatory adjustments to other sections.
648.53	Acceptable biological catch, annual catch limits, annual catch targets, DAS allocations, and individual fishing quotas.	Overfishing limit, acceptable biological catch, annual catch limits, annual catch targets, DAS allocations, and individual fishing quotas.	Amendment 19, Regulatory Streamlining, & Corrections.	Changes address Amendment 19 specifications process, condense allocations into a single table, and condense the explanations of OFL, ABC, and ACL in to a single section. The current regulations have this information repeated again at § 648.55. Also, NMFS adds back in text, at § 648.53(c), regarding limited access accountability measures that was unintentionally removed during scallop Framework Adjustment 27.
648.54	State waters exemption	Same	Corrections	The change to this section updates an old reference that should have occurred during scallop Framework Adjustment 26 rulemaking but was inadvertently overlooked.
648.55	Framework adjustments to management measures.	Specifications and framework adjustments to management measures.	Amendment 19 & Regulatory Streamlining.	Changes to this section address Amendment 19 changes, but also fine-tune previous regulations and remove repetitive regulations that are now consolidated into § 648.53, specifically the explanation of OFL, ABC, and ACL.
648.56	Scallop research	Same	Amendment 19 & Regulatory Streamlining.	Changes update references that will change based on other regulatory adjustments and support the Amendment 19 alternative to change the fishing year to April 1. Changes would push back the 90-day RSA carryover timeframe by a month (from May 31 to June 30) to accommodate the change in fishing year.
648.57	Sea scallop area rotation program.	Reserved	Amendment 19 & Regulatory Streamlining.	Changes remove unnecessary distinction between rotational closed areas and scallop access areas, clarifying that rotational areas can be open or closed as determined through the specifications or framework process. Consolidates the regulations formerly in this section in to § 648.59.
648.58	Rotational Closed Areas	Reserved	Amendment 19 & Regulatory Streamlining.	Changes remove unnecessary distinction between rotational closed areas and scallop access areas clarifying that rotational areas can be open or closed, as determined through the specifications or framework process. Consolidating the regulations formerly in this section in to §§ 648.59 and 648.60.
648.59	Sea Scallop Access Areas.	Sea scallop rotational area management program and access area program requirements.	Amendment 19 & Regulatory Streamlining.	There are no substantial changes to current regulatory text in this section; portions of this section are reorganized to incorporate regulations formerly in §§ 648.57 and 648.58. Also, the access area program requirements were moved to this section from § 648.60 for clarity.

TABLE 1—SUMMARY OF REGULATORY CHANGES TO 50 CFR PART 648—Continued

Section	Current title	Title	Type of changes	Summary of changes
648.60	Sea scallop access area program requirements.	Sea scallop rotational areas.	Amendment 19 & Regulatory Streamlining.	There are no substantial changes to current regulatory text in this section; portions of this section are reorganized to incorporate regulations formerly in § 648.58. Also, the access area program requirements were moved from this section to§ 648.59 for clarity.
648.62	Northern Gulf of Maine (NGOM) Management Program.	Same	Amendment 19, Regulatory Streamlining, & Corrections.	Changes to this section support the specifications process and update references that will change based on other regulatory adjustments. Also, changes clarify that NGOM vessels must declare either a Federal NGOM trip or a state-waters NGOM trip.
648.63	General category Sectors and harvesting cooperatives.	Same	Regulatory Streamlining	Changes update references that will change based on regulatory adjustments to other sections.
648.64	Yellowtail flounder sub-ACLs and AMs for the scallop fishery.	Same	Amendment 19	Changes to this section are to support the Amendment 19 alternative to change the fishing year to April 1.
648.65	Windowpane flounder sub-ACL and AM for the scallop fishery.	Same	Amendment 19	Changes to this section are to support the Amendment 19 alternative to change the fishing year to April 1.

Comments and Responses

NMFS received one comment letter in response to the proposed rule, from Lund's Fisheries, Inc. NMFS may only approve, disapprove, or partially approve measures in Amendment 19, and cannot substantively amend, add, or delete measures beyond what is necessary under section 305(d) of the Magnuson-Stevens Act to discharge its responsibility to carry out such measures.

Comment: Lund's Fisheries, Inc., commented in support of Amendment 19 because it eliminates uncertainties with harvesters, processors and their customers created by the late implementation of the scallop specifications.

Response: NMFS appreciates Lund's Fisheries, Inc., support of this action.

Changes From Proposed Rule to Final Rule

There were no changes from the proposed rule.

Classification

Pursuant to section 304(b)(1)(A) of the Magnuson-Stevens Act, the NMFS Assistant Administrator has determined that this final rule is consistent with the FMPs, other provisions of the Magnuson-Stevens Act and other applicable law.

The Office of Management and Budget (OMB) has determined that this final rule is not significant according to Executive Order (E.O.) 12866.

This final rule does not contain policies with federalism or ''takings'' implications, as those terms are defined in E.O. 13132 and E.O. 12630, respectively.

This action does not contain any collection-of-information requirements subject the Paperwork Reduction Act (PRA).

The Chief Counsel for Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration at the proposed rule stage that this rule will not have a significant economic impact on a substantial number of small entities. The factual basis for the certification was published in the proposed rule and is not repeated here. No comments were received regarding this certification. As a result, a regulatory flexibility analysis is not required and none has been prepared.

List of Subjects in 50 CFR Part 648

Fisheries, Fishing, Recordkeeping and reporting requirements.

Dated: October 20, 2016.

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 648 is amended as follows:

PART 648—FISHERIES OF THE NORTHEASTERN UNITED STATES

■ 1. The authority citation for part 648 continues to read as follows:

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

■ 2. Amend § 648.2 by:

■ a. Revising the definitions of ''Fishing year,'' ''Open areas,'' and ''Permit year'';

■ b. Removing the definitions of ''Rotational Closed Area'' and ''Sea Scallop Access Area'';

■ c. Adding the definitions for ''Sea Scallop Access Area, Scallop Access Area, or Access Area'' and ''Sea Scallop Rotational Area, Scallop Rotational Area, or Rotational Area'' in alphabetical order.

The revisions and additions read as follows:

§ 648.2 Definitions.

* * * * *

Fishing year means:

(1) For the Atlantic deep-sea red crab fishery, from March 1 through the last day of February of the following year.

(2) Beginning in 2018, for the Atlantic sea scallop fishery, from April 1 through March 31 of the following year (for 2017, the Atlantic sea scallop fishing year will be from March 1, 2017, through March 31, 2018).

(3) For the NE multispecies, monkfish and skate fisheries, from May 1 through April 30 of the following year.

(4) For the tilefish fishery, from November 1 through October 31 of the following year.

(5) For all other fisheries in this part, from January 1 through December 31.

* * * * *

Open areas, with respect to the Atlantic sea scallop fishery, means any area that is not subject to restrictions of the Sea Scallop Rotational Areas specified in §§ 648.59 and 648.60, EFH Closed Areas specified in § 648.61, or the Northern Gulf of Maine Management Area specified in § 648.62.

* * * * *

Permit year means:

(1) For the Atlantic deep-sea red crab fishery, from March 1 through the last day of February of the following year;

(2) Beginning in 2018, for the Atlantic sea scallop fishery, from April 1 through the last day of March of the following year (for 2017, the Atlantic sea scallop permit year will be from March 1, 2017, through March 31, 2018);

(3) For all other fisheries in this part, from May 1 through April 30 of the following year.

* * * * *

Sea Scallop Access Area, Scallop Access Area, or *Access Area,* with respect to the Atlantic sea scallop fishery, means an area that has been designated under the Atlantic Sea Scallop Fishery Management Plan as a sea scallop rotational area that is open to the scallop fishery in a given fishing year.

* * * * *

Sea Scallop Rotational Area, Scallop Rotational Area, or *Rotational Area,* with respect to the Atlantic sea scallop fishery, means an area that has been designated under the Atlantic Sea Scallop Fishery Management Plan as part of the Sea Scallop Rotational Management Program. A rotational area may be closed or open to the scallop fishery in a given fishing year. A rotational area open to the scallop fishery is termed a Sea Scallop Access Area and has area-specific management measures that are designed to control fishing effort and mortality on only the portion of the scallop resource within the area. Such measures are not applicable as defined in § 648.2 in the definition to Open Areas.

* * * * *

■ 3. In § 648.10, revise paragraph (b)(2), the first sentence in paragraph (f)(4)(i) introductory text, paragraph (h) introductory text, and paragraph (h)(8)(ii) to read as follows:

§ 648.10 VMS and DAS requirements for vessel owners/operators.

* * * * *

(b) * * *

(2) A scallop vessel issued an Occasional limited access permit when fishing under the Sea Scallop Area Access Program specified under § 648.59;

* * * * *

(f) * * *

(4) * * *

(i) The owner or operator of a limited access or LAGC IFQ vessel that fishes for, possesses, or retains scallops, and is not fishing under a NE Multispecies DAS or sector allocation, must submit reports through the VMS, in accordance with instructions to be provided by the Regional Administrator, for each day fished, including open area trips, access area trips as described in § 648.59(b)(9), and trips accompanied by a NMFS-approved observer. * * *

* * * * *

(h) *Call-in notification.* The owner of a vessel issued a limited access monkfish permit who is participating in a DAS program and who is not required to provide notification using a VMS, and a scallop vessel qualifying for a DAS allocation under the occasional category that has not elected to fish under the VMS notification requirements of paragraph (e) of this section and is not participating in the Sea Scallop Area Access program as specified in § 648.59, and any vessel that may be required by the Regional Administrator to use the call-in program under paragraph (i) of this section, are subject to the following requirements:

* * * * *

(8) * * *

(ii) A vessel issued a limited access scallop and LAGC IFQ scallop permit that possesses or lands more than 600 lb (272.2 kg) of scallops, unless otherwise specified in § 648.59(d)(2);

* * * * *

■ 4. Amend § 648.14 by:

■ a. Revising paragraphs (i)(1)(vi), (i)(2)(ii)(B)(*7*), (i)(2)(iii)(B), (i)(2)(iii)(C), (i)(2)(iv)(B), paragraph (i)(2)(vi) introductory text, and paragraph (i)(2)(vi)(A);

■ b. Adding paragraph (i)(2)(vi)(B);

■ c. Revising paragraphs (i)(2)(vi)(D), (i)(3)(iv)(A), (i)(3)(v); and

■ d. Revising paragraph (i)(4)(i)(A).

The additions and revisions read as follows:

§ 648.14 Prohibitions.

* * * * *

(i) * * *

(1) * * *

(vi) *Closed area requirements*—(A) *EFH Closed Areas.* (*1*) Fish for scallops in, or possess or land scallops from, the EFH Closed Areas specified in § 648.61.

(*2*) Transit or enter the EFH Closure Areas specified in § 648.61, except as provided by § 648.61(b).

(B) *Scallop Rotational Areas.* (*1*) Fish for scallops in, or possess or land scallops from, the Scallop Rotational Areas closed to the scallop fishery through the specifications or framework adjustment processes specified in § 648.55.

(*2*) Transit or enter the Scallop Rotational Areas, except as provided by § 648.59(a) or (b).

* * * * *

(2) * * *

(ii) * * *

(B) * * *

(*7*) Fish in a Sea Scallop Access Area, as described in § 648.60, with more persons on board the vessel than the number specified in § 648.51(c) or § 648.51(e)(3)(i), unless otherwise authorized by the Regional Administrator.

* * * * *

(iii) * * *

(B) Fish for, possess, or land more than 50 bu (17.62 hL) of in-shell scallops once inside the VMS Demarcation Line on or by a vessel that, at any time during the trip, fished in or transited any area south of 42°20′ N. lat; or fished in any Sea Scallop Area Access Program specified in § 648.59, except as provided in the state waters exemption, as specified in § 648.54.

(C) Fish for, possess, or land per trip, at any time, scallops in excess of any sea scallop possession and landing limit set by the Regional Administrator in accordance with § 648.59(b)(3) when properly declared into the Sea Scallop Area Access Program as described in § 648.59.

* * * * *

(iv) * * *

(B) Combine, transfer, or consolidate DAS allocations, except as allowed for one-for-one Access Area trip exchanges as specified in § 648.59(b)(3)(ii).

* * * * *

(vi) *Scallop rotational area management program and scallop access area program requirements.* (A) Fail to comply with any of the provisions and specifications of § 648.59.

(B) Transit the Closed Area II Rotational Area or the Closed Area II Extension Rotational Area, as defined § 648.60(d) and (e), respectively, or the Elephant Trunk Closed Area, as defined in § 648.60(b), unless there is a compelling safety reason for transiting the area and the vessel's fishing gear is stowed and not available for immediate use as defined in § 648.2.

* * * * *

(D) Possess more than 50 bu (17.6 hL) of in-shell scallops outside the boundaries of a Sea Scallop Access Area by a vessel that is declared into the Area Access Program as specified in § 648.59.

* * * * *

(3) * * *

(iv) * * *

(A) Fail to comply with any of the VMS requirements specified in §§ 648.10, 648.59, or 648.62.

* * * * *

(v) *Scallop rotational area management program and scallop access area program requirements.* (A)

Fail to comply with any of the requirements specified in § 648.59.

(B) Declare into or leave port for an area specified in § 648.60 after the effective date of a notification published in the **Federal Register** stating that the number of LAGC trips have been taken, as specified in § 648.59.

(C) Fish for or land per trip, or possess in excess of 40 lb (18.1 kg) of shucked scallops at any time in or from any Sea Scallop Access Area specified at § 648.60, unless declared into the Sea Scallop Access Area Program.

(D) Fish for, possess, or land scallops in or from any Sea Scallop Access Area without an observer on board, unless the vessel owner, operator, or manager has received a waiver to carry an observer for the specified trip and area fished.

(E) Transit the Closed Area II Rotational Area or the Closed Area II Extension Rotational Area, as defined § 648.60(d) and (e), respectively, or the Elephant Trunk Closed Area, as defined in § 648.60(b), unless there is a compelling safety reason for transiting the area and the vessel's fishing gear is stowed and not available for immediate use as defined in § 648.2.

* * * * *

(4) * * *

(i) * * *

(A) Fish for or land per trip, or possess at any time, in excess of 600 lb (272.2 kg) of shucked, or 75 bu (26.4 hL) of in-shell scallops per trip, or 100 bu (35.2 hL) in-shell scallops seaward of the VMS Demarcation Line, unless the vessel is carrying an observer as specified in § 648.11 and an increase in the possession limit is authorized by the Regional Administrator and not exceeded by the vessel, as specified in §§ 648.52(g) and 648.59(d).

* * * * *

■ 5. In § 648.51, revise paragraphs (b)(1), (b)(3)(i), paragraph (c) introductory text, and paragraph (f)(1) to read as follows:

§ 648.51 Gear and crew restrictions.

* * * * *

(b) * * *

(1) *Maximum dredge width.* The combined dredge width in use by or in possession on board such vessels shall not exceed 31 ft (9.4 m), measured at the widest point in the bail of the dredge, except as provided under paragraph (e) of this section, in § 648.59(g)(2), and the scallop dredge exemption areas specified in § 648.80. However, component parts may be on board the vessel such that they do not conform with the definition of ''dredge or dredge gear'' in § 648.2, *i.e.,* the metal ring bag and the mouth frame, or bail, of the dredge are not attached, and such that no more than one complete spare dredge could be made from these component's parts.

* * * * *

(3) * * *

(i) Unless otherwise required under the Sea Scallop Area Access program specified in § 648.59(b)(6), the ring size used in a scallop dredge possessed or used by scallop vessels shall not be smaller than 4 inches (10.2 cm).

* * * * *

(c) *Crew restrictions.* A limited access vessel participating in or subject to the scallop DAS allocation program may have no more than seven people aboard, including the operator, and a limited access vessel participating in the Sea Scallop Area Access Program as specified in § 648.59 may have no more than eight people aboard, including the operator, when not docked or moored in port, except as follows:

* * * * *

(f) * * *

(1) A vessel issued a limited access scallop permit fishing for scallops under the scallop DAS allocation program may not fish with, possess on board, or land scallops while in possession of a trawl net, unless such vessel has been issued a limited access trawl vessel permit that endorses the vessel to fish for scallops with a trawl net. A limited access scallop vessel issued a trawl vessel permit that endorses the vessel to fish for scallops with a trawl net and general category scallop vessels enrolled in the Area Access Program as specified in § 648.59, may not fish for scallops with a trawl net in the Closed Area 1, Closed Area II, Closed Area II Extension, and Nantucket Lightship Rotational Areas specified in § 648.60.

* * * * *

■ 6. In § 648.52, revise paragraphs (d), (f), and (g) to read as follows:

§ 648.52 Possession and landing limits.

* * * * *

(d) Owners or operators of vessels with a limited access scallop permit that have properly declared into the Sea Scallop Area Access Program as described in § 648.59 are prohibited from fishing for or landing per trip, or possessing at any time, scallops in excess of any sea scallop possession and landing limit set by the Regional Administrator in accordance with § 648.59(b)(5).

* * * * *

(f) A limited access vessel or an LAGC vessel that is declared into the Sea Scallop Area Access Program as described in § 648.59, may not possess more than 50 bu (17.6 hL) or 75 bu (26.4 hL), respectively, of in-shell scallops outside of the Access Areas described in § 648.60.

(g) *Possession limit to defray the cost of observers for LAGC IFQ vessels.* An LAGC IFQ vessel with an observer on board may retain, per observed trip, up to 1 day's allowance of the possession limit allocated to limited access vessels, as established by the Regional Administrator in accordance with § 648.59(d), provided the observer set-aside specified in § 648.59(d)(1) has not been fully utilized. For example, if the limited access vessel daily possession limit to defray the cost of an observer is 180 lb (82 kg), the LAGC IFQ possession limit to defray the cost of an observer would be 180 lb (82 kg) per trip, regardless of trip length.

■ 7. In § 648.53, revise the section heading and paragraphs (a), (b), (c), (d), (e), (g)(1), (h)(2) introductory text, and paragraphs (h)(2)(i), (h)(2)(v)(B), (h)(3)(i), (h)(3)(ii)(A), (h)(5)(i), and (h)(5)(ii)(A) to read as follows:

§ 648.53 Overfishing limit (OFL), acceptable biological catch (ABC), annual catch limits (ACL), annual catch targets (ACT), DAS allocations, and individual fishing quotas (IFQ).

(a) The following determinations and allocations for the sea scallop rotational areas are defined as follows and shall be established through the specifications or framework adjustment process:

(1) *OFL.* OFL shall be based on an updated scallop resource and fishery assessment provided by either the Scallop PDT or a formal stock assessment. OFL shall include all sources of scallop mortality and shall include an upward adjustment to account for catch of scallops in state waters by vessels not issued Federal scallop permits. The fishing mortality rate (*i.e.* F) associated with OFL shall be the threshold F, above which overfishing is occurring in the scallop fishery. The F associated with OFL shall be used to derive specifications for ABC, ACL, and ACT, as defined in paragraph (a) of this section.

(2) The specification of ABC, ACL, and ACT shall be based upon the following overfishing definition: The F shall be set so that in access areas, averaged for all years combined over the period of time that the area is closed and open to scallop fishing as an access area, it does not exceed the established F threshold for the scallop fishery; in open areas it shall not exceed the F threshold for the scallop fishery; and for access and open areas combined, it is set at a level that has a 75-percent probability of remaining below the F associated with ABC, as defined in

paragraph (a)(3) of this section, taking into account all sources of fishing mortality in the limited access and LAGC fleets of the scallop fishery.

(3) *Overall ABC/ACL.* The overall ABC for sea scallop fishery shall be the catch level that has an associated F that has a 75-percent probability of remaining below the F associated with OFL. The overall ACL shall be equal to the ABC for the scallop fishery, minus discards (an estimate of both incidental and discard mortality). The ABC/ACL, after the discards and deductions specified in paragraph (a)(4) of this section are removed, shall be divided as sub-ACLs between limited access vessels, limited access vessels that are fishing under a LAGC permit, and LAGC vessels as defined in paragraphs (a)(5) and (6) of this section, after the deductions outlined in paragraph (a)(4) of this section.

(4) *Deductions from ABC/ACL.* Incidental catch, as defined in paragraph (a)(7) of this section, shall be removed from ABC/ACL. One percent of ABC/ACL shall be removed from ABC/ACL for observer set-aside. Scallop catch equal to the value specified in § 648.56(d) shall be removed from ABC/ACL for research set-aside. These deductions for incidental catch, observer set-aside, and research set-aside, shall be made prior to establishing sub-ACLs for the limited access and LAGC fleets, as specified in paragraphs (a)(5) and (6) of this section.

(5) *Limited access fleet sub-ACL and sub-ACT*—(i) *Limited access fleet sub-ACL.* After applying the deductions as specified in paragraph (a)(4) of this section, the limited access scallop fleet shall be allocated a sub-ACL equal to 94.5 percent of the ABC/ACL.

(ii) *Limited access fleet sub-ACT.* The ACT for the limited access fishery shall be set at a level that has an associated F with a 75-percent probability of remaining below the F associated with ABC/ACL.

(6) *LAGC IFQ fleet sub-ACL and sub-ACT*—(i) *LAGC IFQ fleet sub-ACL.* After applying the deductions as specified in paragraph (a)(4) of this section, the LAGC IFQ fleet shall be allocated a sub-ACL equal to 5.5 percent of the ABC/ACL, so that 5 percent of ABC/ACL is allocated to the LAGC fleet of vessels that do not also have a limited access scallop permit, and 0.5 percent of the ABC/ACL is allocated to the LAGC fleet of vessels that have limited access scallop permits. This specification of sub-ACLs shall not account for catch reductions associated with the application of AMs or adjustment of the sub-ACL as a result of the limited access AM exception as specified in paragraph (c)(1) of this section.

(ii) *LAGC IFQ fleet sub-ACT.* The LAGC IFQ fishery sub-ACT shall be equal to the LAGC IFQ fishery's sub-ACL. The sub-ACT for the LAGC IFQ fishery for vessels issued only a LAGC IFQ scallop permit shall be equal to 5 percent of the ABC/ACL specified in paragraph (a)(3) of this section, after applying the deductions as specified in paragraph (a)(4) of this section. The sub-ACT for the LAGC IFQ fishery for vessels issued both a LAGC IFQ scallop permit and a limited access scallop permit shall be 0.5 percent of the ACL specified in paragraph (a)(3) of this section, after applying the deductions as specified in paragraph (a)(4) of this section.

(7) *Scallop incidental catch target TAC.* The annual incidental catch target TAC is the catch available for harvest for vessels with incidental catch scallop permits. This incidental catch target will be removed from the ABC/ACL defined in paragraph (a)(3) of this section prior to establishing the limited access and LAGC IFQ sub-ACLs and sub-ACTs defined in paragraphs (a)(5) and (6) of this section.

(8) The following catch limits will be effective for the 2016 and 2017 fishing years:

SCALLOP FISHERY CATCH LIMITS

Catch limits	2016 (mt)	2017 (mt) *
Overfishing Limit	68,418	68,418
Acceptable Biological Catch/ACL (discards removed)	37,852	37,852
Incidental Catch	23	23
Research Set-Aside (RSA)	567	567
Observer Set-Aside	379	379
ACL for fishery	36,884	36,884
Limited Access ACL	34,855	34,855
LAGC ACL	2,029	2,029
LAGC IFQ	1,845	1,845
Limited Access with LAGC IFQ	184	184
Limited Access ACT	18,290	18,290

* The catch limits for the 2017 fishing year are subject to change through a future specifications action or framework adjustment.

(b) *DAS specifications and allocations.* DAS specifications and allocations for limited access scallop trips in open areas are defined as follows and shall be specified through the specifications or framework adjustment processes defined in § 648.55, as follows:

(1) *DAS allocations.* DAS allocations shall be determined by distributing the portion of the limited access ACT defined in paragraph (a)(3) of this section, as reduced by access area allocations defined in § 648.59, and dividing that amount among vessels in the form of DAS calculated by applying estimates of open area landings per unit effort (LPUE) projected through the specifications or framework adjustment processes used to set annual allocations.

(2) *Assignment to DAS categories*—(i) Limited access vessels shall be categorized as full-time, part-time, or occasional. Allocations for part-time and occasional scallop vessels shall be 40 percent and 8.33 percent of the full-time DAS allocations, respectively.

(ii) Subject to the vessel permit application requirements specified in § 648.4, for each fishing year, each vessel issued a limited access scallop permit shall be assigned to the DAS category (full-time, part-time, or occasional) it was assigned to in the preceding year, except as provided under the small dredge program specified in § 648.51(e).

(3) The DAS allocations for limited access scallop vessels for fishing years 2016 and 2017 are as follows:

SCALLOP OPEN AREA DAS ALLOCATIONS

Permit category	2016	2017*
Full-Time	34.55	34.55
Part-Time	13.82	13.82
Occasional	2.88	2.88

*The DAS allocations for the 2017 fishing year are subject to change through a future specifications action or framework adjustment.

(c) *Accountability measures (AM) for limited access vessels.* Unless the limited access AM exception is implemented in accordance with the provision specified in paragraph (c)(1) of this section, if the limited access sub-ACL defined in paragraph (a)(5) of this section is exceeded for the applicable fishing year, the DAS for each limited access vessel shall be reduced by an amount equal to the amount of landings in excess of the sub-ACL divided by the applicable LPUE for the fishing year in which the AM will apply as projected by the specifications or framework adjustment process specified in § 648.55, then divided by the number of scallop vessels eligible to be issued a full-time limited access scallop permit. For example, assuming a 300,000-lb (136-mt) overage of the limited access fishery's sub-ACL in 2011, an open area LPUE of 2,500 lb (1.13 mt) per DAS in 2012, and 313 full-time vessels, each full-time vessel's DAS for 2012 would be reduced by 0.38 DAS (300,000 lb (136 mt)/2,500 lb (1.13 mt) per DAS = 120 lb (0.05 mt) per DAS/313 vessels = 0.38 DAS per vessel). Deductions in DAS for part-time and occasional scallop vessels shall be 40 percent and 8.33 percent of the full-time DAS deduction, respectively, as calculated pursuant to paragraph (b)(2) of this section. The AM shall take effect in the fishing year following the fishing year in which the overage occurred. For example, landings in excess of the limited access fishery's sub-ACL in fishing year 2011 would result in the DAS reduction AM in fishing year 2012. If the AM takes effect, and a limited access vessel uses more open area DAS in the fishing year in which the AM is applied, the vessel shall have the DAS used in excess of the allocation after applying the AM deducted from its open area DAS allocation in the subsequent fishing year. For example, a vessel initially allocated 32 DAS in 2011 uses all 32 DAS prior to application of the AM. If, after application of the AM, the vessel's DAS allocation is reduced to 31 DAS, the vessel's DAS in 2012 would be reduced by 1 DAS.

(1) *Limited access AM exception.* If NMFS determines that the fishing mortality rate associated with the limited access fleet's landings in a fishing year is less than 0.34, the AM specified in paragraph (c) of this section shall not take effect. The fishing mortality rate of 0.34 is the fishing mortality rate that is one standard deviation below the fishing mortality rate for the scallop fishery ACL, currently estimated at 0.38.

(2) *Limited access fleet AM and exception provision timing.* The Regional Administrator shall determine whether the limited access fleet exceeded its sub-ACL defined in paragraph (a)(5) of this section by July of the fishing year following the year for which landings are being evaluated. On or about July 1, the Regional Administrator shall notify the New England Fishery Management Council of the determination of whether or not the sub-ACL for the limited access fleet was exceeded, and the amount of landings in excess of the sub-ACL. Upon this notification, the Scallop Plan Development Team (PDT) shall evaluate the overage and determine if the fishing mortality rate associated with total landings by the limited access scallop fleet is less than 0.34. On or about September 1 of each year, the Scallop PDT shall notify the Council of its determination, and the Council, on or about September 30, shall make a recommendation, based on the Scallop PDT findings, concerning whether to invoke the limited access AM exception. If NMFS concurs with the Scallop PDT's recommendation to invoke the limited access AM exception, in accordance with the APA, the limited access AM shall not be implemented. If NMFS does not concur, in accordance with the APA, the limited access AM shall be implemented as soon as possible after September 30 each year.

(d) *End-of-year carry-over for open area DAS.* With the exception of vessels that held a Confirmation of Permit History as described in § 648.4(a)(2)(i)(J) for the entire fishing year preceding the carry-over year, limited access vessels that have unused open area DAS on the last day of February of any year may carry over a maximum of 10 DAS, not to exceed the total open area DAS allocation by permit category, into the next year. DAS carried over into the next fishing year may only be used in open areas. Carry-over DAS are accounted for in setting the sub-ACT for the limited access fleet, as defined in paragraph (a)(5)(ii) of this section. Therefore, if carry-over DAS result or contribute to an overage of the ACL, the limited access fleet AM specified in paragraph (c) of this section would still apply, provided the AM exception specified in paragraph (c)(1) of this section is not invoked.

(e) *Accrual of DAS.* All DAS fished shall be charged to the nearest minute. A vessel carrying an observer and authorized to be charged fewer DAS in Open Areas based on the total available DAS set aside under paragraph (g) of this section shall be charged at a reduced rate as specified in paragraph (g)(1) of this section.

* * * * *

(g) * * *

(1) To help defray the cost of carrying an observer, 1 percent of the ABC/ACL defined in paragraph (a)(3) of this section shall be set aside to be used by vessels that are assigned to take an at-sea observer on a trip. This observer set-aside is specified through the specifications or framework adjustment process defined in § 648.55.

* * * * *

(h) * * *

(2) *Calculation of IFQ.* The ACL allocated to IFQ scallop vessels, and the ACL allocated to limited access scallop vessels issued IFQ scallop permits, as defined in paragraph (a)(4) of this section, shall be used to determine the IFQ of each vessel issued an IFQ scallop permit. Each fishing year, the Regional Administrator shall provide the owner of a vessel issued an IFQ scallop permit issued pursuant to § 648.4(a)(2)(ii) with the scallop IFQ for the vessel for the upcoming fishing year.

(i) *Individual fishing quota.* The IFQ for an IFQ scallop vessel shall be the vessel's contribution percentage as specified in paragraph (h)(2)(iii) of this section and determined using the steps specified in paragraphs (h)(2)(ii) of this section, multiplied by the ACL allocated to the IFQ scallop fishery, or limited access vessels issued an IFQ scallop permit, as defined in paragraph (a)(4) of this section.

* * * * *

(v) * * *

(B) For accounting purposes, the combined total of all vessels' IFQ carry-over shall be added to the LAGC IFQ fleet's applicable sub-ACL for the carry-over year. Any IFQ carried over that is landed in the carry-over fishing year shall be counted against the sub-ACL defined in paragraph (a)(6) of this section, as increased by the total carry-over for all LAGC IFQ vessels, as specified in this paragraph (h)(2)(v)(B). IFQ carry-over shall not be applicable to the calculation of the IFQ cap specified in paragraph (h)(3)(i) of this section and the ownership cap specified in paragraph (h)(3)(ii) of this section.

* * * * *

(3) * * *

(i) *IFQ scallop vessel IFQ cap.* (A) Unless otherwise specified in paragraphs (h)(3)(i)(B) and (C) of this section, a vessel issued an IFQ scallop permit or confirmation of permit history shall not be issued more than 2.5 percent of the sub-ACL allocated to the IFQ scallop vessels as described in paragraph (a)(6) of this section.

(B) A vessel may be initially issued more than 2.5 percent of the sub-ACL allocated to the IFQ scallop vessels as described in paragraph (a)(6) of this section, if the initial determination of its contribution factor specified in accordance with § 648.4(a)(2)(ii)(E) and paragraph (h)(2)(ii) of this section, results in an IFQ that exceeds 2.5 percent of the sub-ACL allocated to the IFQ scallop vessels as described in paragraph (a)(6) of this section. A vessel that is allocated an IFQ that exceeds 2.5 percent of the sub-ACL allocated to the IFQ scallop vessels as described in paragraph (a)(6) of this section, in accordance with this paragraph (h)(3)(i)(B), may not receive IFQ through an IFQ transfer, as specified in paragraph (h)(5) of this section. All scallops that have been allocated as part of the original IFQ allocation or transferred to a vessel during a given fishing year shall be counted towards the vessel cap.

(C) A vessel initially issued a 2008 IFQ scallop permit or confirmation of permit history, or that was issued or renewed a limited access scallop permit or confirmation of permit history for a vessel in 2009 and thereafter, in compliance with the ownership restrictions in paragraph (h)(3)(i)(A) of this section, is eligible to renew such permit(s) and/or confirmation(s) of permit history, regardless of whether the renewal of the permit or confirmations of permit history will result in the 2.5-percent IFQ cap restriction being exceeded.

(ii) * * *

(A) For any vessel acquired after June 1, 2008, a vessel owner is not eligible to be issued an IFQ scallop permit for the vessel, and/or a confirmation of permit history, and is not eligible to transfer IFQ to the vessel, if, as a result of the issuance of the permit and/or confirmation of permit history, or IFQ transfer, the vessel owner, or any other person who is a shareholder or partner of the vessel owner, will have an ownership interest in more than 5 percent of the sub-ACL allocated to the IFQ scallop vessels as described in paragraph (a)(6) of this section.

* * * * *

(5) * * *

(i) *Temporary IFQ transfers.* Subject to the restrictions in paragraph (h)(5)(iii) of this section, the owner of an IFQ scallop vessel (and/or IFQ scallop permit in confirmation of permit history) not issued a limited access scallop permit may temporarily transfer (*e.g.,* lease) its entire IFQ allocation, or a portion of its IFQ allocation, to another IFQ scallop vessel. Temporary IFQ transfers shall be effective only for the fishing year in which the temporary transfer is requested and processed. IFQ, once temporarily transferred, cannot be temporarily transferred again to another vessel. IFQ can be temporarily transferred more than once (*i.e.,* re-transferred). For example, if a vessel temporarily transfers IFQ to a vessel, the transferee vessel may re-transfer any portion of that IFQ to another vessel. There is no limit on how many times IFQ can be re-transferred in a fishing year. The Regional Administrator has final approval authority for all temporary IFQ transfer requests.

(ii) * * *

(A) Subject to the restrictions in paragraph (h)(5)(iii) of this section, the owner of an IFQ scallop vessel (and/or IFQ scallop permit in confirmation of permit history) not issued a limited access scallop permit may transfer IFQ permanently to or from another IFQ scallop vessel. Any such transfer cannot be limited in duration and is permanent as to the transferee, unless the IFQ is subsequently permanently transferred to another IFQ scallop vessel. IFQ may be permanently transferred to a vessel and then be re-transferred (temporarily transferred (*i.e.,* leased) or permanently transferred) by such vessel to another vessel in the same fishing year. There is no limit on how many times IFQ can be re-transferred in a fishing year.

* * * * *

■ 8. In § 648.54, revise paragraph (e) to read as follows:

§ 648.54 State waters exemption.

* * * * *

(e) *Notification requirements.* Vessels fishing under the exemptions specified in paragraph (b), (c) and/or (d) of this section must notify the Regional Administrator in accordance with the provisions of § 648.10(f).

* * * * *

■ 9. Amend § 648.55 by:

■ a. Revising the section heading and paragraph (a);

■ b. Removing and reserving paragraph (b);

■ c. Revising paragraph (c);

■ d. Removing and reserving paragraph (e); and

■ e. Revising paragraph (f) introductory text and paragraph (f)(38).

The revisions read as follows:

§ 648.55 Specifications and framework adjustments to management measures.

(a) *Specifications.* (1) The Scallop Plan Development Team (PDT) shall meet at least every two years to assess the status of the scallop resource and to develop and recommend the following specifications for a period of up to 2 years, as well as second or third-year default measures, for consideration by the New England Fishery Management Council's Atlantic Sea Scallop Oversight Committee and Advisory Panel: OFL, overall ABC/ACL, sub-ACLs, sub-ACTs, DAS open area allocations, possession limits, modifications to rotational area management (*e.g.,* schedule, rotational closures and openings, seasonal restrictions, modifications to boundaries, etc.), access area limited access poundage allocations and LAGC IFQ fleet-wide trip allocations, annual incidental catch target TAC, and NGOM TAC.

(2) Based on the PDT recommendations and any public comments received, the Atlantic Sea Scallop Oversight Committee shall recommend appropriate specifications to the New England Fishery Management Council.

(3) The Council shall review these recommendations and, after considering public comments, shall recommend appropriate specifications for up to 2 years, as well as second or third-year default measures, to NMFS. NMFS shall approve, disapprove, or partially approve the specifications recommended by the Council and publish the approved specifications in the **Federal Register** in accordance with the APA.

(4) The PDT shall prepare a Stock Assessment and Fishery Evaluation (SAFE) Report at least every two years that provides the information and analysis needed to evaluate potential management adjustments. The preparation of the SAFE Report shall begin on or about June 1 of the year preceding the fishing year in which measures will be adjusted.

(5) The PDT will meet at least once during the interim years to review the status of the stock relative to the overfishing definition if information is available to do so. If the Council determines, based on information provided by the PDT or other stock-related information, that the approved specifications should be adjusted during the 2-year time period, it can do so through the same process outlined in paragraphs (a)(2) through (a)(4) of this section during the interim year.

(6) *Rotational area management guidelines.* The Council's development of rotational area management

adjustments shall take into account at least the following factors: General rotation policy; boundaries and distribution of rotational closures; number of closures; minimum closure size; maximum closure extent; enforceability of rotational closed and re-opened areas; monitoring through resource surveys; and re-opening criteria. Rotational closures should be considered where projected annual change in scallop biomass is greater than 30 percent. Areas should be considered for Sea Scallop Rotational Areas where the projected annual change in scallop biomass is less than 15 percent.

(7) *Second and Third-year default specifications.* The specifications action shall include default specifications that shall be effective in the second year after 1-year specifications and the third year after the 2-year specifications expire until replaced by the measures included in the next specifications action. If the specifications action is not published in the **Federal Register** with an effective date on or before April 1, the following year's default specifications shall be effective beginning April 1 of each fishing year until any new specifications action is implemented and made effective during the second or third year, or for the entire fishing year if the specifications action is not completed or is not implemented by NMFS during the following year. The specifications action shall specify the measures necessary to address inconsistencies between specifications and default allocations for the period after April 1 but before the specifications action is implemented for that year. The default specifications, if implemented, shall remain in effect until they are revised through a subsequent specifications action.

(b) [Reserved]

(c) *OFL, overall ABC/ACL, sub-ACLs, and sub-ACTs.* The Council shall specify OFL, ABC, ACL, and ACT, as defined in § 648.53, for each year covered under the specifications.

* * * * *

(e) Reserved]

(f) *Framework adjustments.* The Council may at any time initiate a framework adjustment to add or adjust management measures within the Scallop FMP if it finds that action is necessary to meet or be consistent with the goals and objectives of the FMP. The Council shall develop and analyze appropriate management actions over the span of at least two Council meetings. To address interactions between the scallop fishery and sea turtles and other protected species, such adjustments may include proactive measures including, but not limited to, the timing of Sea Scallop Access Area openings, seasonal closures, gear modifications, increased observer coverage, and additional research. The Council shall provide the public with advance notice of the availability of both the proposals and the analyses, and opportunity to comment on them prior to and at the second Council meeting. The Council's recommendation on adjustments or additions to management measures may include specifications measures specified in paragraph (a) of this section, which must satisfy the criteria set forth § 648.53(a) in order to prevent overfishing of the available biomass of scallops and ensure that OY is achieved on a continuing basis. Other measures that may be changed or implemented through framework action include:

* * * * *

(38) Adjustments to aspects of ACL management, including accountability measures;

* * * * *

■ 10. In § 648.56, revise paragraphs (a), (d), (f), and (g) to read as follows:

§ 648.56 Scallop research.

(a) At least biennially, in association with the biennial framework process, the Council and NMFS shall prepare and issue an announcement of Federal Funding Opportunity (FFO) that identifies research priorities for projects to be conducted by vessels using research set-aside as specified in paragraph (d) of this section and § 648.59(e), provides requirements and instructions for applying for funding of a proposed RSA project, and specifies the date by which applications must be received. The FFO shall be published as soon as possible by NMFS and shall provide the opportunity for applicants to apply for projects to be awarded for 1 or 2 years by allowing applicants to apply for RSA funding for the first year, second year, or both.

* * * * *

(d) Available RSA allocation shall be 1.25 million lb (567 mt) annually, which shall be deducted from the ABC/ACL specified in § 648.53(a) prior to setting ACLs for the limited access and LAGC fleets, as specified in § 648.53(a)(3) and (4), respectively. Approved RSA projects shall be allocated an amount of scallop pounds that can be harvested in open areas and available access areas. The specific access areas that are open to RSA harvest shall be specified through the framework process as identified in § 648.59(e)(1). In a year in which a framework adjustment is under review by the Council and/or NMFS, NMFS shall make RSA awards prior to approval of the framework, if practicable, based on total scallop pounds needed to fund each research project. Recipients may begin compensation fishing in open areas prior to approval of the framework, or wait until NMFS approval of the framework to begin compensation fishing within approved access areas

* * * * *

(f) If all RSA pounds awarded to a project cannot be harvested during the applicable fishing year, RSA TAC awarded to that project may be harvested through June 30 of the fishing year subsequent to the fishing year in which the set-aside is awarded.

(g) Vessels conducting research under an approved RSA project may be exempt from crew restrictions specified in § 648.51, seasonal closures of access areas specified in § 648.60, and the restriction on fishing in only one access area during a trip specified in § 648.59(b)(4). The RSA project proposal must list which of these measures for which an exemption is required. An exemption shall be provided by Letter of Authorization issued by the Regional Administrator. RSA compensation fishing trips and combined compensation and research trips are not eligible for these exemptions.

* * * * *

§ 648.57 [Removed and reserved]

■ 11. Remove and reserve § 648.57.

§ 648.58 [Removed and reserved]

■ 12. Remove and reserve § 648.58.

■ 13. Revise § 648.59 to read as follows:

§ 648.59 Sea Scallop Rotational Area Management Program and Access Area Program requirements.

(a) The Sea Scallop Rotational Area Management Program consists of Scallop Rotational Areas, as defined in § 648.2. Guidelines for this area rotation program (*i.e.,* when to close an area and reopen it to scallop fishing) are provided in § 648.55(a)(6). Whether a rotational area is open or closed to scallop fishing in a given year, and the appropriate level of access by limited access and LAGC IFQ vessels, are specified through the specifications or framework adjustment processes defined in § 648.55. When a rotational area is open to the scallop fishery, it is called an Access Area and scallop vessels fishing in the area are subject to the Access Area Program Requirements specified in this section. Areas not defined as Scallop Rotational Areas specified in § 648.60, EFH Closed Areas

specified in § 648.61, or areas closed to scallop fishing under other FMPs, are governed by other management measures and restrictions in this part and are referred to as Open Areas.

(1) When a Scallop Rotational Area is closed to scallop fishing, a vessel issued any scallop permit may not fish for, possess, or land scallops in or from the area unless the vessel is transiting pursuant to paragraph (a)(2) of this section. A vessel may fish for species other than scallops within the rotational closed areas, provided the vessel does not fish for, catch, or retain scallops or intend to fish for, catch, or retain scallops. When a Scallop Rotational Area is open to scallop fishing (henceforth referred to as an Access Area), a scallop vessel may not fish for, possess, or land scallops in or from the area unless it is participating in, and complies with the requirements of, the Scallop Access Area Program Requirements defined in paragraphs (b) through (g) of this section or the vessel is transiting pursuant to paragraph (a)(3) of this section.

(2) *Transiting a Closed Scallop Rotational Area.* No vessel possessing scallops may enter or be in the area(s) specified in this section when those areas are closed, as specified through the specifications or framework adjustment processes defined in § 648.55, unless the vessel is transiting the area and the vessel's fishing gear is stowed and not available for immediate use as defined in § 648.2, or there is a compelling safety reason to be in such areas without such gear being stowed. A vessel may only transit the Closed Area II Scallop Rotational Area or the Closed Area II Extension Scallop Rotational Area, as defined § 648.60(d) and (e), respectively, or the Elephant Trunk Closed Area, as defined in § 648.60(b), if there is a compelling safety reason for transiting the area and the vessel's fishing gear is stowed and not available for immediate use as defined in § 648.2.

(3) *Transiting a Scallop Access Area.* Any sea scallop vessel that has not declared a trip into the Scallop Area Access Program may enter a Scallop Access Area, and possess scallops not caught in the Scallop Access Areas, for transiting purposes only, provided the vessel's fishing gear is stowed and not available for immediate use as defined in § 648.2. Any scallop vessel that has declared a trip into the Scallop Area Access Program may not enter or be in another Scallop Access Area on the same trip except such vessel may transit another Scallop Access Area provided its gear is stowed and not available for immediate use as defined in § 648.2, or there is a compelling safety reason to be in such areas without such gear being stowed. A vessel may only transit the Closed Area II Scallop Rotational Area or the Closed Area II Extension Scallop Rotational Area, as defined in § 648.60(d) and (e), respectively, or the Elephant Trunk Closed Area, as defined in § 648.60(b) if there is a compelling safety reason for transiting the area and the vessel's fishing gear is stowed and not available for immediate use as defined in § 648.2.

(b) A limited access scallop vessel may only fish in the Scallop Rotational Areas, defined in § 648.60, when the areas are open (*i.e.,* Access Areas), as specified through the specifications or framework adjustment processes defined in § 648.55, subject to any additional restrictions specified in § 648.60, provided the vessel complies with the requirements specified in paragraphs (b)(1) through (b)(9), and (c) through (f) of this section. An LAGC scallop vessel may fish in the Scallop Rotational Areas, defined in § 648.60, when the areas are open (*i.e.,* Access Areas), as specified through the specifications or framework adjustment processes defined in § 648.55, subject to any additional requirements specified in § 648.60, provided the vessel complies with the requirements specified in paragraph (g) of this section.

(1) *VMS.* Each vessel participating in the Scallop Access Area Program must have installed on board an operational VMS unit that meets the minimum performance criteria specified in §§ 648.9 and 648.10, and paragraphs (b)(9) and (f) of this section.

(2) Vessels participating in the Scallop Access Area Program must comply with the trip declaration requirements specified in § 648.10(f) and vessel notification requirements specified in § 648.11(g) for observer deployment.

(3) *Scallop Access Area Allocations*—(i) *Limited access vessel allocations and possession limits.* (A) Except as provided in paragraph (c) of this section, the specifications or framework adjustment processes defined in § 648.55 determine the total amount of scallops, in weight, that a limited access scallop vessel may harvest from Scallop Access Areas during applicable seasons specified in § 648.60. A vessel may not possess or land in excess of its scallop allocation assigned to specific Scallop Access Areas, unless authorized by the Regional Administrator, as specified in paragraph (d) of this section, unless the vessel owner has exchanged an area-specific scallop allocation with another vessel owner for additional scallop allocation in that area, as specified in paragraph (b)(3)(ii) of this section. A vessel may harvest its scallop allocation on any number of trips in a given fishing year, provided that no single trip exceeds the possession limits specified in the specifications or framework adjustment processes defined in § 648.55, unless authorized by the Regional Administrator, as specified in paragraphs (c) and (d) of this section. No vessel declared into the Scallop Access Areas may possess more than 50 bu (17.62 hL) of in-shell scallops outside of the Scallop Rotational Area boundaries defined in § 648.60.

(B) The following access area allocations and possession limits for limited access vessels will be effective for the 2016 and 2017 fishing years:

Fishing year	Access area		Permit category		
			Full-time	Part-time	Occasional
2016	Mid-Atlantic Access Area	Allocation	51,000 lb (23,133 kg)	20,400 lb (9,253 kg)	4,250 lb (1,928 kg).
		Possession limit	17,000 lb (57,711 kg)	10,200 lb (4,627 kg)	1,420 lb (644 kg).
2017*	Mid-Atlantic Access Area	Allocation	17,000 lb (57,711 kg)	10,200 lb (4,627 kg)	1,420 lb (644 kg).
		Possession limit	17,000 lb (57,711 kg)	10,200 lb (4,627 kg)	1,420 lb (644 kg).

*The limited access fishery's access area allocations and possession limits for the 2017 fishing year are subject to change through a future specifications action or framework adjustment.

(ii) *Limited access vessels' one-for-one area access allocation exchanges.* The owner of a vessel issued a limited access scallop permit may exchange unharvested scallop pounds allocated into one access area for another vessel's unharvested scallop pounds allocated into another Scallop Access Area. These exchanges may only be made for the

amount of the current trip possession limit, as specified in paragraph (b)(3)(i)(B) of this section. For example, if the access area trip possession limit for full-time vessels is 17,000 lb (7,711 kg), a full-time vessel may exchange no less than 17,000 lb (7,711 kg), from one access area for no more or less than 17,000 lb (7,711 kg) allocated to another vessel for another access area. In addition, these exchanges may be made only between vessels with the same permit category: A full-time vessel may not exchange allocations with a part-time vessel, and vice versa. Vessel owners must request these exchanges by submitting a completed Access Area Allocation Exchange Form at least 15 days before the date on which the applicant desires the exchange to be effective. Exchange forms are available from the Regional Administrator upon request. Each vessel owner involved in an exchange is required to submit a completed Access Area Allocation Form. The Regional Administrator shall review the records for each vessel to confirm that each vessel has enough unharvested allocation remaining in a given access area to exchange. The exchange is not effective until the vessel owner(s) receive a confirmation in writing from the Regional Administrator that the allocation exchange has been made effective. A vessel owner may exchange equal allocations up to the current possession limit between two or more vessels under his/her ownership. A vessel owner holding a Confirmation of Permit History is not eligible to exchange allocations between another vessel and the vessel for which a Confirmation of Permit History has been issued.

(4) *Area fished.* While on a Scallop Access Area trip, a vessel may not fish for, possess, or land scallops in or from areas outside the Scallop Access Area in which the vessel operator has declared the vessel will fish during that trip, and may not enter or exit the specific declared Scallop Access Area more than once per trip. A vessel on a Scallop Access Area trip may not enter or be in another Scallop Access Area on the same trip except such vessel may transit another Scallop Access Area as provided for under paragraph (a)(3) of this section.

(5) *NE multispecies possession limits*—(i) *Maximum possession limit of NE Multispecies combined.* A vessel owner or operator of a limited access scallop vessel issued a valid NE multispecies permit as specified in § 648.4(a)(1), that has declared into a Scallop Access Area and fishes within the open Scallop Rotational Area boundaries defined in § 648.60, may fish for, possess, and land, per trip, up to a maximum of 1,000 lb (453.6 kg) of all NE multispecies combined, excluding yellowtail flounder, subject to the minimum commercial fish size restrictions specified in § 648.83(a)(1), and the additional restrictions for Atlantic cod, haddock, and yellowtail flounder specified in paragraphs (b)(5)(ii) through (iv) of this section.

(ii) *Atlantic cod.* Such vessel may bring onboard and possess only up to 100 lb (45.4 kg) of Atlantic cod per trip, provided such fish is intended for personal use only and cannot be not sold, traded, or bartered.

(iii) *Haddock.* Such vessel may possess and land haddock up to the overall possession limit of all NE multispecies combined, as specified in paragraph (b)(5)(ii) of this section, except that such vessel are prohibited from possessing or landing haddock from January 1 through June 30.

(iv) *Yellowtail flounder.* Such vessel is prohibited from fishing for, possessing, or landing yellowtail flounder.

(6) *Gear restrictions.* (i) The minimum ring size for dredge gear used by a vessel fishing on a Scallop Access Area trip is 4 inches (10.2 cm) in diameter. Dredge or trawl gear used by a vessel fishing on a Scallop Access Area trip must be in accordance with the restrictions specified in § 648.51(a) and (b).

(ii) Vessels fishing in the Closed Area I, Closed Area II, Closed Area II Extension, and Nantucket Lightship Scallop Rotational Areas defined in § 648.60 are prohibited from fishing with trawl gear as specified in § 648.51(f)(1).

(7) *Transiting.* While outside a Sea Scallop Access Area (*i.e.,* in open areas) on a Scallop Access Area trip, the vessel must have all fishing gear stowed and not available for immediate use as defined in § 648.2, unless there is a compelling safety reason to be transiting open areas without gear stowed. Regulations pertaining to transiting Scallop Rotational Areas are provided for under paragraph (a)(3) of this section.

(8) *Off-loading restrictions.* The vessel may not offload its catch from a Scallop Access Area trip at more than one location per trip.

(9) *Reporting.* The owner or operator must submit scallop catch reports through the VMS, as specified in § 648.10(f)(4)(i), and limited access scallop access area pre-landing notification forms, as specified in § 648.10(f)(4)(iii).

(c) *Scallop Access Area scallop allocation carryover.* With the exception of vessels that held a Confirmation of Permit History as described in § 648.4(a)(2)(i)(J) for the entire fishing year preceding the carry-over year, a limited access scallop vessel operator may fish any unharvested Scallop Access Area allocation from a given fishing year within the first 60 days of the subsequent fishing year if the Scallop Access Area is open, unless otherwise specified in this section. For example, if a full-time vessel has 7,000 lb (3,175 kg) remaining in the Mid-Atlantic Access Area at the end of fishing year 2016, that vessel may harvest 7,000 lb (3,175 kg) from its 2017 fishing year scallop access area allocation during the first 60 days that the Mid-Atlantic Access Area is open in fishing year 2017 (March 1, 2017, through April 29, 2018). Unless otherwise specified through the specifications or framework adjustment processes defined in § 648.55, if a Scallop Access Area is not open in the subsequent fishing year, then the unharvested scallop allocation would expire at the end of the fishing year that the scallops were allocated.

(d) *Increase in possession limit to defray costs of observers*—The Regional Administrator may increase the sea scallop possession limit through the specifications or framework adjustment processes defined in § 648.55 to defray costs of at-sea observers deployed on area access trips subject to the limits specified § 648.53(g). An owner of a scallop vessel shall be notified of the increase in the possession limit through a permit holder letter issued by the Regional Administrator. If the observer set-aside is fully utilized prior to the end of the fishing year, the Regional Administrator shall notify owners of scallop vessels that, effective on a specified date, the increase in the possession limit is no longer available to offset the cost of observers. Unless otherwise notified by the Regional Administrator, vessel owners shall be responsible for paying the cost of the observer, regardless of whether the vessel lands or sells sea scallops on that trip, and regardless of the availability of set-aside for an increased possession limit.

(e) *Sea Scallop Research Set-Aside Harvest in Scallop Access Areas.*—Unless otherwise specified, RSA may be harvested in any access area that is open in a given fishing year, as specified through a specifications action or framework adjustment and pursuant to § 648.56. The amount of scallops that can be harvested in each access area by vessels participating in approved RSA projects shall be determined through the RSA application review and approval process.

(f) *VMS polling.* For the duration of the Sea Scallop Area Access Program, as defined in this section, all sea scallop vessels equipped with a VMS unit shall be polled at a minimum of twice per hour, regardless of whether the vessel is enrolled in the Sea Scallop Area Access Program. Vessel owners shall be responsible for paying the costs of polling twice per hour.

(g) *Limited Access General Category vessels.* (1) An LAGC scallop vessel may only fish in the scallop rotational areas specified in § 648.60 or in paragraph (g)(3)(iv) of this section, subject to any additional restrictions specified in § 648.60, subject to the possession limit and access area schedule specified in the specifications or framework adjustment processes defined in § 648.55, provided the vessel complies with the requirements specified in paragraphs (b)(1), (b)(2), (b)(6) through (9), (d), (e), (f), and (g) of this section. A vessel issued both a NE multispecies permit and an LAGC scallop permit may fish in an approved SAP under § 648.85 and under multispecies DAS in the Closed Area I, Closed Area II, Closed Area II Extension, and Nantucket Lightship Scallop Rotational Areas specified in § 648.60, when open, provided the vessel complies with the requirements specified in § 648.59 and this paragraph (g), but may not fish for, possess, or land scallops on such trips.

(2) *Limited Access General Category Gear restrictions.* An LAGC IFQ scallop vessel authorized to fish in the Scallop Rotational Areas specified in § 648.60 must fish with dredge gear only. The combined dredge width in use by, or in possession on board of, an LAGC scallop vessel fishing in Closed Area I, Closed Area II, Closed Area II Extension, and Nantucket Lightship Access Areas may not exceed 10.5 ft (3.2 m). The combined dredge width in use by, or in possession on board of, an LAGC scallop vessel fishing in the remaining Scallop Rotational Areas defined in § 648.60 may not exceed 31 ft (9.4 m). Dredge width is measured at the widest point in the bail of the dredge.

(3) *LAGC IFQ Access Area trips.* (i) An LAGC scallop vessel authorized to fish in the Scallop Rotational Areas specified in § 648.60 or in paragraph (g)(3)(iv) of this section may land scallops, subject to the possession limit specified in § 648.52(a), unless the Regional Administrator has issued a notice that the number of LAGC IFQ access area trips have been or are projected to be taken. All LAGC IFQ access area trips must be taken in the fishing year that they are allocated (*i.e.,* there are no carryover trips). The total number of LAGC IFQ trips in an Access Area is specified in the specifications or framework adjustment processes defined in § 648.55.

(ii) Scallops landed by each LAGC IFQ vessel on an access area trip shall count against the vessel's IFQ.

(iii) Upon a determination from the Regional Administrator that the total number of LAGC IFQ trips in a specified Access Area have been or are projected to be taken, the Regional Administrator shall publish notification of this determination in the **Federal Register**, in accordance with the Administrative Procedure Act. Once this determination has been made, an LAGC IFQ scallop vessel may not fish for, possess, or land scallops in or from the specified Access Area after the effective date of the notification published in the **Federal Register**.

(iv) *Nantucket Lightship North Sea Scallop Access Area.* (A) From March 1, 2016, through February 28, 2018 (*i.e.,* fishing years 2016 and 2017), a vessel issued an LAGC IFQ scallop permit may not fish for, possess, or land scallops in or from the area known as the Nantucket Lightship North Access Area, defined in paragraph (g)(3)(iv)(B) of this section, unless the vessel is participating in, and complying with the requirements of, the area access program defined in this section or the vessel is transiting pursuant to § 648.59(a)(3).

(B) The Nantucket Lightship North Sea Scallop Access Area is defined by straight lines connecting the following points in the order stated (copies of a chart depicting this area are available from the Regional Administrator upon request):

Point	Latitude	Longitude
NLNAA1	40°50′ N	69°00′ W.
NLNAA2	40°30′ N	69°00′ W.
NLNAA3	40°30′ N	69°30′ W.
NLNAA4	40°50′ N	69°30′ W.
NLNAA1	40°50′ N	69°00′ W.

(v) The following LAGC IFQ access area allocations will be effective for the 2016 and 2017 fishing years:

Scallop rotational area	2016	2017*
Mid-Atlantic Access Area	2,068	602
Nantucket Lightship North	485	0

*The LAGC IFQ access area trip allocations for the 2017 fishing year are subject to change through a future specifications action or framework adjustment.

(4) *Possession limits*—(i) *Scallops.* A vessel issued a NE multispecies permit and a general category scallop permit that is fishing in an approved SAP under § 648.85 under multispecies DAS, and that has not declared into the Scallop Access Area Program, is prohibited from possessing scallops. An LAGC scallop vessel authorized to fish in the Scallop Rotational Areas specified in § 648.60 may possess scallops up to the possession limit specified in § 648.52(a).

(ii) *Other species.* Unless issued an LAGC scallop permit and fishing under an approved NE multispecies SAP under NE multispecies DAS, an LAGC IFQ vessel fishing in the Closed Area I, Closed Area II, Closed Area II Extension, and Nantucket Lightship Rotational Areas specified in § 648.60, and the Nantucket Lightship North Sea Scallop Access Area specified in paragraph (g)(3)(iv) of this section is prohibited from possessing any species of fish other than scallops and monkfish, as specified in § 648.94(c)(8)(i). Such a vessel may fish in an approved SAP under § 648.85 and under multispecies DAS in the scallop access area, provided that it has not declared into the Scallop Access Area Program. Such a vessel is prohibited from fishing for, possessing, or landing scallops.

■ 14. Revise § 648.60 to read as follows:

§ 648.60 Sea Scallop Rotational Areas.

(a) *Mid-Atlantic Scallop Rotational Area.* (1) The Mid-Atlantic Scallop Rotational Area is comprised of the following scallop access areas: The Delmarva Scallop Rotational Area, as defined in paragraph (a)(2) of this section; the Elephant Trunk Scallop Rotational Area, as defined in paragraph (a)(3) of this section; and the Hudson Canyon Scallop Rotational Area, as defined in paragraph (a)(4) of this section.

(2) *Delmarva Scallop Rotational Area.* The Delmarva Scallop Rotational Area is defined by straight lines connecting the following points in the order stated (copies of a chart depicting this area are available from the Regional Administrator upon request):

Point	Latitude	Longitude
DMV1	38°10′ N	74°50′ W.
DMV2	38°10′ N	74°00′ W.
DMV3	37°15′ N	74°00′ W.
DMV4	37°15′ N	74°50′ W.
DMV1	38°10′ N	74°50′ W.

(3) *Elephant Trunk Scallop Rotational Area.* The Elephant Trunk Scallop Rotational Area is defined by straight lines connecting the following points in the order stated (copies of a chart depicting this area are available from the Regional Administrator upon request):

Point	Latitude	Longitude
ETAA1	38°30′ N	74°20′ W.

Point	Latitude	Longitude
ETAA2	38°30′ N	73°50′ W.
ETAA3	38°40′ N	73°50′ W.
ETAA4	38°40′ N	73°40′ W.
ETAA5	38°50′ N	73°40′ W.
ETAA6	38°50′ N	73°30′ W.
ETAA7	38°10′ N	73°30′ W.
ETAA8	38°10′ N	74°20′ W.
ETAA1	38°30′ N	74°20′ W.

(4) *Hudson Canyon Scallop Rotational Area.* The Hudson Canyon Scallop Rotational Area is defined by straight lines connecting the following points in the order stated (copies of a chart depicting this area are available from the Regional Administrator upon request):

Point	Latitude	Longitude
H1	39°30′ N	73°10′ W.
H2	39°30′ N	72°30′ W.
H3	38°30′ N	73°30′ W.
H4	38°50′ N	73°30′ W.
H5	38°50′ N	73°42′ W.
H1	39°30′ N	73°10′ W.

(b) *Elephant Trunk Closed Area.* The Elephant Trunk Closed Area is defined by straight lines connecting the following points in the order stated (copies of a chart depicting this area are available from the Regional Administrator upon request).

Point	Latitude	Longitude
ETCA 1	38°50′ N	74°20′ W.
ETCA 2	38°50′ N	73°40′ W.
ETCA 3	38°40′ N	73°40′ W.
ETCA 4	38°40′ N	73°50′ W.
ETCA 5	38°30′ N	73°50′ W.
ETCA 6	38°30′ N	74°20′ W.
ETCA 1	38°50′ N	74°20′ W.

(c) *Closed Area I Scallop Rotational Area.* (1) The Closed Area I Scallop Rotational Area is defined by straight lines connecting the following points in the order stated (copies of a chart depicting this area are available from the Regional Administrator upon request), and so that the line connecting points CAIA3 and CAIA4 is the same as the portion of the western boundary line of Closed Area I, defined in § 648.81(a)(1), that lies between points CAIA3 and CAIA4:

Point	Latitude	Longitude	Note
CAIA1	41°26′ N	68°30′ W.	
CAIA2	40°58′ N	68°30′ W.	
CAIA3	40°54.95′ N	68°53.37′ W	(1)
CAIA4	41°04′ N	69°01′ W.	(1)
CAIA1	41°26′ N	68°30′ W.	

[1] From Point CAIA3 to Point CAIA4 along the western boundary of Closed Area I, defined in § 648.81(a)(1).

(d) *Closed Area II Scallop Rotational Area.* (1) The Closed Area II Scallop Rotational Area is defined by straight lines, except where noted, connecting the following points in the order stated (copies of a chart depicting this area are available from the Regional Administrator upon request):

Point	Latitude	Longitude	Note
CAIIA1	41°00′ N	67°20′ W.	
CAIIA2	41°00′ N	66°35.8′ W	
CAIIA3	41°18.45′ N	(1)	(2)
CAIIA4	41°30′ N	(3)	(2)
CAIIA5	41°30′ N	67°20′ W.	
CAIIA1	41°00′ N	67°20′ W.	

[1] The intersection of 41°18.45′ N. lat. and the U.S.-Canada Maritime Boundary, approximately 41°18.45′ N. lat. and 66°24.89′ W. long.

[2] From Point CAIIA3 connected to Point CAIIA4 along the U.S.-Canada Maritime Boundary.

[3] The intersection of 41°30′ N. lat. and the U.S.-Canada Maritime Boundary, approximately 41°30′ N. lat., 66°34.73′ W. long.

(2) *Season.* A vessel issued a scallop permit may not fish for, possess, or land scallops in or from the area known as the Closed Area II Sea Scallop Rotational Area, defined in paragraph (d)(1) of this section, during the period of August 15 through November 15 of each year the Closed Area II Access Area is open to scallop vessels, unless transiting pursuant to § 648.59(a).

(e) *Closed Area II Extension Scallop Rotational Area.* The Closed Area II Extension Rotational Area is defined by straight lines, except where noted, connecting the following points in the order stated (copies of a chart depicting this area are available from the Regional Administrator upon request):

Point	Latitude	Longitude	Note
CAIIE1	40°30′ N	67°20′ W.	
CAIIE2	41°00′ N	67°20′ W.	
CAIIE3	41°00′ N	66°35.8′ W	
CAIIE4	41°18.45′ N	(1)	(2)
CAIIE5	40°30′ N	(3)	(2)
CAIIE1	40°30′ N	67°20′ W.	

[1] The intersection of 41°18.45′ N. lat. and the U.S.-Canada Maritime Boundary, approximately 41°18.45′ N. lat. and 66°24.89′ W. long.

[2] From Point CAIIE4 to Point CAIIE5 following the U.S.-Canada Maritime Boundary.

[3] The intersection of 40°30′ N. lat. and the U.S.-Canada Maritime Boundary, approximately, 65°44.34′ W. long.

(f) *Nantucket Lightship Scallop Rotational Area.* (1) The Nantucket Lightship Scallop Rotational Area is defined by straight lines connecting the following points in the order stated (copies of a chart depicting this area are available from the Regional Administrator upon request):

Point	Latitude	Longitude
NLAA1	40°50′ N	69°30′ W.
NLAA2	40°50′ N	69°00′ W.
NLAA3	40°33′ N	69°00′ W
NLAA4	40°33′ N	68°48′ W
NLAA5	40°20′ N	68°48′ W
NLAA6	40°20′ N	69°30′ W.
NLAA1	40°50′ N	69°30′ W.

■ 15. In § 648.62, revise paragraph (a)(3), (b) introductory text, and paragraphs (b)(3), and (c) to read as follows:

§ 648.62 Northern Gulf of Maine (NGOM) Management Program.

(a) * * *

(3) Scallop landings by all vessels issued LAGC IFQ scallop permits and fishing in the NGOM scallop management area shall be deducted from the NGOM scallop total allowable catch specified in the specifications or framework adjustment processes defined in § 648.55. Scallop landings by IFQ scallop vessels fishing in the NGOM scallop management area shall be deducted from their respective scallop IFQs. Landings by incidental catch scallop vessels and limited access scallop vessels fishing under the scallop DAS program shall not be deducted from the NGOM total allowable catch specified in paragraph (b) of this section.

* * * * *

(b) *Total allowable catch.* The total allowable catch for the NGOM scallop management area shall be specified through the framework adjustment process. The total allowable catch for the NGOM scallop management area shall be based on the Federal portion of the scallop resource in the NGOM. The total allowable catch shall be determined by historical landings until additional information on the NGOM scallop resource is available, for example through an NGOM resource survey and assessment. The ABC/ACL as defined in § 648.53(a) shall not include the total allowable catch for the NGOM scallop management area, and landings from the NGOM scallop management area shall not be counted against the ABC/ACL defined in § 648.53(a).

* * * * *

(3) If the annual NGOM TAC is exceeded, the amount of NGOM scallop landings in excess of the TAC specified in paragraph (b)(1) of this section shall be deducted from the NGOM TAC for the subsequent fishing year, as soon as

practicable, once scallop landings data for the NGOM fishery is available.

(c) *VMS requirements.* Except scallop vessels issued a limited access scallop permit pursuant to § 648.4(a)(2)(i) that have declared a trip under the scallop DAS program, a vessel issued a scallop permit pursuant to § 648.4(a)(2) that intends to fish for scallops in the NGOM scallop management area or fishes for, possesses, or lands scallops in or from the NGOM scallop management area, must declare a NGOM scallop management area trip and report scallop catch through the vessel's VMS unit, as required in § 648.10. If the vessel has a NGOM permit, the vessel must declare either a Federal NGOM trip or a state-waters NGOM trip. If a vessel intends to fish any part of a NGOM trip in Federal NGOM waters, it may not declare into the state water NGOM fishery.

* * * * *

■ 16. In § 648.63, revise paragraph (b)(2)(iii) to read as follows:

§ 648.63 General category Sectors and harvesting cooperatives.

* * * * *

(b) * * *

(2) * * *

(iii) A sector shall not be allocated more than 20 percent of the ACL for IFQ vessels defined in § 648.53(a)(4).

* * * * *

■ 17. In § 648.64, revise paragraph (e) to read as follows:

§ 648.64 Yellowtail flounder sub-ACLs and AMs for the scallop fishery.

* * * * *

(e) *Process for implementing the AM*—(1) *If reliable information is available to make a mid-year determination:* On or about January 15 of each year, based upon catch and other information available to NMFS, the Regional Administrator shall determine whether a yellowtail flounder sub-ACL was exceeded, or is projected to be exceeded, by scallop vessels prior to the end of the scallop fishing year. The determination shall include the amount of the overage or projected amount of the overage, specified as a percentage of the overall sub-ACL for the applicable yellowtail flounder stock, in accordance with the values specified in paragraph (a) of this section. Based on this initial projection in mid-January, the Regional Administrator shall implement the AM in accordance with the APA and notify owners of limited access and LAGC scallop vessels by letter identifying the length of the closure and a summary of the yellowtail flounder catch, overage, and projection that resulted in the closure.

(2) *If reliable information is not available to make a mid-year determination:* Once NMFS has compiled the necessary information (*e.g.,* when the previous fishing year's observer and catch data are fully available), the Regional Administrator shall determine whether a yellowtail flounder sub-ACL was exceeded by scallop vessels following the end of the scallop fishing year. The determination shall include the amount of the overage, specified as a percentage of the overall sub-ACL for the applicable yellowtail flounder stock, in accordance with the values specified in paragraph (a) of this section. Based on this information, the Regional Administrator shall implement the AM in accordance with the APA in Year 3 (*e.g.,* an accountability measure would be implemented in fishing year 2016 for an overage that occurred in fishing year 2014) and notify owners of limited access and LAGC scallop vessels by letter identifying the length of the closure and a summary of the yellowtail flounder catch and overage information.

* * * * *

■ 18. In § 648.65, revise paragraph (c) to read as follows:

§ 648.65 Windowpane flounder sub-ACL and AM for the scallop fishery.

* * * * *

(c) *Process for implementing the AM*—(1) *If reliable information is available to make a mid-year determination:* On or about January 15 of each year, based upon catch and other information available to NMFS, the Regional Administrator shall determine whether the SNE/MA windowpane flounder sub-ACL was exceeded, or is projected to be exceeded, and if an accountability measure was triggered as described in § 648.90(a)(5)(iv), by scallop vessels prior to the end of the scallop fishing year. The determination shall include the amount of the overage or projected amount of the overage, specified as a percentage of the overall sub-ACL for the SNE/MA windowpane flounder stock, in accordance with the values specified in paragraph (a) of this section. Based on this initial determination in mid-January, the Regional Administrator shall implement the AM in the following fishing year in accordance with the APA and attempt to notify owners of limited access and LAGC scallop vessels by letter identifying the length of the gear restricted area and a summary of the SNE/MA windowpane flounder catch, overage, and projection that resulted in the gear restricted area.

(2) *If reliable information is not available to make a mid-year determination:* Once NMFS has compiled the necessary information (*e.g.,* when the previous fishing year's observer and catch data are fully available), the Regional Administrator shall determine whether the SNE/MA windowpane flounder sub-ACL was exceeded and if an accountability measure was triggered as described in § 648.90(a)(5)(iv), by scallop vessels following the end of the scallop fishing year. The determination shall include the amount of the overage, specified as a percentage of the overall sub-ACL for the SNE/MA windowpane flounder stock, in accordance with the values specified in paragraph (a) of this section. Based on this information, the Regional Administrator shall implement the AM in accordance with the APA in Year 3 (*e.g.,* an accountability measure would be implemented in fishing year 2016 for an overage that occurred in fishing year 2014) and attempt to notify owners of limited access and LAGC scallop vessels by letter identifying the length of the gear restricted area and a summary of the SNE/MA windowpane flounder catch and overage information.

* * * * *

[FR Doc. 2016–25963 Filed 11–2–16; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 150916863–6211–02]

RIN 0648–XF012

Fisheries of the Exclusive Economic Zone Off Alaska; Reallocation of Pacific Cod 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; reallocation.

SUMMARY: NMFS is reallocating the projected unused amount of Pacific cod from catcher vessels using trawl gear and American Fisheries Act (AFA) trawl catcher processors (C/Ps) to catcher vessels less than 60 feet (18.3 meters (m)) LOA using hook-and-line or pot gear, C/Ps using hook-and-line gear, and Amendment 80 (A80) C/Ps in the Bering Sea and Aleutian Islands (BSAI) management area. This action is necessary to allow the 2016 total allowable catch (TAC) of Pacific cod to be harvested.

DATES: Effective upon November 2, 2016 through 2400 hours, Alaska local time (A.l.t.), December 31, 2016.

FOR FURTHER INFORMATION CONTACT: Josh Keaton, 907–586–7228.

SUPPLEMENTARY INFORMATION: NMFS manages the groundfish fishery in the Bering Sea and Aleutian Islands (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 2016 Pacific cod TAC specified for catcher vessels using trawl gear in the BSAI is 48,638 metric tons(mt) as established by the final 2016 and 2017 harvest specifications for groundfish of the BSAI (81 FR 14773; March 18, 2016) and reallocation (81 FR 69445; October 6, 2016). The Regional Administrator has determined that catcher vessels using trawl gear will not be able to harvest 2,000 mt of the remaining 2016 Pacific cod TAC allocated to those vessels under § 679.20(a)(7)(ii)(A)(*9*).

The 2016 Pacific cod TAC specified for AFA trawl C/Ps in the BSAI is 4,666 mt as established by the final 2016 and 2017 harvest specifications for groundfish of the BSAI (81 FR 14773; March 18, 2016) and reallocation (81 FR 61143; September 6, 2016). The Regional Administrator has determined that AFA trawl C/Ps will not be able to harvest 850 mt of the remaining 2016 Pacific cod TAC allocated to those vessels under § 679.20(a)(7)(ii)(A)(*7*).

Therefore, in accordance with § 679.20(a)(7)(iii)(A) and § 679.20(a)(7)(iii)(B), NMFS reallocates 2,850 mt of Pacific cod to catcher vessels less than 60 feet (18.3 m) LOA using hook-and-line or pot gear, C/Ps using hook-and-line gear, and A80 C/Ps in the Bering Sea and Aleutian Islands management area.

The harvest specifications for Pacific cod included in the final 2016 and 2017 harvest specifications for groundfish of the BSAI (81 FR 14773; March 18, 2016, 81 FR 57491; August 23, 2016, 81 FR 61143; September 6, 2016, 81 FR 69445; October 6, 2016) are revised as follows: 46,638 mt for catcher vessels using trawl gear, 3,816 mt for AFA trawl C/Ps, 10,674 for catcher vessels less than 60 feet (18.3 m) LOA using hook-and-line or pot gear, 109,533 for C/Ps using hook-and-line gear, and 31,397 mt for A80 C/Ps.

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 reallocation of Pacific cod specified from multiple sectors to catcher vessels less than 60 feet (18.3 m) LOA using hook-and-line or pot gear, C/Ps using hook-and-line gear, and A80 C/Ps in the Bering Sea and Aleutian Islands management area. Since these fisheries are currently open, it is important to immediately inform the industry as to the revised allocations. Immediate notification is necessary to allow for the orderly conduct and efficient operation of this fishery, to allow the industry to plan for the fishing season, and to avoid potential disruption to the fishing fleet as well as processors. NMFS was unable to publish a notice providing time for public comment because the most recent, relevant data only became available as of October 27, 2016.

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: October 28, 2016.

Emily H. Menashes,

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

[FR Doc. 2016–26504 Filed 11–2–16; 8:45 am]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 81, No. 213
Thursday, November 3, 2016

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

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2014–0603; Directorate Identifier 2013–CE–026–AD]

RIN 2120–AA64

Airworthiness Directives; Meggitt (Troy), Inc. Combustion Heaters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Supplemental notice of proposed rulemaking (SNPRM); reopening of comment period.

SUMMARY: We are revising a notice of proposed rulemaking (NPRM) for certain Meggitt (Troy), Inc. (previously known as Stewart Warner South Wind Corporation and as Stewart Warner South Wind Division) Model Series (to include all the variants) 921, 930, 937, 940, 944, 945, 977, 978, 979, 8240, 8253, 8259, and 8472 combustion heaters that proposed to supersede airworthiness directive (AD) 81–09–09. The NPRM proposed to retain most actions from AD 81–09–09, add a calendar time to the repetitive inspections, add more detailed actions to the inspections, and add a pressure decay test. The NPRM was prompted by an airplane accident and reports we received of the heater malfunctioning. This action revises the NPRM by adding combustion heater models series to the applicability and modifying the compliance times. We are proposing this SNPRM to correct the unsafe condition on these products. Since these actions impose an additional burden over that proposed in the NPRM, we are reopening the comment period to allow the public the chance to comment on these proposed changes.

DATES: The comment period for the NPRM published in the **Federal Register** on August 20, 2014 (79 FR 49249) is reopened. We must receive comments on this SNPRM by December 19, 2016.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov*. Follow the instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.
- *Hand Delivery:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this proposed AD, contact Meggitt Control Systems, 3 Industrial Drive, Troy, Indiana 47588; telephone: (812) 547–7071; fax: (812) 547–2488; email: *infotroy@meggitt.com;* Internet: *www.stewart-warner.com.* You may view this referenced service information at the FAA, Small Airplane Directorate, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329–4148.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2014–0603; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (phone: 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Chung-Der Young, Aerospace Engineer, Chicago Aircraft Certification Office, FAA, Small Airplane Directorate, 2300 East Devon Avenue, Des Plaines, IL 60018–4696; telephone (847) 294–7309; fax (847) 294–7834 email: *chung-der.young@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2014–0603; Directorate Identifier 2013–CE–026–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD because of those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this proposed AD.

Discussion

On April 16, 1981, we issued AD 81–09–09, Amendment 39–4102 (46 FR 24936, May 4, 1981) (''AD 81–09–09''), for certain Meggitt (Troy), Inc. (previously known as Stewart Warner South Wind Corporation and as Stewart Warner South Wind Division) Model Series 8240, 8253, 8259, and 8472 combustion heaters. AD 81–09–09 resulted from a hazardous condition caused by deterioration of the combustion heater. AD 81–09–09 currently requires repetitive inspections of the combustion heater; repetitive installation inspections of the combustion heater; and, for combustion heaters having 1,000 hours or more time-in-service (TIS), overhaul of the combustion heater.

We issued a notice of proposed rulemaking (NPRM) to supersede AD 81–09–09 on August 13, 2014, which published in the **Federal Register** on August 20, 2014 (79 FR 49249). The NPRM was prompted by an airplane accident and reports we received of the heater malfunctioning. The NPRM proposed to retain most actions from AD 81–09–09, add a calendar time to the repetitive inspections, add more detailed actions to the inspections, and add a pressure decay test.

Actions Since the NPRM Was Issued

Since we issued the NPRM, we received comments from the public during the comment period that resulted

in our decision to issue this SNPRM. This SNPRM proposes to increase the applicability and modify the compliance time. We also completed an initial regulatory flexibility analysis to determine the impact of the proposed AD on small entities (this was at the request of one of the comments received on the NPRM). Adopted on September 5, 2014, the National Transportation Safety Board issued the probable cause for the airplane accident that initiated this investigation. The probable cause was identified as malfunction of the cabin heater, which resulted in an inflight fire and smoke in the airplane.

Comments

We gave the public the opportunity to comment on the NPRM. The following presents the comments received on the NPRM and the FAA's response to each comment.

Request To Allow Repair of the Combustion Tube

James W. Tarter Jr. from Meggitt (Troy), Inc. identified that the Meggitt Inspection Procedure, Document No. IP–347, dated May 17, 2014, allows repair of combustion tubes that do not pass the pressure decay test (PDT); however, the proposed AD required a combustion tube replacement. We infer that the commenter wants to allow the repair of the combustion tube when it fails the PDT.

We disagree with allowing repair of the combustion tube when it fails the PDT. The cracked combustion tube metal wall becomes oxidized and the cross-section of the crack is contaminated by combusted fuel residuals; therefore, there is no way to make a reliable repair. The welding will crack again in an unpredictable period of service time.

We did not make any changes to this SNPRM as a result to this comment.

Request To Delay Issuance of AD Until PDT Procedure Is Publically Available

Anthony Saxton requested we delay the issuance of the final rule until the PDT procedure is publicly available. He stated that he had a difficult time getting a copy of the procedure.

We do not agree with the commenter about delaying the rule. By policy, the FAA cannot post to the public docket service information that is part of the proposed action until the publication of the final rule unless there is written permission from the design approval holder. The FAA does not currently have such written permission. We encourage the commenter to obtain a copy of this document from the design approval holder. After the final rule is published in the **Federal Register**, the PDT procedure will be readily available to the public in the docket.

We did not make changes to this SNPRM based on this comment.

Request To Change Number of Airplanes Affected and Number of Labor Hours Required To Comply

Anthony Saxton commented that the number of airplanes affected was too low and the labor cost was too low.

We partially agree with the commenter. We agree the number of airplanes affected was not complete, but was the FAA's best estimate at the time. We obtained our initial information from the FAA aircraft registry, and the registry does not identify which airplanes have combustion heaters. An FAA economist has completed a more complete assessment of the number of affected aircraft during the development of the initial regulatory flexibility analysis. The estimated number of affected airplanes has been modified based on the initial regulatory flexability analysis.

We disagree with modifying the labor hours to perform the labor without more substantive information to support a different number.

Request To Withdraw the NPRM

William West commented that AD action is not needed. He requested we withdraw the NPRM and provide guidance to owners/operators reminding them that if the heater malfunctions to not use it until it has been properly inspected.

We disagree with this comment. We completed a review of the accident/incident data as well as service difficulty reports over several years. The level of risk identified in the data review shows that we should address this unsafe condition through mandatory action rather than guidance. This proposed AD action is consistent with AD actions taken against other similar products. We have no way of assuring that the unsafe condition has been mitigated through voluntary guidance action.

We did not make changes to this SNPRM based on this comment.

Request To Allow Limited Decay in the PDT

Harold Haskins commented that we should do a PDT that allows some leakage as per AD 2004–21–05 (69 FR 61993, October 22, 2004). He commented that the test identified in the Meggitt (Troy), Inc. procedure is not really a pressure decay test because no decay is allowed. Allowing a certain amount of decay/leakage is consistent with other AD actions.

We agree with the commenter that there are other ADs where the required pressure decay tests allow a certain amount of leakage; however, we disagree with modifying the SNPRM because Meggitt (Troy), Inc., as the design approval holder, has the responsibility to develop what they believe is appropriate procedures to maintain their combustion heaters. Owners/operators may provide substantiating data and request approval of an alternative method of compliance (AMOC) using the procedures found in 14 CFR 39.19 and specified in paragraph (m) of this SNPRM.

We did not make changes to this SNPRM based on this comment.

Request To Change the Listing of the Part Numbers or Model Numbers Affected

Sin Kwong Chew, Anthony Saxton, and the National Transportation Safety Board (NTSB) commented that we should use the part numbers or more detailed model numbers for the affected heaters. Another commenter suggested we use the four upper level model series number.

We agree with changing how the model and series numbers are listed in the Applicability, paragraph (c) of this proposed AD. We want to ensure that the applicability of the proposed AD will address all affected model/part number heaters.

We modified the Applicability, paragraph (c) of this proposed AD, to state the upper level model number of the heaters and to specify that all the part number heaters and dash numbers are included under that higher level designation.

Request Change to Procedures

William Sandmann requested we change the heater disconnect procedures to cap off the fuel supply as near to the fuel source as possible to reduce the possibility that fuel may leak from the fuel line.

We disagree with this comment. The manufacturer's instructions are FAA approved and acceptable. The commenter's suggestion may be an improvement on the manufacturer's instructions, but it is not required and is too detailed a level to include in this proposed AD.

We did not make changes to this SNPRM as a result of this comment.

Request Change to Credit for Previous Inspections

Chris (no last name or company affiliation given) requested we allow

credit for PDTs previously done using the manufacturer's instructions within the last 2 years/250 hours. The commenter also requested that we do not allow credit for the general inspection of the combustion heater because previous instructions are not sufficient to meet the new inspection criteria.

We agree with the commenter's suggestions. The proposed AD contains the language ''unless already done'' in paragraph (f) Compliance. That language allows credit for any of the actions required by the AD that were performed before the effective date of the AD using the instructions required by the AD. That language does not allow credit for the previous instructions in AD 81–09–09 since we agree that they are not sufficient to meet the inspection criteria.

We did not make changes to the SNPRM based on this comment.

Request Replacement of Combustion Heater Instead of Overhaul

Anthony Saxton and the Aircraft Owners and Pilot's Association (AOPA) requested we require replacement of the combustion heater tube instead of an overhaul of the combustion heater if a combustion heater fails the PDT. An overhaul is a costly requirement that adds no additional safety benefit.

We agree with the commenters' suggestion. Additional inspections in the proposed AD would require inspection and possible replacement of individual components of the combustion heater. Therefore, if the heater fails the PDT, replacement of the combustion heater tube would be a better option rather than heater overhaul.

We have modified the corrective action language for a PDT failure to replacement, disable, or remove the combustion heater.

Request Removal of Combustion Heater Model 8248

Harold Haskins and William Sandmann commented they were unaware of a Model 8248 combustion heater.

We agree with this comment. The Model 8248 was included based on the FAA technical standard order (TSO) database. After further research, Meggitt (Troy), Inc. verified that the Model 8248 was included in the database in error and did not exist.

We have removed the Model 8248 combustion heater from the Applicability, paragraph (c) of this proposed AD.

Request the Addition of Service Information

Harold Haskins requested we add the service information for the Model 8240 and 8259 combustion heaters.

We agree with the commenter's suggestion.

We have added South Wind Service Manual for Stewart Warner South Wind Aircraft Heaters 8240–A, 8240–C, 8259–A, 8259–C, 8259–DL, 8259–FL1, 8259–GL1, 8259–GL2, Form No. 09–998 (Rev. 12–69) to the service information required for this proposed AD.

Request To Delete Piper From Possible Combustion Heater Installation

Harold Haskins requested that we delete Piper Aircraft, Inc. (Piper) airplanes from possible airplanes that may have the affected combustion heaters installed. He does not know of any Piper airplanes that have the affected heaters installed.

We disagree with this comment. The proposed AD addressed the combustion heaters at the component level, and they have the potential for installation on various airplanes. Also, this AD as proposed in this SNPRM would expand the applicability to include combustion heaters that are installed on Piper airplanes as well as any other airplanes not listed, thus the reason for the phrase ''are installed on, but not limited to'' in the applicability.

Request Increasing the Time Allowed for Initial Compliance Time

Anthony Saxton and AOPA requested modifying the initial compliance time to provide a longer period of time to comply. Two commenters suggested modifing the compliance time to better coincide with a normal maintenance schedule—within the next 10 hours of time-in-service of the combustion heater or at the next scheduled 100-hour inspection, annual inspection, or phase inspection. This would allow maintenance shops to better accommodate owners/operators in complying with the AD.

We agree with the commenters. Since the NPRM, this SNPRM adds combustion heater models to the Applicability, paragraph (c) of this proposed AD. It would be appropriate to allow more time to assure that maintenance facilities are able to support doing the work required by the AD.

We have modified the wording for the initial inspection compliance times for the combustion heater inspection, combustion heater installation inspection, and the PDT to better coincide with regularly scheduled maintenance.

Request Adding Document Number to Service Information

James W. Tartar Jr. and Meggitt (Troy), Inc. requested adding the document number for the Meggitt (Troy), Inc. inspection procedure for the PDT for clarity.

We agree with this comment. In this proposed AD, we cite the Meggitt (Troy), Inc. inspection procedure for the PDT as Meggitt Inspection Procedure, Document No. IP–347, dated May 17, 2014.

Request the AD Include an Analysis of the Impact on Small Businesses

Anthony Saxton requested that we include in the AD an analysis of the AD's impact on small businesses. The commenter stated they are aware of a number of small businesses that operate the affected airplanes.

We agree with this comment. The commenter has a good understanding of the usage of the airplanes affected by this SNPRM. Also, this proposed AD adds combustion heater models to the Applicability, paragraph (c) of this proposed, that will affect additional airplanes over that affected in the proposed rule.

We have completed an initial regulatory flexability analysis that we have included in its entirety in this SNPRM.

Support of Proposed AD

AOPA, NTSB, William Sandmann, and Anthony Saxton all supported the general intent of the proposed AD action.

Related Service Information Under 1 CFR Part 51

We reviewed the following service information that applies to this proposed AD:

—Stewart-Warner South Wind Corporation South Wind Service Manual for Stewart Warner South Wind Aircraft Heaters 8240–A, 8240–C, 8259–A, 8259–C, 8259–DL, 8259–FL1, 8259–GL1, 8259–GL2, Form No. 09–998, revised: December 1969;

—South Wind Division Stewart-Warner Corporation Service Manual Beech Aircraft Corporation PM–20688, Part No. 404–001039 Heater Assy. (SW 8253–B), revised: April 1965;

—South Wind Division Stewart-Warner Corporation Service Manual South Wind Aircraft Heater 8472 Series, Form No. 09–1015, issued: April 1975; and

The service information above describes procedures for inspection of the combustion heater and inspection of the installation of the combustion heater for the applicable heater models.

We also reviewed Meggitt Inspection Procedure, Pressure Decay Test, Aircraft Heaters, dated May 17, 2014. This service information describes procedures for the PDT for airplane combustion heaters for all heater models.

This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

FAA's Determination

We are proposing this SNPRM because we evaluated all the relevant information and determined the unsafe condition described previously is likely to exist or develop in other products of the same type design. Certain changes described above expand the scope of this rulemaking. As a result, we have determined that it is necessary to reopen the comment period to provide additional opportunity for the public to comment on this SNPRM.

Proposed Requirements of This SNPRM

This SNPRM would require repetitive inspections of the combustion heater and repetitive general inspections of the combustion heater installation, replacing any parts or components as necessary. This SNPRM would also require repetitive PDTs, with replacement of the combustion heater tube, disabling, or removal of the combustion heater in the event of PDT failure. This SNPRM also modifies the inspection and PDT compliance times allowing for the inspections to coincide with regularly scheduled maintenance. This SNPRM would not allow repair of the combustion heater tube.

For combustion heater models other than Models 8240, 8253, 8259, and 8472, this SNPRM does not have referenced service information associated with certain required inspections and the PDT and, if necessary, any replacement(s) that may be required. Appendix 1 of this SNPRM contains a listing of service information that provides specific instructions, for certain inspections and replacements, that may be used to apply for an AMOC. However, the listing in appendix 1 to this SNPRM does not include any instructions for the required PDT because these procedures do not exist. If you are unable to obtain instructions for the PDT, you must disable or remove the combustion heater.

The service information listed in appendix 1 of this SNPRM did not meet Office of the Federal Register regulatory requirements for incorporation by reference approval due to the condition of the documents.

We are evaluating the actions required in AD 69–13–03 (38 FR 33765, December 7, 1973) and may take further AD action in the future.

Differences Between This SNPRM and the Service Information

The proposed AD would prohibit repair of any defective combustion tube while the service information does not specify this.

Costs of Compliance

We estimate that this proposed AD affects 6,300 combustion heaters installed on, but not limited to, certain Beech, Britten-Norman, Cessna Aircraft Company, and Piper Aircraft, Inc. airplanes of U.S. registry.

We estimate the following costs to comply with this proposed AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Inspections and pressure decay test of the combustion heater.	7 work-hours × $85 per hour = $595.	Not applicable	$595	$3,748,500

We estimate the following costs to do any necessary combustion heater disable/removal/related replacement that would be required based on the results of the proposed inspections/test. We have no way of determining the number of aircraft that might need a combustion heater disable/removal/related replacement:

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
Replace combustion heater tube	8 work-hours × $85 per hour = $680	$3,900	$4,580
Replace temperature switches	1 work-hour × $85 per hour = $85	$320	405
Repair pump	2 work-hours × $85 per hour = $170	$470	640
Disable heater	2 work-hours × $85 per hour = $170	Not Applicable	170
Remove heater	3 work-hours × $85 per hour = $255	Not Applicable	255

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. ''Subtitle VII: Aviation Programs'' describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: ''General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Initial Regulatory Flexibility Analysis

This section presents the initial regulatory flexibility analysis (IRFA) that was done for this action. We have reworded and reformatted for **Federal Register** publication purposes. The IRFA in its original form can be found in the docket at *http://www.regulations.gov.*

Introduction and Purpose of This Analysis

The Regulatory Flexibility Act of 1980 (Pub. L. 96–354) (RFA) establishes ''as a principle of regulatory issuance that agencies shall endeavor, consistent with the objectives of the rule and of applicable statutes, to fit regulatory and informational requirements to the scale of the businesses, organizations, and governmental jurisdictions subject to regulation.'' To achieve this principle, the RFA requires agencies to solicit and consider flexible regulatory proposals and to explain the rationale for their actions to assure that such proposals are seriously considered.'' The RFA covers a wide-range of small entities, including small businesses, not-for-profit organizations, and small governmental jurisdictions.

Agencies must perform a review to determine whether a rule will have a significant economic impact on a substantial number of small entities. If the agency determines that it will, the agency must prepare an initial regulatory flexibility analysis (IRFA) as described in the RFA. The FAA finds that the proposed AD would have a significant economic impact on a substantial number of small entities. Accordingly, in the following sections we discuss the compliance requirements of the proposed AD, the cost of compliance, and the economic impact on small entities.

Section 603(a) of the RFA requires that each initial regulatory flexibility analysis contain:

—A description of the reasons action by the agency is being considered;

—A succinct statement of the objectives of, and legal basis for, the proposed rule;

—A description of and, where feasible, an estimate of the number of small entities to which the proposed rule will apply;

—A description of the projected reporting, recordkeeping and other compliance requirements of the proposed rule, including an estimate of the classes of small entities which will be subject to the requirement and the type of professional skills necessary for preparation of the report or record; and to the extent practicable, an identification of all relevant Federal rules which may duplicate, overlap or conflict with the proposed rule; and

—A description of any significant alternatives to the proposed rule which accomplish the stated objectives of applicable statues and which minimize any significant economic impact of the proposed rule on small entities.

1. Objectives of, and Legal Basis for, the Proposed Rule

Title 49 of the U.S. Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the FAA's authority.

We are issuing this rulemaking under the authority described in subtitle VII, part A, subpart III, section 44701, ''General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on the airplanes identified in this proposed AD.

2. A Description of the Reasons Action by the Agency Is Being Considered

This proposed AD stems from the crash of a Cessna 401 near Chanute, Kansas, on May 11, 2012, killing the pilot and three of the four passengers aboard, and seriously injuring the fourth passenger. According to the NTSB report, the crash occurred after dark smoke emanated from the cabin heater and entered the cabin obscuring the occupants' vision. According to the Report: ''The smoke likely interfered with the pilot's ability to identify a safe landing site.'' When the pilot attempted an emergency landing in a field, the airplane's wing contacted the ground and the airplane cartwheeled.

The NTSB determined the probable cause of the accident to be:

> The malfunction of the cabin heater, which resulted in an inflight fire and smoke in the airplane. Contributing to the accident was the pilot's lack of understanding concerning the status of the airplane's heater system following an earlier overheat event and the risk of its continued use. Also contributing were the inadequate inspection criteria for the cabin heater.

As result of this accident, the FAA is proposing this AD to detect and correct a hazardous condition caused by deterioration of the combustion heater, a condition that could lead to ignition of heater components and result in smoke and fumes in the airplane cabin.

3. A Description of and an Estimate of the Number of Small Entities To Which the Proposed Rule Will Apply

This proposed AD would supersede AD 81–09–09, which applies to 8000 series Meggitt combustion heaters installed on certain twin-engine piston airplanes, primarily Cessna 300 and 400 series airplanes, but also installed on the Beech D18S twin-engine airplane and some Britten Norman twin-engine piston airplanes. The proposed AD would extend applicability to 900 series Meggitt combustion heaters installed on certain Cessna single-engine piston airplanes, Cessna 310 twin-engine airplanes, Lake LA–4 and LA–250 airplanes, certain Ryan Navion single-engine piston airplanes and certain Piper PA–23 and PA–30 airplanes. The FAA estimates that there are 4,121 airplanes equipped with 8000 series Meggitt combustion heaters, and 2,123 airplanes equipped with 900 series Meggitt combustion heaters. Since many of these airplanes are registered to Limited Liability Companies (LLCs), Limited Liability Partnerships (LLPs) and other company forms typically suited for single proprietors, small partnerships, etc., we conclude that the proposed rule would affect a substantial number of small entities.

4. Duplicative, Overlapping or Conflicting Federal Rules

The FAA is unaware of any Federal rules that duplicate, overlap, or conflict with this proposed AD.

5. Significant Alternatives to the Proposed Rule

Because of an unsafe condition that is likely to exist or develop on the airplanes identified in this proposed AD, there is no feasible significant alternative to requiring the actions of this proposed AD. The FAA invites public comment on this determination.

The FAA considered allowing more flight hours or calendar time before requiring compliance, but this alternative would increase the risk of another fatal accident. This proposed AD allows the combustion heater to be disconnected or removed, but, as noted above, operating without a heater is unlikely to be viable.

6. Reporting, Recordkeeping, and Other Compliance Requirements of the Proposed Rule

Small entities would incur no new reporting and recordkeeping requirements as a result of this rule.

Compliance Requirements

This proposed AD would carry over the following requirements from AD 81–09–09:

—Conduction of the 250-hour heater inspection every 250 hours of heater operation, in accordance with the manufacturer's service manual. We estimate the labor cost of this action to be 2 hours × $85 = $170.

—General inspection of the heater installation at the same time as the 250-hour inspection. We estimate the labor cost of this action to also be 2 hours × $85 = $170.

Since the proposed rule would extend applicability to 900 series heaters Meggitt combustion heaters, which are installed on certain airplanes, there is an incremental cost associated with the existing requirement for these two inspections. There is no incremental cost associated with applicability to 8000 series heaters, installed on certain airplanes, as the current rule already applies to these heaters.

This proposed AD would add the following new provisions, which will apply to both 900 and 8000 series heaters installed on certain airplanes:

—During each 250-hour inspection more detailed actions would be required, namely inspection of the thermostat and upper limit switches, and inspection of the solenoid valve and fuel pump. In conjunction with the 250-hour and installation inspections already required, the labor cost of these more detailed actions would be one hour of labor at $85. ''On-condition'' costs to replace the temperature switches would be an additional hour of labor ($85) and $320 in materials cost, for a total of $405. On-condition costs to repair/overhaul the pump would be an additional two hours of labor ($170) and $470 in materials cost for a total of $640.

—Operators would be required to replace defective combustion tubes with new tubes as repair of combustion tubes would be prohibited. We estimate the cost of prohibiting repair of combustion tubes to be minimal as industry reports that the Meggitt heater combustion tubes are effectively non-repairable.

—At the same time as the 250-hour and installation inspection, a combustion heater pressure decay test (PDT) would be required. The PDT would cost $170. If the combustion heater fails the PDT, the operator would be required to replace the combustion tube at an installed cost of $4,580.

—Operators have the options of disabling the heater at an estimated cost of $170 or removing it at estimated cost of $255.

Cost of Compliance

In calculating the cost of compliance, we assume that operating without a heater is unlikely to be viable. We estimate the ten-year cost of the proposed rule. Based on data in the 2014 GA Survey, we can somewhat conservatively assume that average flight hours per airplane per year are about 100 hours. We estimate heater time to be 50 percent of airplane flight hours so, on average, flight hours will accumulate to about 1,000 hours in ten years and heater time will accumulate to about 500 hours. Since requirements for inspection internals are ''250 hours of combustion heater operations or two years, whichever occurs first,'' we expect inspections to usually occur every two years. As will be seen below, compliance costs are dominated by the almost immediate requirement for the PDT test.

Pressure Decay Test

The FAA estimates that 90 percent of combustion tubes tested will fail the first PDT test. Since replacing the combustion tube, like an overhaul, requires complete disassembly of the combustion heater, we somewhat conservatively assume that operators will overhaul their combustion heaters at $4,580, rather than simply replace the combustion tube, at $4,900. Major components such as the combustion tube, fuel pump, and temperature switches that are typically replaced or overhauled in a combustion heater overhaul have service lives of 750 heater hours, equivalent to about 1,500 flight hours or 15 years. Therefore, we assume that once replaced or overhauled, these components will not need to be replaced during our 10-year period of cost estimation. So aside from the initial tube replacement, we estimate that, for inspections required by this proposed AD, ''on-condition'' costs would be minimal.

Table 1 below shows our calculation of compliance cost for airplanes with the affected Meggitt combustion heaters. We assume the rule to be effective in 2017 and, as discussed above, in the first year we assume the combustion heater fails the PDT resulting in a subsequent overhaul. For the 8000 series heaters note that the $935 labor cost for 2017 includes three hours of labor ($255) for the detailed inspection and the PDT in addition to eight hours of labor for the overhaul ($680).

As the table shows, we estimate the present value cost of compliance to be $6,020 for airplanes equipped with 8000 series Meggitt combustion heaters and $7,514 for airplanes equipped with 900 series Meggitt combustion heaters. The lower cost for airplanes with 8000 series combustion heaters reflects the previously noted fact that 8000 series heaters are currently subject to the 250-hour inspection and installation inspection requirements, and, therefore, the incremental cost would be correspondingly less for airplanes with 8000 series combustion heaters compared to airplanes with 900 series heaters.

Economic Impact on Small Entities

If the cost of compliance is greater than 2 percent of the value of an operator's airplane, the FAA considers the cost impact to be significant. So if the value of an airplane equipped with an affected Meggitt combustion heater is less than 50 times the cost of compliance, we consider that the operator of the airplane would incur a substantial economic impact. With a present value cost of about $6,000 for airplanes equipped with 8000 series Meggitt combustion heaters, the FAA considers the cost impact to be significant for all such airplanes with values below about $300,000. With a present value cost of about $7,500 for airplanes equipped with 900 series Meggitt combustion heaters, the FAA considers the cost impact to be significant for all such airplanes with values below about $350,000. The airplanes equipped with the affected heaters are single- and twin-engine piston airplanes that, for the most part, were manufactured from the 1940s to the 1980s, and range in price from about $350,000 for a Cessna 221C Golden Eagle down to a price as low as $30,000 for a Piper 23–150 Apache. Accordingly, most of the 6,244 airplanes equipped with Meggitt combustion heaters have values low enough to consider that the airplane operators would incur a significant economic impact. As noted above, many of these airplanes are registered to LLCs and other small companies.

The FAA therefore concludes that this proposed AD would have a significant economic impact on a substantial number of small entities.

TABLE 1—COSTS OF COMPLIANCE

Year	Materials cost	Labor cost	Mtls + labor cost	Actions	Discount factor (@7%)	PV Cost
Airplanes with 8000 Series Meggitt Combustion Heaters						
2017	$4,220	$935	$5,155	Detailed inspection (1 hr labor), PDT (2 hrs labor)—Overhaul after assumed failure (8 hrs labor, $4,220 materials).	1.000	$5,155
2019		255	255	Detailed inspection (1 hr labor), PDT inspection (2 hrs labor).	0.873	223
2021		255	255	Detailed inspection (1 hr labor), PDT inspection (2 hrs labor).	0.763	195
2023		255	255	Detailed inspection (1 hr labor), PDT inspection (2 hrs labor).	0.666	170
2025		255	255	Detailed inspection (1 hr labor), PDT inspection (2 hrs labor).	0.582	148
2027		255	255	Detailed inspection (1 hr labor), PDT inspection (2 hrs labor).	0.508	130
Total PV Cost						6,020
Airplanes with 900 Series Combustion Meggitt Heaters						
2017	4,220	1,275	5,495	250-hr inspection (2 hrs labor), installation inspection (2 hrs labor), detailed inspection (1 hr labor), PDT (2 hrs labor)—Overhaul after assumed failure (8 hrs labor, 4,220 materials).	1.000	5,495
2019		595	595	250-hr inspection (2 hrs labor), installation inspection (2 hrs labor), detailed inspection (1 hr labor), PDT (2 hrs labor).	0.873	520
2021		595	595	250-hr inspection (2 hrs labor), installation inspection (2 hrs labor), detailed inspection (1 hr labor), PDT (2 hrs labor).	0.763	454
2023		595	595	250-hr inspection (2 hrs labor), installation inspection (2 hrs labor), detailed inspection (1 hr labor), PDT (2 hrs labor).	0.666	396
2025		595	595	250-hr inspection (2 hrs labor), installation inspection (2 hrs labor), detailed inspection (1 hr labor), PDT (2 hrs labor).	0.582	346
2027		595	595	250-hr inspection (2 hrs labor), installation inspection (2 hrs labor), detailed inspection (1 hr labor), PDT (2 hrs labor).	0.508	302
Total PV Cost						7,514

Regulatory Findings

We determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify this proposed regulation:

(1) Is not a ''significant regulatory action'' under Executive Order 12866,

(2) Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979),

(3) Will not affect intrastate aviation in Alaska, and

(4) Will have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by removing AD 81–09–09, Amendment 39–4102 (46 FR 24936, May 4, 1981) and adding the following new airworthiness directive (AD):

Meggitt (Troy), Inc.: Docket No. FAA–2014–0603; Directorate Identifier 2013–CE–026–AD.

(a) Comments Due Date

We must receive comments by December 19, 2016.

(b) Affected ADs

This AD replaces AD 81–09–09, Amendment 39–4102 (46 FR 24936, May 4, 1981).

(c) Applicability

(1) This AD applies to Meggitt (Troy), Inc. (previously known as Stewart Warner South Wind Corporation and as Stewart Warner South Wind Division) Models (to include all dash number and model number variants) 921, 930, 937, 940, 944, 945, 977, 978, 979, 8240, 8253, 8259, and 8472 combustion heaters that:

(i) Are installed on, but not limited to, certain Beech, Britten-Norman, Cessna Aircraft Company, and Piper Aircraft, Inc. airplanes; and

(ii) certificated in any category.

(d) Subject

Joint Aircraft System Component (JASC)/Air Transport Association (ATA) of America Code 2140; Heating System.

(e) Unsafe Condition

This AD was prompted by an airplane accident and reports we received that the combustion heater was malfunctioning. We are issuing this AD to detect and correct a hazardous condition caused by deterioration of the combustion heater, which could lead to ignition of components and result in smoke and fumes in the cabin.

(f) Compliance

Comply with this AD by doing one of the actions in paragraphs (f)(1), (2), or (3) of this AD at the compliance times indicated, unless already done. If the hours of combustion heater operation cannot be determined, use 50 percent of the airplane's hours time-in-service (TIS):

(1) Perform the actions specified in paragraphs (g) through (j) of this AD;

(2) Disable the heater following the instructions in paragraph (k)(1) of this AD; or

(3) Remove the heater following the instructions in paragraph (k)(2) of this AD.

(g) Inspections and Pressure Decay Test (PDT) of the Combustion Heater

Within the next 10 hours TIS of the combustion heater after the effective date of this AD or the next scheduled 100-hour inspection, annual inspection, or phase inspection that occurs 30 days after the effective date of this AD, whichever occurs first, and repetitively thereafter at intervals not to exceed 250 hours of combustion heater operation or two years, whichever occurs first, do the following inspections and PDT listed in paragraphs (g)(1) through (4) of this AD. You may do one of the actions in paragraph (k)(1) or (2) of this AD in lieu of doing the inspections required by paragraph (g).

(1) Inspections using the instructions in paragraph (i)(1) or (j) of this AD, as applicable.

(2) Inspections using the steps listed in paragraphs (g)(2)(i) through (v) of this AD:

(i) Inspect the thermostat switch (external from heater) and upper limit switch (located on the heater). In cold static condition, both switches should be in closed position; in operation (hot) condition, both switches should regulate their sensed temperatures within +/−10 degrees F.

(ii) Inspect the solenoid valve and fuel pump for fuel leak, corrosion, diaphragm crack, metal shavings, and excess grease.

(iii) With the heater operating, inspect the fuel pump output pressure for proper gauge hook up and pressure range readings.

(iv) Inspect the combustion heater's fuel pump operating pressure to assure it is not affected by other on-board pumps.

(v) Inspect the heater to assure it instantly responds to the on/off switch.

(3) Installation inspections and checks using the steps listed in paragraphs (g)(3)(i) through (iv) of this AD:

(i) Inspect ventilating air and combustion air inlets and exhaust outlet correcting any restrictions and ensure attachment security.

(ii) Inspect drain line and ensure it is free of obstruction.

(iii) Check all fuel lines for security at joints and shrouds, correcting/replacing those showing evidence of looseness or leakage.

(iv) Check all electrical wiring for security at attachment points, correcting conditions leading to arcing, chafing or looseness.

(4) Pressure decay test using the instructions in paragraph (i)(2) or (j) of this AD, as applicable.

(h) Replacement of the Heater Tube and/or Correct or Replace Other Assemblies

If any discrepancies are found during any of the inspections/tests required in paragraphs (g)(1), (2), (3), and/or (4) of this AD, before further flight, replace the defective heater tube and/or correct or replace other defective assemblies as necessary. You must use the instructions in paragraph (i) or (j) of this AD, as applicable, to do any necessary replacements. This AD does not allow repair of the combustion tube. You may do one of the actions in paragraph (k)(1) or (2) of this AD in lieu of doing the replacements required by paragraph (h).

(i) Procedures for Inspection, PDT, and Replacement for Models 8240, 8253, 8259, and 8472

(1) For the inspections required in paragraph (g)(1) of this AD and the replacement(s) that may be required in paragraph (h) of this AD, use the service information listed in paragraphs (i)(1)(i) through (iii) of this AD, as applicable, or do one of the actions in paragraph (k)(1) or (2) of this AD.

(i) Stewart-Warner South Wind Corporation South Wind Service Manual for Stewart Warner South Wind Aircraft Heaters 8240–A, 8240–C, 8259–A, 8259–C, 8259–DL, 8259–FL1, 8259–GL1, 8259–GL2, Form No. 09–998, revised: December 1969;

(ii) South Wind Division Stewart-Warner Corporation Beech Aircraft Corporation Service Manual PM–20688, Part No. 404–001039 Heater Assy. (SW 8253–B), revised: April 1965; or

(iii) South Wind Division Stewart-Warner Corporation Service Manual South Wind Aircraft Heater 8472 Series, Form No. 09–1015, issued: April 1975.

(2) For the pressure decay test (PDT) required in paragraph (g)(4) of this AD, use Meggitt Inspection Procedure, Pressure Decay Test, Aircraft Heaters, IP–347, dated May 17, 2014, or do one of the actions in paragraph (k)(1) or (2) of this AD.

(j) Procedures for Inspection, PDT, and Replacement for Models Other Than Models 8240, 8253, 8259, and 8472

This AD does not have referenced service information associated with the mandatory requirements of this AD for models other than Models 8240, 8253, 8259, and 8472. For the required inspections and PDT specified in paragraphs (g)(1) and (4) of this AD and, if necessary, any replacement(s) specified in paragraph (h) of this AD, you must contact the manufacturer to obtain FAA-approved inspection, replacement, and PDT procedures approved specifically for this AD and implement those procedures through an alternative method of compliance (AMOC) or do one of the actions in paragraph (k)(1) or (2) of this AD. You may use the contact information found in paragraph (n)(2) to contact the manufacturer. Appendix 1 of this AD contains a listing of service information that provides specific instructions, for certain inspections and replacements, that you may use to apply for an AMOC following paragraph (m) of this AD. The service information listed in appendix 1 of this AD did not meet Office of the Federal Register regulatory requirements for incorporation by reference approval due to the condition of the documents. However, the listing in appendix 1 to this AD does not include any instructions for the PDT required in paragraph (g)(4) because these procedures do not exist.

(k) Disable or Removal of the Combustion Heater

As an option to the inspection and replacement actions specified in paragraphs (g) and (h) of this AD, within the next 10 hours TIS of the combustion heater after the effective date of this AD or the next scheduled 100-hour inspection, annual inspection, or phase inspection that occurs 30 days after the effective date of this AD, whichever occurs first, do one of the following actions:

(1) *Disable the heater by the following actions:*

(i) Disconnect and cap the heater fuel supply;

(ii) Disconnect circuit breakers;

(iii) Tag the main switch ''Heater Inoperable''; and

(iv) The ventilation blower can stay functional.

(v) If you re-enable the combustion heater, you must perform one of the actions in paragraphs (f)(1) through (3) of this AD.

(2) *Remove the heater by the following actions:*

(i) Disconnect and cap the heater fuel supply;

(ii) Disconnect/remove circuit breakers;

(iii) Remove exhaust pipe extension;

(iv) Cap the exhaust opening;
(v) Remove the heater; and
(vi) Do weight and balance for the aircraft.
(vii) If you install an applicable combustion heater, you must perform one of the actions in paragraphs (f)(1) through (3) of this AD.

(l) Special Flight Permit

Special flight permits are permitted in accordance with 14 CFR 39.23 with the following limitation: Use of the heater is not allowed.

(m) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Chicago Aircraft Certification Office (ACO), FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the ACO, send it to the attention of the person identified in paragraph (o)(1) of this AD.

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(3) AMOCs approved for AD 81–09–09 (46 FR 24936, May 4, 1981) are not approved as AMOCs for this AD.

(n) Related Information

(1) For more information about this AD, contact Chung-Der Young, Aerospace Engineer, Chicago Aircraft Certification Office, FAA, Small Airplane Directorate, 2300 East Devon Avenue, Des Plaines, IL 60018–4696; telephone (847) 294–7309; fax (847) 294–7834 email: *chung-der.young@faa.gov*.

(2) For service information identified in this AD, contact Meggitt Control Systems, 3 Industrial Drive, Troy, Indiana 47588; telephone: (812) 547–7071; fax: (812) 547–2488; email: *infotroy@meggitt.com;* Internet: *www.stewart-warner.com*. You may view this referenced service information at the FAA, Small Airplane Directorate, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329–4148.

Appendix 1 to Docket No. FAA–2016–0603

The following service information applies to certain combustion heater models affected by this AD, but the service information can not be required by the AD. You may use this service information for procedural guidance when applying for an alternative method of compliance.

—South Wind Service Manual P.M. 35710 Aircraft Heaters 8240–E, 8259–HL1, HL2, -L, supplements attached HR2.JR2.M;
—South Wind Service Manual PM35710 Aircraft Heaters
—Stewart-Warner Corporation South Wind Division Service Manual South Wind Aircraft Heaters Series 921 and 930, Ind-506, Revision 4–53;
—Stewart-Warner Corporation South Wind Division Service Manual SouthWind Series 940 Heater, PM–10035, Revision 3–82;
—Stewart-Warner Corporation South Wind Division Service Manual South Wind Model 978 Personal Heater, Form No. PM6348 (12–56);
—South Wind Service Manual Model 979–B1 Aircraft Heater, South Wind Division of Stewart-Warner Corporation, (3–51);
—Navion Model 977–B Installation Manual Section I, Section II, Section III, and Section IV.

Issued in Kansas City, Missouri, on October 27, 2016.

Pat Mullen,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2016–26428 Filed 11–2–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2015–0165; Directorate Identifier 2015–NE–02–AD]

RIN 2120–AA64

Airworthiness Directives; General Electric Company Turbofan Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to supersede airworthiness directive (AD) 2015–15–03, which applies to all General Electric Company (GE) GEnx turbofan engine models. AD 2015–15–03 precludes the use of certain full authority digital engine control (FADEC) software on GEnx turbofan engines. Since we issued AD 2015–15–03, GE implemented final design changes that remove the unsafe condition. This proposed AD would require removing a specific part and replacing it with a part eligible for installation and specifying the FADEC software version for the affected GEnx turbofan engines. We are proposing this AD to prevent engine failure, loss of thrust control, and damage to the airplane.

DATES: We must receive comments on this proposed AD by January 3, 2017.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov*. Follow the instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.
- *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this NPRM, contact General Electric Company, GE Aviation, Room 285, 1 Neumann Way, Cincinnati, OH 45215; phone: 513–552–3272; email: *geae.aoc@ge.com*. You may view this service information at the FAA, Engine & Propeller Directorate, 1200 District Avenue, Burlington, MA. For information on the availability of this material at the FAA, call 781–238–7125.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2015–0165; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (phone: 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Christopher McGuire, Aerospace Engineer, Engine Certification Office, FAA, Engine & Propeller Directorate, 1200 District Avenue, Burlington, MA 01803; phone: 781–238–7120; fax: 781–238–7199; email: *chris.mcguire@faa.gov*.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2015–0165; Directorate Identifier 2015–NE–02–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this NPRM. We will consider all comments received by the closing date and may amend this NPRM because of those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this NPRM.

Discussion

On July 13, 2015, we issued AD 2015–15–03, Amendment 39–18212 (80 FR 42707, July 20, 2015), (''AD 2015–15–03''), for all GE GEnx–1B turbofan engines with FADEC software, version B175 or earlier, installed, and all GE GEnx–2B turbofan engines with FADEC software, version C065 or earlier, installed. AD 2015–15–03 precludes the use of FADEC software, version B175 or earlier, in GEnx–1B engines, and the use of FADEC software, version C065 or earlier, in GEnx–2B engines. AD 2015–15–03 resulted from engine power loss due to ice crystal icing conditions. We issued AD 2015–15–03 to prevent engine failure, loss of thrust control, and damage to the airplane.

Actions Since AD 2015–15–03 Was Issued

Since we issued AD 2015–15–03, GE implemented final design changes that remove the unsafe condition.

Related Service Information

We reviewed GE GEnx–2B Service Bulletin (SB) 72–0241 R00, dated March 16, 2016 that describes removal and installation procedures for fan hub stator assembly booster outlet guide vane (BOGV); GE GEnx–2B SB 73–0041 R00, dated July 2, 2015 that describes reprograming procedures for electronic engine control (EEC) software version C075; and GE GEnx–1B SB 73–0044 R00, dated July 1, 2015 that describes reprograming procedures for EEC software version B185.

FAA's Determination

We are proposing this AD because we evaluated all the relevant information and determined the unsafe condition described previously is likely to exist or develop in other products of the same type design.

Proposed AD Requirements

This NPRM would require removing from service the GEnx–2B fan hub stator assembly BOGV, P/N B1316–00720, and replacing with a part eligible for installation. This NPRM would also specify the FADEC software version for GEnx–1B and GEnx–2B engines.

Costs of Compliance

We estimate that this proposed AD affects 130 engines installed on airplanes of U.S. registry. We estimate that it would take about 1 hour per engine to comply with the software installation proposed by this AD. We also estimate that 32 engines would require hardware replacement, which would take about 60 hours per engine. Required parts cost about $390,000 per engine. The average labor rate is $85 per hour. Based on these figures, we estimate the cost of this proposed AD on U.S. operators to be $12,654,250.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, Section 106, describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701, ''General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We have determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that the proposed regulation:

(1) Is not a ''significant regulatory action'' under Executive Order 12866,

(2) Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979),

(3) Will not affect intrastate aviation in Alaska to the extent that it justifies making a regulatory distinction, and

(4) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by removing airworthiness directive (AD) 2015–15–03, Amendment 39–18212 (80 FR 42707, July 20, 2015), and adding the following new AD:

General Electric Company: Docket No. FAA–2015–0165; Directorate Identifier 2015–NE–02–AD.

(a) Comments Due Date

The FAA must receive comments on this AD action by January 3, 2017.

(b) Affected ADs

This AD replaces AD 2015–15–03, Amendment 39–18212 (80 FR 42707, July 20, 2015).

(c) Applicability

This AD applies to all General Electric Company (GE) GEnx–1B and GEnx–2B turbofan engines.

(d) Unsafe Condition

This AD was prompted by final design changes that remove the unsafe condition. We are issuing this AD to prevent engine failure, loss of thrust control, and damage to the airplane.

(e) Compliance

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

(1) Thirty days after the effective date of this AD, do not operate any GE GEnx–1B engine with electronic engine control (EEC) full authority digital engine control (FADEC) software, version B180 or earlier, installed.

(2) Thirty days after the effective date of this AD, do not operate any GE GEnx–2B engine with EEC FADEC software, version C068 or earlier, installed.

(3) At the next shop visit after the effective date of this AD, remove from service all GE GEnx–2B67, –2B67B, and –2B67/P fan hub stator assembly booster outlet guide vanes, part number B1316–00720, and replace with a part eligible for installation.

(f) Installation Prohibition

After removing any software, version B180 or earlier, for the GE GEnx–1B engines; or software, version C068 or earlier, for the GE GEnx–2B engines, do not operate those engines with any software, version earlier than B180 or C068.

(g) Definition

For the purpose of this AD, an ''engine shop visit'' is the induction of an engine into the shop for maintenance involving the separation of pairs of major mating engine case flanges, except for the following situations which do not constitute an engine shop visit:

(1) Separation of engine flanges solely for the purposes of transportation without

subsequent maintenance does not constitute an engine shop visit.

(2) Separation of engine flanges solely for the purpose of replacing the fan or propulsor without subsequent maintenance does not constitute an engine shop visit.

(h) Alternative Methods of Compliance (AMOCs)

The Manager, Engine Certification Office, FAA, may approve AMOCs for this AD. Use the procedures found in 14 CFR 39.19 to make your request. You may email your request to: *ANE-AD-AMOC@faa.gov.*

(i) Related Information

For more information about this AD, contact Christopher McGuire, Aerospace Engineer, Engine Certification Office, FAA, Engine & Propeller Directorate, 1200 District Avenue, Burlington, MA 01803; phone: 781–238–7120; fax: 781–238–7199; email: *chris.mcguire@faa.gov.*

Issued in Burlington, Massachusetts, on October 24, 2016.

Colleen M. D'Alessandro,

Manager, Engine & Propeller Directorate, Aircraft Certification Service.

[FR Doc. 2016–26011 Filed 11–2–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Parts 33, 40, 45, 153, 157, 340–347, 380

[Docket No. AD12–6–002]

Retrospective Analysis of Existing Rules; Notice of Staff Memorandum

Take notice that the Commission staff is issuing a memorandum setting forth certain proposed revisions to the Commission's regulations affecting interlocking directorates, seismic data requirements for liquefied natural gas facilities, and oil pipeline rates. The memorandum is being issued pursuant to the November 8, 2011 *Plan for Retrospective Analysis of Existing Rules* prepared in response to Executive Order 13579, which requested independent regulatory agencies issue plans for periodic retrospective analysis of their existing regulations.

The Staff Memorandum is being placed in the record in the above-referenced administrative docket. The Staff Memorandum will also be available on the Commission's Web site at *http://www.ferc.gov.*

Comments on the Staff Memorandum should be filed within 30 days of the issuance of this Notice. The Commission encourages electronic submission of comments in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original of the comment to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

All filings in this docket are accessible on-line at *http://www.ferc.gov*, using the ''eLibrary'' link. 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. 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.

Questions regarding this Notice should be directed to: Kenneth Yu, Office of the General Counsel, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, 202–502–8482, *Kenneth.Yu@ferc.gov.*

Dated: October 28, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–26539 Filed 11–2–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–114734–16]

RIN 1545–BN51

United States Property Held by Controlled Foreign Corporations Through Partnerships With Special Allocations

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: This document contains proposed regulations that provide rules regarding the determination of the amount of United States property treated as held by a controlled foreign corporation (CFC) through a partnership. The proposed regulations affect United States shareholders of CFCs.

DATES: Written or electronic comments and requests for a public hearing must be received by February 1, 2017.

ADDRESSES: Send submissions to: CC:PA:LPD:PR (REG–114734–16), Room 5203, Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand-delivered Monday through Friday between the hours of 8 a.m. and 4 p.m. to CC:PA:LPD:PR (REG–114734–16), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue NW., Washington, DC, or sent electronically via the Federal eRulemaking Portal at *http://www.regulations.gov* (IRS REG–114734–16).

FOR FURTHER INFORMATION CONTACT: Concerning the proposed regulations, Rose E. Jenkins, (202) 317–6934; concerning submissions of comments or requests for a public hearing, Regina Johnson, (202) 317–6901 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Background

In the Rules and Regulations section of this issue of the **Federal Register**, the Department of Treasury (Treasury Department) and the IRS are issuing final regulations that amend the Income Tax Regulations (26 CFR part 1) relating to sections 954 and 956. Under § 1.956–4(b), a CFC that is a partner in a partnership determines its share of United States property held by the partnership in accordance with the CFC's liquidation value percentage in the partnership, or, when relevant, based on a special allocation of income (or, where appropriate, gain) from the property. This document proposes to amend § 1.956–4(b) so that a CFC that is a partner in a controlled partnership determines its share of United States property held by the partnership under the liquidation value percentage method, regardless of the existence of any special allocation of income or gain from the property.

Explanation of Provisions

Section 956 determines the amount that a United States shareholder (as defined in section 951(b)) of a CFC must include in gross income with respect to the CFC under section 951(a)(1)(B). This amount is determined, in part, based on the average of the amounts of United States property held, directly or indirectly, by the CFC at the close of each quarter during its taxable year. For this purpose, in general, the amount taken into account with respect to any United States property is the adjusted basis of the property, reduced by any liability to which the property is subject. See section 956(a) and § 1.956–1(e). Section 956(e) grants the Secretary authority to prescribe such regulations as may be necessary to carry out the purposes of section 956, including regulations to prevent the avoidance of section 956 through reorganizations or otherwise.

Under § 1.956–4(b), a CFC that is a partner in a partnership generally is treated as holding its share of United States property held by the partnership

in accordance with the CFC partner's liquidation value percentage in the partnership. However, if there is a special allocation of income (or, where appropriate, gain) from United States property that does not have a principal purpose of avoiding the purposes of section 956, the partner's attributable share of that property is determined solely by reference to the special allocation. See § 1.956–4(b)(2)(ii). The Treasury Department and the IRS have concluded that, in general, these rules provide a reasonable means of determining a partner's interest in property held by a partnership for purposes of section 956 because they generally result in an allocation of specific items of property that corresponds with each partner's economic interest in that property, including any income or gain that may be subject to special allocations.

The Treasury Department and the IRS are concerned, however, that special allocations with respect to a partnership that is controlled by a single multinational group are unlikely to have economic significance for the group as a whole and can facilitate tax planning that is inconsistent with the purposes of section 956. Accordingly, these proposed regulations propose to revise § 1.956–4(b) such that a partner's attributable share of each item of property of a partnership controlled by the partner would be determined solely in accordance with the partner's liquidation value percentage, even if income or gain from the property is subject to a special allocation. Specifically, under proposed § 1.956–4(b)(2)(iii), the rule in § 1.956–4(b)(2)(ii) requiring a partner's attributable share of partnership property to be determined by reference to special allocations with respect to the property would not apply in the case of a partnership controlled by the partner. For this purpose, a partner is treated as controlling a partnership if the partner and the partnership are related within the meaning of section 267(b) or section 707(b), substituting ''at least 80 percent'' for ''more than 50 percent''. The examples in § 1.956–4(b)(3) are proposed to be modified in accordance with the proposed rule.

These proposed regulations are proposed to be effective for taxable years of CFCs ending on or after the date of publication in the **Federal Register** of the Treasury decision adopting them as final regulations, and taxable years of United States shareholders in which or with which such taxable years end, with respect to property acquired on or after the date of publication in the **Federal Register** of the Treasury decision adopting them as final regulations. The IRS may, where appropriate, challenge transactions under currently applicable Code or regulatory provisions or judicial doctrines.

Special Analyses

Certain IRS regulations, including these regulations, are exempt from the requirements of Executive Order 12866, as supplemented and reaffirmed by Executive Order 13563. Therefore, a regulatory assessment is not required. It has also 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 the 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), this notice of proposed rulemaking has been submitted to the Chief Counsel of Advocacy of the Small Business Administration for comment on its impact on small business.

Comments and Requests for Public Hearing

Before these proposed regulations are adopted as final regulations, consideration will be given to any comments that are submitted timely to the IRS as prescribed in this preamble under the ''Addresses'' heading. The Treasury Department and the IRS request comments on all aspects of the proposed rules. All comments will be available at *www.regulations.gov* or upon request. A public hearing will be scheduled if requested in writing by any person that timely submits electronic or written comments. If a public hearing is scheduled, notice of the date, time, and place for the public hearing will be published in the **Federal Register**.

Drafting Information

The principal author of these proposed regulations is Rose E. Jenkins of the Office of Associate Chief Counsel (International). However, other personnel from the Treasury Department and the IRS participated in their development.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Proposed Amendments to the Regulations

Accordingly, 26 CFR part 1 is proposed to be 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 * * *

Section 1.956–4 also issued under 26 U.S.C. 956(d) and 956(e).

Par. 2. Section 1.956–4 is amended by:

■ 1. Revising paragraph (b)(2)(ii).
■ 2. Adding paragraph (b)(2)(iii).
■ 3. Adding a sentence at the end of paragraph (i) of *Example 2* of paragraph (b)(3).
■ 4. Revising paragraph (ii) of *Example 2* of paragraph (b)(3).
■ 5. Revising *Example 3* of paragraph (b)(3).
■ 6. Adding *Example 4* to paragraph (b)(3).
■ 7. Revising paragraph (f)(1).

The revisions and additions read as follows:

§ 1.956–4 Certain rules applicable to partnerships.

* * * * *

(b) * * *

(2) * * *

(ii) *Special allocations.* Except as otherwise provided in paragraph (b)(2)(iii) of this section, for purposes of paragraph (b)(1) of this section, if a partnership agreement provides for the allocation of book income (or, where appropriate, book gain) from a subset of the property of the partnership to a partner other than in accordance with the partner's liquidation value percentage in a particular taxable year (a *special allocation*), then the partner's attributable share of that property is determined solely by reference to the partner's special allocation with respect to the property, provided the special allocation does not have a principal purpose of avoiding the purposes of section 956.

(iii) *Limitation on special allocations in the case of a controlled partnership.* Paragraph (b)(2)(ii) of this section does not apply to determine a partner's attributable share of partnership property in the case of a partnership controlled by the partner. For purposes of this paragraph (b)(2)(iii), a partner controls a partnership when the partner and the partnership are related within the meaning of section 267(b) or section 707(b), determined by substituting ''at least 80 percent'' for ''more than 50 percent'' wherever it appears.

(3) * * *

Example 2. (i) *Facts.* * * * FS does not control FPRS within the meaning of paragraph (b)(2)(iii) of this section.

(ii) *Result.* Under paragraph (b)(1) of this section, for purposes of section 956, FS is treated as holding its attributable share of the property held by FPRS with an adjusted basis equal to its attributable share of FPRS's adjusted basis in such property. In general, FS's attributable share of property held by

FPRS is determined in accordance with FS's liquidation value percentage. However, because FS does not control FPRS within the meaning of paragraph (b)(2)(iii) of this section and because the special allocation does not have a principal purpose of avoiding the purposes of section 956, under paragraph (b)(2)(ii) of this section, FS's attributable share of the FPRS property is determined by reference to its special allocation. FS's special allocation percentage for the FPRS property is 80%, and thus FS's attributable share of the FPRS property is 80% and its attributable share of FPRS's basis in the FPRS property is $80x. Accordingly, for purposes of determining the amount of United States property held by FS as of the close of quarter 1 of year 1, FS is treated as holding United States property with an adjusted basis of $80x.

Example 3. (i) *Facts.* USP, a domestic corporation, wholly owns FS, a controlled foreign corporation, which, in turn, owns a 25% capital and profits interest in FPRS, a foreign partnership. The remaining 75% capital and profits interest in FPRS is owned by an unrelated foreign person. Thus, FS does not control FPRS within the meaning of paragraph (b)(2)(iii) of this section. FPRS holds property (the ''FPRS property'') that would be United States property if held by FS directly. The FPRS property has an adjusted basis of $100x and is anticipated to appreciate in value but generate relatively little income. The FPRS partnership agreement, which satisfies the requirements of section 704(b), specially allocates 80% of the income with respect to the FPRS property to the unrelated foreign person and 80% of the gain with respect to the disposition of FPRS property to FS. The special allocation does not have a principal purpose of avoiding the purposes of section 956.

(ii) *Result.* Because FPRS is not controlled by FS within the meaning of paragraph (b)(2)(iii) of this section, and the special allocation does not have a principal purpose of avoiding the purposes of section 956, under paragraph (b)(2)(ii) of this section, FS's attributable share of the FPRS property is determined by reference to a special allocation with respect to the FPRS property. Given the income and gain anticipated with respect to the FPRS property, it is appropriate to determine FS's attributable share of the property in accordance with the special allocation of gain. Accordingly, for purposes of determining the amount of United States property held by FS in each year that FPRS holds the FPRS property, FS's attributable share of the FPRS property is 80% and its attributable share of FPRS's basis in the FPRS property is $80x. Thus, FS is treated as holding United States property with an adjusted basis of $80x.

Example 4. (i) *Facts.* The facts are the same as in *Example 3* of this paragraph (b)(3), except that USP owns the 75% capital and profits interest in FPRS rather than an unrelated foreign person. Thus, FS controls FPRS within the meaning of paragraph (b)(2)(iii) of this section. At the close of quarter 1 of year 1, the liquidation value percentage, as determined under paragraph (b)(2) of this section, for FS with respect to FPRS is 25%.

(ii) *Result.* Because FPRS is controlled by FS within the meaning of paragraph (b)(2)(iii) of this section, under paragraph (b)(2)(iii) of this section, FS's attributable share of the FPRS property is not determined by reference to the special allocation of gain with respect to the FPRS property. Accordingly, for purposes of determining the amount of United States property held by FS in each year that FPRS holds the FPRS property, FS's attributable share of the FPRS property is determined under paragraph (b)(2)(i) in accordance with FS's liquidation value percentage, which is 25%, and its attributable share of FPRS's basis in the FPRS property is $25x. Thus, FS is treated as holding United States property with an adjusted basis of $25x.

* * * * *

(f) * * *

(1) Except as otherwise provided in this paragraph (f)(1), paragraph (b) of this section applies to taxable years of controlled foreign corporations ending on or after November 3, 2016, and taxable years of United States shareholders in which or with which such taxable years end, with respect to property acquired on or after November 3, 2016. Paragraphs (b)(2)(ii) and (iii) of this section, as well as *Example 2*, *Example 3*, and *Example 4* of paragraph (b)(3) of this section, apply to taxable years of controlled foreign corporations ending on or after the date of publication in the **Federal Register** of the Treasury decision adopting this rule as a final regulation, and taxable years of United States shareholders in which or with which such taxable years end, with respect to property acquired on or after the date of publication in the **Federal Register** of the Treasury decision adopting this rule as a final regulation. For purposes of this paragraph (f)(1), a deemed exchange of property pursuant to section 1001 on or after November 3, 2016 constitutes an acquisition of the property on or after that date, and a deemed exchange of property pursuant to section 1001 on or after the date of publication in the **Federal Register** of the Treasury decision adopting this rule as a final regulation constitutes an acquisition of the property on or after that date.

See § 1.956–2(a)(3), as contained in 26 CFR part 1 revised as of April 1, 2016, for the rules applicable to taxable years of a controlled foreign corporation beginning on or after July 23, 2002, and ending before November 3, 2016, and with respect to property acquired before November 3, 2016, to taxable years of a controlled foreign corporation beginning on or after July 23, 2002.

John Dalrymple,

Deputy Commissioner for Services and Enforcement.

[FR Doc. 2016–26424 Filed 11–2–16; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–122387–16]

RIN 1545–BL86

Treatment of Related Person Factoring Income; Certain Investments in United States Property; and Stock Redemptions Through Related Corporations

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Partial withdrawal of notice of proposed rulemaking.

SUMMARY: This document withdraws portions of a notice of proposed rulemaking (INTL–49–86, subsequently converted to REG–209001–86) published in the **Federal Register** (53 FR 22186) on June 14, 1988, (the 1988 NPRM). The withdrawn portions relate to stock redemptions through related corporations, the application of section 956 to United States property indirectly held by a controlled foreign corporation (CFC), and certain related party factoring transactions, as well as the definition of the term ''obligation'' for purposes of section 956.

DATES: Sections 1.304–4, 1.956–1(b)(4), 1.956–2(d)(2), and 1.956–3(b)(2)(ii) of proposed rules published in the **Federal Register** on June 14, 1988, are withdrawn as of November 3, 2016.

FOR FURTHER INFORMATION CONTACT: Rose E. Jenkins, (202) 317–6934 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

On June 14, 1988, the Department of Treasury (Treasury Department) and the IRS published in the **Federal Register** proposed regulations (INTL–49–86, subsequently converted to REG–209001–86, 53 FR 22186), including: (i) Proposed 1.304–4, which provides a special rule regarding the use of a related corporation to acquire for property the stock of another commonly owned corporation; (ii) proposed § 1.956–1(b)(4), which describes United States property indirectly held by a CFC

for purposes of section 956; (iii) proposed § 1.956–2(d)(2), which sets forth the definition of ''obligation'' for purposes of section 956; and (iv) proposed § 1.956–3, which provides guidance on the treatment of certain trade or service receivables received in factoring transactions as United States property for purposes of section 956, including rules in proposed § 1.956–3(b)(2)(ii) that address the acquisition of a trade or service receivable by a nominee or pass-through entity. The regulations were proposed by cross-reference to temporary regulations in §§ 1.304–4T, 1.956–1T(b)(4), 1.956–2T(d), and 1.956–3T that were published in the same issue of the **Federal Register** (TD 8209, 53 FR 22163). This document withdraws certain of these proposed regulations because the rules in the proposed regulations are supplanted by final regulations or other proposed regulations.

Specifically, in the Rules and Regulations section of this issue of the **Federal Register**, the Treasury Department and the IRS are issuing final regulations that contain rules in § 1.956–1(b) concerning United States property indirectly held by a CFC for purposes of section 956, and rules in § 1.956–3(b)(2)(ii) concerning the acquisition by a nominee, pass-through entity, or related foreign corporation for purposes of the section 956 rules governing factoring transactions. The final regulations in §§ 1.956–1(b) and 1.956–3(b)(2)(ii) were included in a notice of proposed rulemaking (REG–155164–09) published in the **Federal Register** on September 2, 2015 (80 FR 53058, as corrected at 80 FR 66485). Thus, the rules in proposed §§ 1.956–1(b)(4) and 1.956–3(b)(2)(ii) provided in the 1988 NPRM are withdrawn. As described in the preamble to the final regulations published in the Rules and Regulations section of this issue of the **Federal Register**, the remainder of the rules in § 1.956–3 proposed in the 1988 NPRM also are included in the final regulations, with minor modifications.

Additionally, on December 30, 2009, the Treasury Department and the IRS published in the **Federal Register** proposed regulations (74 FR 69043), which contain in proposed § 1.304–4 special rules regarding the use of related corporations to avoid the application of section 304 that supplant the rules set forth in the 1988 NPRM. On December 26, 2012, final regulations including § 1.304–4 as proposed in 2009 were published in the **Federal Register** (TD 9606, 77 FR 75844). Accordingly, the rule in the 1988 NPRM that addresses section 304 is withdrawn.

Furthermore, on April 8, 2016, the Treasury Department and the IRS published in the **Federal Register** proposed regulations (81 FR 20588), which contain in proposed § 1.956–2(d) a definition of obligation for purposes of section 956, as well as several exceptions from the definition, including those set forth in the 1988 NPRM. Accordingly, the rule in the 1988 NPRM that addresses the definition of obligation is withdrawn.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Partial Withdrawal of a Notice of Proposed Rulemaking

Accordingly, under the authority of 26 U.S.C. 7805, §§ 1.304–4, 1.956–1(b)(4), 1.956–2(d)(2), and 1.956–3(b)(2)(ii) of the notice of proposed rulemaking (INTL–49–86) published in the **Federal Register** on June 14, 1988, (53 FR 22186) are withdrawn.

John M. Dalrymple,

Deputy Commissioner for Services and Enforcement.

[FR Doc. 2016–26423 Filed 11–2–16; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2016–0799]

RIN 1625–AA87

Safety and Security Zones; New York Marine Inspection and Captain of the Port Zone

AGENCY: Coast Guard, DHS.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: The Coast Guard is requesting public comments from any and all waterway users regarding the permanent security zone that encompasses all waters within 150 yards of the bridge connecting Liberty State Park and Ellis Island. The Coast Guard is considering restoring navigational access to the waterway between Ellis Island and Liberty State Park by modifying the security zone around the Ellis Island Bridge. The purpose removal of the security zone would be to increase navigational safety in New York Harbor by allowing vessels to transit under the Ellis Island Bridge, rather than being required to transit the Anchorage Channel.

DATES: Comments and related material must be received by the Coast Guard on or before January 3, 2017.

ADDRESSES: You may submit comments identified by docket number USCG–2016–0799 using the Federal eRulemaking Portal at *http://www.regulations.gov*. See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email MST1 Kristina Pundt, Waterways Management, U.S. Coast Guard; telephone (718) 354–4352, email *Kristina.H.Pundt@uscg.mil*.

SUPPLEMENTARY INFORMATION:

Table of Acronyms

ANPRM Advance notice of proposed rulemaking
NPRM Notice of proposed rulemaking
DHS Department of Homeland Security
FR Federal Register
MARSEC Maritime Security
NYCWTA New York City Water Trail Association

A. Public Participation and Request for Comments

We view public participation as essential to effective rulemaking, and will consider all comments and material received during the comment period. Your comment can help shape the outcome of this possible rulemaking. If you submit a comment, please include the docket number for this rulemaking, indicate the specific section of this document to which each comment applies, indicate the specific question number to which each comment applies, and provide a reason for each suggestion or recommendation.

We encourage you to submit comments through the Federal eRulemaking Portal at *http://www.regulations.gov*. If your material cannot be submitted using *http://www.regulations.gov,* contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions.

We accept anonymous comments. All comments received will be posted without change to *http://www.regulations.gov* and will include any personal information you have provided. For more about privacy and the docket, you may review a Privacy Act notice regarding the Federal Docket Management System in the March 24, 2005, issue of the **Federal Register** (70 FR 15086).

Documents mentioned in this ANPRM as being available in the docket, and all

public comments, will be in our online docket at *http://www.regulations.gov* and can be viewed by following that Web site's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted and if we publish rulemaking documents related to this ANPRM.

B. Regulatory History and Information

On November 27, 2002, the Coast Guard published a notice of proposed rulemaking (NPRM) entitled, ''Safety and Security Zones; New York Marine Inspection and Captain of the Port Zone'' in the **Federal Register** (67 FR 70892). The NPRM proposed to establish a permanent safety and security zone encompassing all waters within 150 yards of Liberty Island, Ellis Island, and the bridge between Liberty State Park and Ellis Island. We received no comments on the proposed rule. No public hearing was requested and none was held. The current 150-yard permanent security zone around the Ellis Island Bridge became effective on January 1, 2003 as enacted by a final rule entitled, ''Safety and Security Zones; New York Marine Inspection Zone and Captain of the Port Zone'' published in the **Federal Register** (68 FR 2886, January 22, 2003). On May 6, 2008 the Coast Guard published a notice of proposed rulemaking (NPRM) entitled, ''Safety and Security Zones; New York Marine Inspection Zone and Captain of the Port'' in the **Federal Register** (73 FR 24889). The NPRM proposed to modify several aspects of the permanent safety and security zone regulations within the New York Captain of the Port Zone. We received 15 comments regarding the proposed rule. A public meeting was requested to discuss the proposed expansion of the Liberty and Ellis Island security zones to include all waters within 400 yards of these two islands instead of the existing security zone within a 150 yard radius of Liberty and Ellis Islands. Based on the comments received, the Coast Guard withdrew the proposed change to the Liberty and Ellis Island security zones and therefore a public meeting was no longer needed.

C. Basis and Purpose

The legal basis and authority for this ANPRM is 33 U.S.C. 1231; 50 U.S.C. 191; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; and Department of Homeland Security Delegation No. 0170.1.

On April 18, 2016, the Coast Guard received a request from the New York City Water Trail Association (NYCWTA) to consider restoring navigational access to the waterway between Ellis Island and Liberty State Park by removing the security zone around the Ellis Island Bridge. The purpose of this ANPRM is to solicit comments on potential proposed rulemakings to modify the existing security zone around the Ellis Island Bridge.

D. Discussion of Possible Proposed Rule

The existing security zone surrounding the Ellis Island Bridge prohibits all vessels from transiting underneath the Ellis Island Bridge and the protected waters between Ellis Island and Liberty State Park. All vessels must transit in the Anchorage Channel to the east of Ellis Island, where larger commercial vessel traffic is prevalent. Small passenger vessels that transit to Ellis Island also use this channel. Due to congestion of the waterway as a result of this traffic, the Coast Guard is considering a modification of the existing Ellis Island Bridge security zone. Modifying or eliminating this zone would provide smaller vessels the opportunity to transit underneath the bridge instead of within the Anchorage Channel, therefore, decreasing channel congestion and increasing navigational safety in the harbor. The existing 25 yard security zone surrounding any bridge pier or abutment would still apply to this bridge as per 33 CFR 165.169(a)(5).

E. Information Requested

Public participation is requested to assist in determining the best way forward with respect to modifying the existing security zone surrounding the Ellis Island Bridge. To aid us in developing a possible proposed rule, we seek any comments, whether positive or negative, including but not limited to, the impacts that the existing security zone surrounding the Ellis Island Bridge has on navigational safety.

We are also seeking comments on the current vessel traffic and the types of vessels that transit in this area. To aid us in developing a proposed rule, we seek your responses to the following questions.

1. Should the existing security zone surrounding the bridge only be enforced between sunset and sunrise or during daylight hours as well? Why?

2. Should there be any security zone or vessel operating restrictions enforced surrounding the Ellis Island Bridge?

3. Should the Ellis Island Bridge only have a designated 25-yard security zone surrounding its piers as currently applies to all other bridges south of the Troy Lock on the Hudson River (33 CFR 165.169(a)(5))?

4. What types and sizes of vessels should be allowed to transit under the Ellis Island bridge?

5. Are there tide, weather, or other variables that preclude vessels from transiting under the bridge?

6. What are the pros of modifying the security zone?

7. What are the cons of modifying the security zone?

8. What are the risks to the bridge of resuming vessel traffic underneath?

9. What are the risks to commercial and recreational vessel traffic by requiring small recreational motor, and human powered, vessels to continue transiting through the Anchorage Channel near Ellis Island?

10. Should the U.S. Park Service screen vessels that transit underneath the bridge?

11. Are there other bridges in the COTP Area that should not be available for recreational vessels to transit underneath?

12. Should alternative security measures be established for access control to the Ellis Island Bridge, as per 33 CFR 105.255?

13. Should alternative security measures be established for restricted areas, such as the Ellis Island Bridge, as per 33 CFR 105.260?

14. Should additional security measures be established for monitoring the Ellis Island Bridge as per 33 CFR 105.275?

15. Should there be different levels of vessel transit restrictions underneath the bridge based on the current MARSEC Level? MARSEC Level means the level set to reflect the prevailing threat environment to the marine elements of the national transportation system, including ports, vessels, facilities, and critical assets and infrastructure located on or adjacent to waters subject to the jurisdiction of the U.S. (33 CFR 101.105 and 33 CFR 105.230).

16. What restrictions would you recommend be established for vessel transits underneath the bridge during MARSEC Level 1, 2, or 3?

Please submit comments or concerns you may have in accordance with the ''Public Participation and Request for Comments'' section above.

Dated: October 17, 2016.

M.H. Day,

Captain, U.S. Coast Guard, Captain of the Port New York.

[FR Doc. 2016–26599 Filed 11–2–16; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2016–0215; FRL–9954–91–Region 9]

Partial Approval and Partial Disapproval of California Air Plan Revisions; South Coast Air Quality Management District

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing a partial approval and partial disapproval of a revision to the South Coast Air Quality Management District (SCAQMD or District) portion of the California State Implementation Plan (SIP). This revision concerns the District's demonstration regarding Reasonably Available Control Technology (RACT) requirements for the 2008 8-hour ozone National Ambient Air Quality Standard (NAAQS) in the South Coast Air Basin and Coachella Valley ozone nonattainment areas. We are proposing action on a local SIP revision under the Clean Air Act (CAA or the Act). We are taking comments on this proposal and plan to follow with a final action.

DATES: Any comments must arrive by December 5, 2016.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R09–OAR–2016–0215 at *http://www.regulations.gov,* or via email to *Steckel.Andrew@epa.gov*. For comments submitted at *Regulations.gov*, follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. For either manner of submission, the EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.* on the Web, cloud, or other file sharing system). For additional submission methods, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets*.

FOR FURTHER INFORMATION CONTACT: Stanley Tong, EPA Region IX, (415) 947–4122, *tong.stanley@epa.gov*.

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

Table of Contents

I. The State's Submittal

A. What document did the State submit?

Table 1 lists the document addressed by this proposal with the date that it was adopted by the local air agency and submitted by the California Air Resources Board (CARB).

TABLE 1—SUBMITTED DOCUMENT

Local agency	Document	Adopted	Submitted
SCAQMD	SCAQMD 2016 Air Quality Management Plan (AQMP) Reasonably Available Control Technology (RACT) Demonstration ''2016 AQMP RACT SIP''.	06/06/14	07/18/14

On January 18, 2015, the submittal for the SCAQMD 2016 AQMP RACT SIP was deemed by operation of law to meet the completeness criteria in 40 CFR part 51 Appendix V, which must be met before formal EPA review.

B. Are there other versions of this document?

There is no previous version of this document in the SCAQMD portion of the California SIP for the 2008 8-hour ozone standard.

C. What is the purpose of the RACT SIP submission?

Volatile Organic Compounds (VOCs) and nitrogen oxides (NO_X) help produce ground-level ozone, smog and particulate matter (PM), which harm human health and the environment. Section 110(a) of the CAA requires states to submit regulations that control VOC and NO_X emissions. Sections 182(b)(2) and (f) require that SIPs for ozone nonattainment areas classified as moderate or above implement RACT for any source covered by a Control Techniques Guidelines (CTG) document and for any major source of VOCs or NO_X.

The SCAQMD is subject to the RACT requirement as it is authorized under state law to regulate stationary sources in the South Coast Air Basin (''South Coast''), which is classified as an extreme nonattainment area, and in the Coachella Valley portion of Riverside County (''Coachella Valley''), which is classified as a severe-15 nonattainment area for the 2008 8-hour ozone NAAQS (40 CFR 81.305); 77 FR 30088 at 30101 and 30103 (May 21, 2012). Therefore, the SCAQMD must, at a minimum, adopt RACT-level controls for all sources covered by a CTG document and for all major non-CTG sources of VOCs or NO_X within the two nonattainment areas. Any stationary source that emits or has the potential to emit at least 10 tons per year of VOCs or NO_X is a major stationary source in an extreme ozone nonattainment area (CAA section 182(e) and (f)), and any stationary source that emits or has the potential to emit at least 25 tons per year of VOCs or NO_X is a major stationary source in a severe ozone nonattainment area (CAA section 182(d) and (f)).

Section III.D of the preamble to the EPA's final rule to implement the 2008 ozone NAAQS (80 FR 12264, March 6, 2015) discusses RACT requirements. It states in part that RACT SIPs must contain adopted RACT regulations, certifications where appropriate that existing provisions are RACT, and/or negative declarations that there are no sources in the nonattainment area covered by a specific CTG source category and that states must submit appropriate supporting information for

their RACT submissions as described in the EPA's implementation rule for the 1997 ozone NAAQS. *See id.,* at 12278; 70 FR 71612, at 71652 (November 29, 2005). The submitted document provides SCAQMD's analyses of its compliance with the CAA section 182 RACT requirements for the 2008 8-hour ozone NAAQS. The EPA's technical support document (TSD) has more information about the District's submission and the EPA's evaluation thereof.

II. The EPA's Evaluation and Proposed Action

A. How is the EPA evaluating the RACT SIP submission?

SIP rules must be enforceable (see CAA section 110(a)(2)), must not interfere with applicable requirements concerning attainment and reasonable further progress or other CAA requirements (see CAA section 110(l)), and must not modify certain SIP control requirements in nonattainment areas without ensuring equivalent or greater emissions reductions (see CAA section 193). Generally, SIP rules must require RACT for each category of sources covered by a CTG document as well as each major source of VOCs or NO_X in ozone nonattainment areas classified as moderate or above (see CAA section 182(b)(2)). The SCAQMD regulates an extreme ozone nonattainment area (*i.e.,* the South Coast Air Basin) and a severe ozone nonattainment area (*i.e.,* Coachella Valley) (see 40 CFR 81.305), so the District's rules must implement RACT.

Guidance and policy documents that we use to evaluate enforceability, revision/relaxation and rule stringency requirements for the applicable criteria pollutants include the following:

1. ''Final Rule to Implement the 8-hour Ozone National Ambient Air Quality Standard—Phase 2'' (70 FR 71612; November 29, 2005).
2. ''State Implementation Plans; General Preamble for the Implementation of Title I of the Clean Air Act Amendments of 1990,'' 57 FR 13498 (April 16, 1992); 57 FR 18070 (April 28, 1992).
3. ''Issues Relating to VOC Regulation Cutpoints, Deficiencies, and Deviations,'' EPA, May 25, 1988 (the Bluebook, revised January 11, 1990).
4. ''Guidance Document for Correcting Common VOC & Other Rule Deficiencies,'' EPA Region 9, August 21, 2001 (the Little Bluebook).
5. ''State Implementation Plans; Nitrogen Oxides Supplement to the General Preamble; Clean Air Act Amendments of 1990 Implementation of Title I; Proposed Rule,'' (the NO_X Supplement), 57 FR 55620, November 25, 1992.
6. Memorandum from William T. Harnett to Regional Air Division Directors, (May 18, 2006), ''RACT Qs & As—Reasonably Available Control Technology (RACT) Questions and Answers''.
7. RACT SIPs, Letter dated March 9, 2006 from EPA Region IX (Andrew Steckel) to CARB (Kurt Karperos) describing Region IX's understanding of what constitutes a minimally acceptable RACT SIP.
8. RACT SIPs, Letter dated April 4, 2006 from EPA Region IX (Andrew Steckel) to CARB (Kurt Karperos) listing EPA's current CTGs, ACTs, and other documents which may help to establish RACT.
9. ''Implementation of the 2008 National Ambient Air Quality Standards for Ozone: State Implementation Plan Requirements'' (80 FR 12264; March 6, 2015).

B. Does the RACT SIP submission meet the evaluation criteria?

The 2016 AQMP RACT SIP (submitted July 18, 2014) builds on the District's previous RACT SIP demonstrations: The 2006 RACT SIP (73 FR 76947, December 18, 2008), the 2007 AQMP (77 FR 12674, March 1, 2012) and the 2012 AQMP (79 FR 52526, September 3, 2014). The 2016 AQMP RACT SIP concludes, after a review and evaluation of more than 30 rules recently developed by other ozone nonattainment air districts, that SCAQMD's current rules meet the EPA's criteria for RACT acceptability and inclusion in the SIP for the 2008 8-hour ozone NAAQS. A RACT SIP should consider requirements that apply to CTG source categories and all major stationary sources of VOC or NO_X emissions.

With regard to CTG and non-CTG source categories, based on its research of the District's permit databases and telephone directories for sources in the District for the 2007 AQMP, the 2012 AQMP, and the 2016 AQMP RACT SIP, the SCAQMD concluded that all identified sources have applicable RACT rules. As such, we characterize the 2016 AQMP RACT SIP as a certification-type of RACT SIP submittal. Because the District's VOC and NO_X rules apply equally in both the South Coast and Coachella Valley, the District's certification in this regard extends to both ozone nonattainment areas.

Where there are no existing sources covered by a particular CTG document, states may, in lieu of adopting RACT requirements for those sources, adopt negative declarations certifying that there are no such sources in the relevant nonattainment area. The 2007 AQMP indicates there are existing sources for each CTG document issued before 2006, and the 2012 AQMP indicates there are existing sources for each CTG document issued from 2006 to 2008. The EPA has not issued any CTGs since 2008. The SCAQMD did not report any negative declarations in the 2016 AQMP RACT SIP as well.

However, subsequent to its 2016 AQMP RACT SIP submittal, the EPA had several discussions with the SCAQMD and concluded there may be two CTG categories where the District has no sources applicable to the CTGs. For the Paper, Film and Foil coatings CTG, it appears from a review of: The standard industrial codes (SIC) applicable to the CTG, the CARB's emissions inventory, and discussion with the SCAQMD permit engineer, that the SCAQMD has no paper coating sources with coating lines exceeding the CTG's applicability threshold (EPA 453/R–07–003). For the Surface Coating Operations at Shipbuilding and Repair Facilities CTG (61 FR–44050, August 27, 1996 and EPA–453/R–94–032), the SCAQMD indicates it only has one active title V shipyard facility that is subject to Rule 1106, Marine Coating Operations. The one coating category in Rule 1106 that exceeds the CTG's VOC content limit is inorganic zinc and the District indicates inorganic zinc coating is not used at the facility. Consequently, the EPA recommends that the SCAQMD evaluate, and adopt where appropriate, negative declarations for these two CTG categories. The EPA concurs that there are no other negative declarations.

Based on our review and evaluation of the documentation provided by the SCAQMD in the 2016 AQMP RACT SIP and earlier plans, we agree that existing District rules approved in the SIP meet or are more stringent than the corresponding CTG limits and exemption thresholds for each category of VOC sources covered by a CTG document, and given that the CTG documents represent presumptive RACT level of control, we conclude that existing District rules require the implementation of RACT for each category of VOC sources covered by a CTG document located in the South Coast and Coachella Valley.

With respect to major stationary sources of VOC or NO_X emissions, the District provided supplemental information identifying 21 new major title V sources since its 2006 RACT SIP certification and provided a list of equipment at these facilities that emit greater than 5 tpy. The District concluded that the equipment were covered by rules that implement RACT. The District's efforts to identify all new major sources appears to be thorough, and we agree that existing District rules approved in the SIP require implementation of RACT for all major non-CTG VOC sources in the South

Coast and Coachella Valley. We disagree that all major NO_X sources in the South Coast are subject to SIP-approved RACT rules or RACT-equivalent programs as explained in the following section.

C. What are the RACT deficiencies?

Within the South Coast, major NO_X sources are included in SCAQMD's Regulation XX (''Regional Clean Air Incentives Market (RECLAIM)'') program. The District adopted the RECLAIM program in 1993 to reduce emissions from the largest stationary sources of NO_X and oxides of sulfur (SO_X) emissions through a market-based trading program that establishes annual declining NO_X and SO_X allocations (also called ''facility caps'') and allows covered facilities to comply with their facility caps by installing pollution control equipment, changing operations, or purchasing RECLAIM trading credits (RTCs) from the RECLAIM market. Section 40440 of the California Health and Safety Code (CH&SC) requires the District to monitor advances in best available retrofit control technology (BARCT) and periodically to reassess the overall facility caps to ensure that the facility caps are equivalent, in the aggregate, to BARCT emission levels imposed on affected sources.[1] Facilities subject to RECLAIM are exempted from a number of District prohibitory rules that otherwise apply to sources of NO_X and SO_X emissions in the South Coast.[2] With certain exceptions, facilities located in Coachella Valley are not included in the RECLAIM program.

Under longstanding EPA interpretation of the CAA, a market-based cap and trade program may satisfy RACT requirements by ensuring that the level of emission reductions resulting from implementation of the program will be equal, in the aggregate, to those reductions expected from the direct application of RACT on all affected sources within the nonattainment area.[3] The EPA approved the RECLAIM program into the California SIP in June 1998 based in part on a conclusion that the NO_X emission caps in the program satisfied the RACT requirements of CAA section 182(b)(2) and (f) for covered NO_X emission sources in the aggregate.[4] In 2005 and 2010, the District adopted revisions to the NO_X RECLAIM program, which the EPA approved in 2006 and 2011, respectively, based in part on conclusions that the revisions continued to satisfy NO_X RACT requirements.[5] We refer to the current NO_X RECLAIM program as approved into the SIP as the ''2010 RECLAIM program.''

The 2016 AQMP RACT SIP relies on the 2010 RECLAIM program to satisfy the RACT requirements for major NO_X sources in the South Coast and Coachella Valley. However, based on new information contained in SCAQMD's December 2015 Draft Final Staff Report (''2015 staff report'') revising Regulation XX, we find that additional NO_X reductions are now required to achieve RACT as evidenced by the lack of controls on some refinery boiler units and the District's proposal to reduce the NO_X RECLAIM emissions cap.[6] A more detailed discussion about RECLAIM and the requirement that the program ensures, in the aggregate, NO_X emissions reductions equivalent to RACT-level controls can be found in our partial approval/disapproval of the South Coast Moderate Area Plan for the 2006 $PM_{2.5}$ NAAQS.[7]

Thus, based on our evaluation discussed above, we propose to partially approve and partially disapprove the 2016 AQMP RACT SIP certification because, while we find that existing SIP-approved District rules implement RACT for all sources covered by a CTG document and for all major non-CTG VOC sources in both the South Coast and Coachella Valley, we also find that the 2010 RECLAIM program does not achieve NO_X emission reductions equal, in the aggregate, to those reductions expected from the direct application of RACT on all major NO_X sources in the South Coast.[8]

We note that, on December 4, 2015, the SCAQMD adopted a new NO_X emissions cap that reflects a level of 2 ppmv NO_X for refinery boilers/heaters >40 MMBtu/hr indicating that controls ''are either commercially available, achieved-in-practice and/or can be designed to achieve 2 ppmv NO_X in a cost-effective manner.''[9] However, the amended RECLAIM program has not been submitted to the EPA as a SIP revision and such a submittal would need to include a demonstration of how the RECLAIM program, as amended, provides for NO_X emission reductions equal, in the aggregate, to those reductions expected from the direct application of RACT on all major NO_X sources in the South Coast.

D. The EPA's Recommendations To Further Improve the RACT SIP

Our TSD for the 2016 AQMP RACT SIP provides additional recommendations for future rule improvements.

E. Proposed Action and Public Comment

For the reasons discussed above and explained more fully in our TSD, the EPA proposes to partially approve and partially disapprove the CARB's July 18, 2014 submittal of the SCAQMD 2016 AQMP RACT SIP as a revision to the California SIP. Under CAA section 110(k)(3), we propose to approve the 2016 AQMP RACT SIP, with the exception of major NO_X sources in the South Coast, as satisfying the RACT requirements of CAA section 182(b)(2) and (f) for the South Coast and the Coachella Valley ozone nonattainment areas.

Also under CAA section 110(k)(3), we propose to disapprove the 2016 AQMP RACT SIP as it pertains to major NO_X sources in the South Coast based on the EPA's finding that the 2010 RECLAIM program no longer ensures NO_X reductions equivalent to RACT-level controls at each individual major NO_X source in the South Coast.

If finalized, the partial disapproval would trigger the 2-year clock for the federal implementation plan (FIP) requirement under section 110(c). In addition, final disapproval would trigger sanctions under CAA section 179 and 40 CFR 52.31 unless the EPA approves a subsequent SIP revision that corrects the RACT SIP deficiency within

[1] BARCT is defined as ''an emission limitation that is based on the maximum degree of reduction achievable taking into account environmental, energy, and economic impacts by each class or category of source.'' CH&SC section 40406. For the purposes of comparison, the EPA defines RACT as the lowest emission limitation that a particular source is capable of meeting by the application of control technology that is reasonably available considering technological and economic feasibility. 44 FR 53762 (September 17, 1979). As such, we generally find that BARCT level of control meets or exceeds RACT level of control.

[2] District Rule 2001 (''Applicability''), as amended May 6, 2005. Facilities in Coachella Valley are prohibited from entering the RECLAIM program except as allowed under Rule 2001(i)(1)(I).

[3] 59 FR 16690 (April 7, 1994) and EPA, ''Improving Air Quality with Economic Incentive Programs,'' EPA–452/R–01–001 (January 2001), at Section 16.7.

[4] 61 FR 57834 (November 8, 1996) and 63 FR 32621 (June 15, 1998).

[5] 71 FR 51120 (August 29, 2006) and 76 FR 50128 (August 12, 2011).

[6] Draft Final Staff Report, Proposed Amendments to Regulation XX Regional Clean Air Initiatives Market (RECLAIM) NO_X RECLAIM, December 4, 2015 *http://www.aqmd.gov/docs/default-source/Agendas/Governing-Board/2015/2015-dec4-030.pdf?sfvrsn=9.*

[7] 81 FR 22025, 22027 and 22028 (April 14, 2016) discussing an absence of a demonstration that the 2010 RECLAIM program ensures, in the aggregate, NO_X emission reductions equivalent to RACT-level controls.

[8] This finding does not apply to Coachella Valley because we have determined that the two RECLAIM facilities located in Coachella Valley are equipped with control technology that meets or exceeds RACT level of control.

[9] Draft Final Staff Report, Proposed Amendments to Regulation XX Regional Clean Air Initiatives Market (RECLAIM) NO_X RECLAIM, December 4, 2015, (page 92).

18 months of the effective date of the final action. We note that our partial disapproval of the District's Moderate Area Plan for the 2006 $PM_{2.5}$ NAAQS, 81 FR 22025 (April 14, 2016), has already started CAA sanction and FIP clocks for a NO_X RACT deficiency. Termination of those existing clocks by EPA approval of a SIP revision submittal addressing the NO_X RACT deficiency in the Moderate Area Plan would also terminate sanction/FIP clocks associated with final partial disapproval of the RACT SIP if the SIP revision demonstrates compliance with both the Reasonably Available Control Measure (RACM)/RACT requirement for $PM_{2.5}$ and the section 182 RACT requirement for ozone with respect to stationary NO_X sources in the South Coast.

We will accept comments from the public on the proposed partial approval and partial disapproval for the next 30 days.

III. Statutory and Executive Order Reviews

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

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

This proposed action is not a significant regulatory action and was therefore not submitted to the Office of Management and Budget (OMB) for review.

B. Paperwork Reduction Act (PRA)

This proposed action does not impose an information collection burden under the PRA because this action does not impose additional requirements beyond those imposed by state law.

C. Regulatory Flexibility Act (RFA)

I certify that this proposed action will not have a significant economic impact on a substantial number of small entities under the RFA. This action will not impose any requirements on small entities beyond those imposed by state law.

D. Unfunded Mandates Reform Act (UMRA)

This proposed action does not contain any unfunded mandate as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. This action does not impose additional requirements beyond those imposed by state law. Accordingly, no additional costs to state, local, or tribal governments, or to the private sector, will result from this action.

E. Executive Order 13132: Federalism

This proposed action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

F. Executive Order 13175: Coordination With Indian Tribal Governments

This proposed action does not have tribal implications, as specified in Executive Order 13175, because 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, and will not impose substantial direct costs on tribal governments or preempt tribal law. Thus, Executive Order 13175 does not apply to this action.

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

The EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern environmental health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of ''covered regulatory action'' in section 2–202 of the Executive Order. This proposed action is not subject to Executive Order 13045 because it does not impose additional requirements beyond those imposed by state law.

H. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use

This proposed action is not subject to Executive Order 13211, because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act (NTTAA)

Section 12(d) of the NTTAA directs the EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. The EPA believes that this proposed action is not subject to the requirements of section 12(d) of the NTTAA because application of those requirements would be inconsistent with the CAA.

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

The EPA lacks the discretionary authority to address environmental justice in this rulemaking.

List of Subjects in 40 CFR Part 52

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

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

Dated: October 19, 2016.

Alexis Strauss,

Acting Regional Administrator, Region IX.

[FR Doc. 2016–26613 Filed 11–2–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[EPA–HQ–OAR–2010–0682; FRL–9954–94–OAR]

RIN 2060–AT18

National Emission Standards for Hazardous Air Pollutant Emissions: Petroleum Refinery Sector

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule; notice of public hearing and extension of comment period.

SUMMARY: On October 18, 2016, the Environmental Protection Agency (EPA) published a document to announce its reconsideration of and request for public comment on five issues in the final National Emission Standards for Hazardous Air Pollutant Emissions: Petroleum Refinery Sector that was published on December 1, 2015. Petitioners claim that the public was not afforded an adequate opportunity to comment on these five issues. Additionally, the EPA proposed amendments to the final rule to clarify a compliance issue raised by stakeholders subject to the final rule and to correct a referencing error. The EPA is announcing that a public hearing will be held and extending the public comment period.

DATES: The public hearing will be held on November 17, 2016. The comment period for the proposed rule published in the **Federal Register** of October 18, 2016 (81 FR 71661), is extended. Written comments must be received on or before December 19, 2016.

ADDRESSES: The public hearing will be held on November 17, 2016, at the Hartman Community Center, 9311 East Avenue P, Houston, Texas 77012. The hearing will convene at 2:00 p.m. (Central Time) and will conclude at 8:00 p.m. (Central Time). The EPA will make every effort to accommodate all speakers. The EPA's Web site for the rulemaking, which includes the proposal and information about the hearing, can be found at: *https://www.epa.gov/stationary-sources-air-pollution/petroleum-refinery-sector-reconsideration-october-2016.*

Submit your comments, identified by Docket ID No. EPA–HQ–OAR–2010–0682, at *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. 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: If you would like to present oral testimony at the public hearing, registration will begin on November 3, 2016. To register to speak at a hearing, please use the online registration form available at *https://www.epa.gov/stationary-sources-air-pollution/petroleum-refinery-sector-reconsideration-october-2016* or contact Ms. Virginia Hunt at (919) 541–0832 or at *hunt.virginia@epa.gov.* For additional information regarding the hearing see the **SUPPLEMENTARY INFORMATION.**

Questions concerning the proposed rule that was published in the **Federal Register** on October 18, 2016, should be addressed to Ms. Brenda Shine, Office of Air Quality Planning and Standards, Sector Policies and Programs Division (E143–01), Environmental Protection Agency, Research Triangle Park, North Carolina 27711; telephone number: (919) 541–3608; facsimile number: (919) 541–0246; email address: *shine.brenda@epa.gov.*

SUPPLEMENTARY INFORMATION: The last day to pre-register to present oral testimony in advance of the public hearing will be November 15, 2016. If using email, please provide the following information: The time you wish to speak (afternoon or evening), name, affiliation, address, email address, and telephone and fax numbers. Time slot preferences will be given in the order requests are received. Additionally, requests to speak will be taken the day of the hearing at the hearing registration desk, although preferences on speaking times may not be able to be fulfilled. If you require the service of a translator, please let us know at the time of registration. Please note that registration requests received before each hearing will be confirmed by the EPA via email. We cannot guarantee that we can accommodate all timing requests and will provide requestors with the next available speaking time, in the event that their requested time is taken. Please note that the time outlined in the confirmation email received will be the scheduled speaking time. Again, depending on the flow of the day, times may fluctuate. Please note that any updates made to any aspect of the hearings will be posted online at *https://www.epa.gov/stationary-sources-air-pollution/petroleum-refinery-sector-reconsideration-october-2016.* While the EPA expects the hearing to go forward as set forth above, we ask that you monitor our Web site or contact Ms. Virginia Hunt at (919) 541–0832 or at *hunt.virginia@epa.gov* to determine if there are any updates to the information on the hearing. The EPA does not intend to publish a document in the **Federal Register** announcing any such updates.

Public hearing: The proposal for which the EPA is holding the public hearing was published in the **Federal Register** on October 18, 2016, and is available at: *https://www.epa.gov/stationary-sources-air-pollution/petroleum-refinery-sector-reconsideration-october-2016* and also in the docket identified below. The public hearing will provide interested parties the opportunity to present oral comments regarding the EPA's proposed standards, including data, views or arguments concerning the proposal. The EPA may ask clarifying questions during the oral presentations, but will not respond to the presentations at that time. Written statements and supporting information submitted during the comment period will be considered with the same weight as any oral comments and supporting information presented at the public hearing. The period for providing written comments to EPA will remain open until December 19, 2016.

Commenters should notify Ms. Hunt if they will need specific equipment or if there are other special needs related to providing comments at the public hearing. The EPA will provide equipment for commenters to make computerized slide presentations if we receive special requests in advance. Oral testimony will be limited to 5 minutes for each commenter. The EPA encourages commenters to submit to the docket a copy of their oral testimony electronically (via email or CD) or in hard copy form.

The public hearing schedule, including lists of speakers, will be posted on the EPA's Web site at: *https://www.epa.gov/stationary-sources-air-pollution/petroleum-refinery-sector-reconsideration-october-2016.* Verbatim transcripts of the hearing and written statements will be included in the docket for the rulemaking. The EPA will make every effort to follow the schedule as closely as possible on the day of the hearing; however, please plan for the hearing to run either ahead of schedule or behind schedule.

How can I get copies of this document and other related information?

The EPA has established a docket for the proposed rule, ''National Emission Standards for Hazardous Air Pollutant Emissions: Petroleum Refinery Sector'' under Docket ID No. EPA–HQ–OAR–2010–0682, available at *http://www.regulations.gov.*

Dated: October 31, 2016.

Mary Henigin,

Acting Director, Office of Air Quality Planning and Standards.

[FR Doc. 2016–26595 Filed 11–2–16; 8:45 am]

BILLING CODE 6569–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 25

[IB Docket No. 12–267; Report No. 3053]

Petition for Reconsideration of Action in Rulemaking Proceeding

AGENCY: Federal Communications Commission.

ACTION: Petition for reconsideration.

SUMMARY: A Petition for Reconsideration (Petition) has been filed in the Commission's rulemaking proceeding by Nancy J. Eskenazi, on behalf of SES Americom, Inc. and New Skies Satellites B.V.

DATES: Oppositions to the Petition must be filed on or before November 18, 2016. Replies to an opposition must be filed on or before November 28, 2016.

ADDRESSES: Federal Communications Commission, 445 12th Street SW., Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Clay DeCell, International Bureau at: (202) 418–0803 (voice), email: *Clay.DeCell@fcc.gov.*

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's document, Report No. 3053, released October 24, 2016. The full text of the Petition is available for viewing and copying at the FCC Reference Information Center, 445 12th Street SW., Room CY–A257, Washington, DC 20554 or may be accessed online via the Commission's Electronic the Commission's Electronic Comment Filing System at: *https://www.fcc.gov/ecfs/filing/10919110011734/document/10919110011734e7d2.* The Commission will not send a copy of this *Notice* pursuant to the Congressional Review Act, 5 U.S.C. 801(a)(1)(A), because this *Notice* does not have an impact on any rules of particular applicability.

Subject: Comprehensive Review of Licensing and Operating Rules for Satellite Services, Second Report and Order, FCC 15–167, published at 81 FR 55316, August 18, 2016 in IB 12–267. This *Notice* is being published pursuant to 47 CFR 1.429(e). *See also* 47 CFR 1.4(b)(1) and 1.429(f), (g).

Number of Petitions Filed: 1.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. 2016–26553 Filed 11–2–16; 8:45 am]

BILLING CODE 6712–01–P

Notices

Federal Register
Vol. 81, No. 213
Thursday, November 3, 2016

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

October 31, 2016.

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments are requested regarding (1) whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments regarding this information collection received by December 5, 2016 will be considered. Written comments should be addressed to: Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), *OIRA_Submission@omb.eop.gov* or fax (202) 395–5806 and to Departmental Clearance Office, USDA, OCIO, Mail Stop 7602, Washington, DC 20250–7602. Copies of the submission(s) may be obtained by calling (202) 720–8958.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Food and Nutrition Service

Title: Successful Approaches to Reduce Sodium in School Meals.

OMB Control Number: 0584–NEW.

Summary of Collection: The National School Lunch Program (NSLP) and the School Breakfast Program (SBP) are federally assisted meal programs operating in almost 100,000 public schools, non-profit private schools, and residential child-care institutions. Any child enrolled in a participating school may purchase a meal through the SBP and NSLP. Federal regulations (7 CFR 210) set nutritional and other meal requirements for school lunches, including targets for sodium levels. The purpose of this study is to identify, among schools that are successfully meeting the sodium targets, ''best practices'' that could be used to provide technical assistance to School Food Authorities (SFAs) for developing lower sodium menus.

Need and Use of the Information: The purpose of this study is to identify the best practices employed by SFAs that have successfully met or exceed sodium requirements in their schools. The findings will be helpful for SFAs and schools that have difficulty meeting the sodium targets, by providing insight into ways that other similar SFAs have overcome obstacles to successfully serve school meals that meet the sodium requirements. Other important considerations for identifying best practices include the acceptability of meals to children and the additional cost (if any) of providing lower sodium meals. The study will also provide information about the availability of, and strategies for, procuring lower sodium foods for schools to purchase and serve.

Description of Respondents: State, Local, or Tribal Government. Businesses (profit and not for profit). Individuals/Households.

Number of Respondents: 809.

Frequency of Responses: Reporting: once.

Total Burden Hours: 433.

Ruth Brown,

Departmental Information Collection Clearance Officer.

[FR Doc. 2016–26533 Filed 11–2–16; 8:45 am]

BILLING CODE 3410–30–P

DEPARTMENT OF COMMERCE

Census Bureau

Proposed Information Collection; Comment Request; State and Local Government Finance Collections

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 3, 2017.

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 Dale C. Kelly, Chief, International Trade Management Division, U.S. Census Bureau, Room 5K185, 4600 Silver Hill Road, Washington, DC 20233; or by email *dale.c.kelly@census.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

The Census Bureau plans to request clearance for the collection tools necessary to conduct the public finance program, which consists of an annual collection of information and a quinquennial collection in the census years ending in ''2'' and ''7''. During the upcoming three years, we intend to conduct the 2017 Census of Governments—Finance and the 2018 and 2019 Annual Surveys of State and Local Government Finances.

The Census of Governments—Finance and Annual Surveys of State and Local Government Finances collect data on state government finances and estimates

of local government revenue, expenditure, debt, assets, and pension systems nationally and within state areas. The surveys include the Annual Survey of State Government Finances, the Annual Survey of Local Government Finances, and the Annual Survey of Public Pensions. Data are collected for all agencies, departments, and institutions of the fifty state governments and for a sample of all local governments (counties, municipalities, townships, and special districts). Data for school districts are collected under a separate survey. In the census year, equivalent data are collected from all local governments. These three separate data collections are necessary to create the comprehensive financial picture for state and local governments. The combined data are released as part of the State and Local Government Finance statistical series. The three collections also produce individual data products that focus on state governments, local governments and public pensions in greater detail than the combined financial series as a by-product of their collections for the combined data series.

The Census Bureau provides these data to the Bureau of Economic Analysis to develop the public sector components of the National Income and Product Accounts and to the Federal Reserve Board for use in the Flow of Funds Accounts. Other Federal agencies that make use of the data include the Council of Economic Advisors, the Government Accountability Office, and the Department of Justice. Other users include state and local governments and related organizations, public policy groups, researchers, and private sector businesses.

Statistics are produced as data files in electronic formats. The program has collected comprehensive and comparable governmental statistics since 1957.

Starting with the 2017 collection, the Census Bureau proposes modifying the existing questions concerning actuarial funding of public pension plans for state-administered plans and adding these questions to the survey for locally-administered plans. These changes reflect changes in accounting standards and the needs of data users inside and outside the federal statistical system.

II. Method of Collection

These surveys use multiple modes for data collection including Internet collection with a mailed invitation, telephone, and central collection. Other methods used to collect data and maximize response include collecting state and local government data through submitted financial audits, state financial reports, and comprehensive financial reports.

The Census Bureau developed central collection agreements with state and large local government officials to collect the data from their dependent agencies and report to the Census Bureau as a central respondent. These arrangements eliminate the need for a mail invitation for approximately 5,500 governmental units in a sample year and 36,000 during the Census of Governments. The arrangements reduce burden by greatly reducing the number of people who have to fill out a collection as the data are collected from a centralized source instead of from multiple sources. Currently, the Census Bureau has central collection arrangements to collect local government data with 27 states and state government data from all 50 states. The Census Bureau continues to expand the conversion of paper submissions into electronic formats by collaborating with state and local governments regarding electronic reporting of central collection data, and encouraging electronic responses from individual governments.

III. Data

OMB Control Number: 0607–0585.

Form Number: F–5, F–11, F–12, F–13, F–25, F–28, F–29, F–32, and F–42.

Type of Review: Regular submission.

Affected Public: State and local governments.

Estimated Number of Respondents: 18,568/90,607 sample year/census year.

Estimated Time per Response: 2.034/1.643 hours sample year/census year.

Estimated Total Annual Burden Hours: 37,767/148,867 hours sample year/census year.

Estimated Total Annual Cost: $0.

Respondents Obligation: Voluntary.

Legal Authority: Title 13 U.S.C. Sections 161 and 182.

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.

Sheleen Dumas,

PRA Departmental Lead, Office of the Chief Information Officer.

[FR Doc. 2016–26606 Filed 11–2–16; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

[Docket No. 160323279–6279–01]

Privacy Act of 1974; Amended System of Records

AGENCY: U.S. Census Bureau, U.S. Department of Commerce.

ACTION: Notice of Amendment, Privacy Act System of Records; COMMERCE/CENSUS–8, Statistical Administrative Records System.

SUMMARY: In accordance with the Privacy Act of 1974, as amended, Title 5 United States Code (U.S.C.) 552a(e)(4) and (11); and Office of Management and Budget (OMB) Circular A–130, Appendix I, ''Federal Agency Responsibilities for Maintaining Records About Individuals,'' the Department of Commerce (Department) is issuing notice of intent to amend the system of records under COMMERCE/CENSUS–8, Statistical Administrative Records System, to update information concerning the location of the system of records, the categories of individuals and categories of records covered by the system, the policies and practices for retention, disposal, and safeguarding the system of records, the storage, the system manager and address, the notification procedures, the records source categories; and other minor administrative updates. Accordingly, the COMMERCE/CENSUS–8, Statistical Administrative Records System notice published in the **Federal Register** on October 27, 2010 (66 FR 3202), is amended as below. We invite public comment on the system amendment announced in this publication.

DATES: To be considered, written comments must be submitted on or before December 5, 2016. Unless comments are received, the amended system of records will become effective as proposed on December 13, 2016. If comments are received, the Department will publish a subsequent notice in the **Federal Register** within 10 days after the comment period closes, stating that the current system of records will remain in effect until publication of a final action in the **Federal Register**.

ADDRESSES: Please address comments to: Chief, Privacy Compliance Branch, Policy Coordination Office, Room HQ—8H021, U.S. Census Bureau, Washington, DC 20233–3700.

FOR FURTHER INFORMATION CONTACT: Chief, Privacy Compliance Branch, Policy Coordination Office, Room HQ—8H021, U.S. Census Bureau, Washington, DC 20233–3700.

SUPPLEMENTARY INFORMATION: This update makes eight program-related changes. The first of eight proposed changes revises the location of the system to account for records maintained by the Federal Risk and Authorization Management Program (FEDRAMP)-approved cloud service provider. The second of eight proposed changes to program-related provisions updates the categories of individuals to include individuals from territories of the United States. The third proposed change updates the categories of records and clarifies the three types of record components maintained in the system. The fourth change updates the system manager and address to reflect the Census Bureau's reorganization. The fifth change updates the notification procedure to reflect that records maintained for statistical purposes are exempt from notification. The sixth change updates the policies and practices for the retention, disposal, and safeguarding the records in the system. The seventh change updates the storage element in the system of records notice (SORN) to address the storage of paper copies, magnetic media, and to include storage by a cloud service provider. The eighth change updates the source of the records to more accurately reflect the entities from which the information may be obtained. Additionally, the amendment provides other minor administrative updates. The entire resulting system of records notice, as amended, appears below.

COMMERCE/CENSUS–8

SYSTEM NAME:

Statistical Administrative Records System.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

Bowie Computer Center, Bureau of the Census, 17101 Melford Blvd., Bowie, Maryland 20715; and at a FEDRAMP-approved cloud services facility.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

This system covers the population of the United States and territories. In order to approximate coverage of the population in support of its statistical programs, the Census Bureau will acquire administrative record files from agencies such as the Departments of Agriculture, Education, Health and Human Services, Homeland Security, Housing and Urban Development, Labor, Treasury, Veterans Affairs, the Office of Personnel Management, the Social Security Administration, the Selective Service System, and the U.S. Postal Service. Comparable data may also be sought from state agencies and commercial sources and Web sites.

CATEGORIES OF RECORDS IN THE SYSTEM:

Records in this system of records are organized into three components:

- The first category contains records with personal identifiers (names and Social Security Numbers (SSNs)), with access restricted to a limited number of sworn Census Bureau staff. These records are only used for a brief period of time while the personal identifiers are replaced with unique non-identifying codes. In a controlled Information Technology (IT) environment, the identifying information (SSN) contained in source files is removed and replaced with unique non-identifying codes. The Census Bureau does not collect SSNs in Title 13 surveys or censuses. Title 13, Section 6, authorizes the Census Bureau to acquire information from other federal departments and agencies and for the acquisition of reports of other governmental or private sources. Data acquired by the Census Bureau to meet this directive may include direct identifiers such as name, address, date of birth, driver's license number, and SSN. The direct identifiers are used to identify duplicate lists and link across multiple sources.
- The Census Bureau has developed software to standardize and validate incoming person records to assign a unique Census Bureau linkage identifier. This identifier, called the Protected Identification Key (PIK), is retained on files so that SSNs can be removed. This process occurs through the Person Identification Validation System (PVS). The PVS software processes direct identifiers from input files. Census Bureau staff use the person linkage keys to merge files when conducting approved research and operations activities. The software is also used to facilitate record linkage for Census Bureau research partners within the Federal Statistical System. Through legal agreements, linkage keys may be created by the Census Bureau for other Federal Statistical Agencies to produce statistics. The PVS system does not append additional identifying information, only a unique identifier to facilitate record linkage.
- The second category contains records that are maintained on unique data sets that are extracted or combined on an as-needed basis in approved projects. Records are extracted or combined as needed using the unique non-identifying codes, not by name or SSN, to prepare numerous statistical products. These records may contain information such as: Demographic information—date of birth, sex, race, ethnicity, household and family characteristics, education, marital status, tribal affiliation, and veteran's status, etc.; Geographical information—address and geographic codes, etc.; Mortality information—cause of death and hospitalization information; Health information—type of provider, services provided, cost of services, and quality indicators, etc.; Economic information—housing characteristics, income, occupation, employment and unemployment information, health insurance coverage, Federal and State program participation, assets, and wealth.
- The third category contains two types of records that use name data for specific research activities. The Census Bureau has policies and procedures to review and control name data from administrative records providers and third party sources. This category refers to name data used to plan contact operations for surveys and censuses and for research on names. The first type of records includes Respondent contact information—name (or username), address, telephone number (both landline and cell phone number), and email address or equivalent. The second type of records includes name data used to set Demographic Characteristics Flags—names are compared to lookup tables and used in models to assign sex and ethnicity. Records in this category are maintained on unique data sets that are extracted or combined on an as-needed basis using the unique non-identifying codes that replaced the SSNs, but with some name information retained.

AUTHORITIES FOR MAINTENANCE OF THE SYSTEM:

Title 13 U.S.C. 6.

PURPOSE(S):

This system of records supports the Census Bureau's core mission of producing economic and demographic statistics. To accomplish this mission the Census Bureau is directed to acquire information from public and private sources to ensure the efficient and economical conduct of its censuses and

surveys by using that information instead of conducting direct inquiries. To provide the information on which the American public, businesses, policymakers, and analysts rely, the Statistical Administrative Records System efficiently re-uses data from external sources, thereby eliminating the need to collect information again. Therefore, the purpose of this system is to centralize and control the use of personally identifiable information by providing a secure repository that supports statistical operations. The system removes SSNs contained in source files and replaces them with unique non-identifying codes called Protected Identification Keys (PIKs) prior to use by other Census Bureau operating units. Census Bureau staff use the PIK to merge files to conduct approved research projects. Through legal agreements documenting permitted uses of the external data, linked files may be created to produce statistics. By combining survey and census data with administrative record data from other agencies, and data procured from commercial sources, the Census Bureau will improve the quality and usefulness of its statistics and reduce the respondent burden associated with direct data collection efforts. The system will also be used to plan, evaluate, and enhance survey and census operations; improve questionnaire design and selected survey data products; and produce research and statistical products such as estimates of the demographic, social, and economic characteristics of the population.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

None. The Statistical Administrative Records System will be used only for statistical purposes. No disclosures which permit the identification of individual respondents, and no determinations affecting individual respondents will be made.

DISCLOSURE TO CONSUMER REPORTING AGENCIES:

None.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records will be stored in a secure computerized system and on magnetic media; output data will be electronic. Magnetic media will be stored in a secure area within a locked drawer or cabinet. Source data sets containing personal identifiers will be maintained in a secure restricted-access IT environment. Records may also be stored by or at a secure FEDRAMP-approved cloud service provider or facility.

RETRIEVABILITY:

Staff producing statistical products will have access only to data sets from which SSNs have been deleted and replaced by unique non-identifying codes internal to the Census Bureau. Only a limited number of sworn Census Bureau staff, who work within a secure restricted-access environment, will be permitted to retrieve records containing direct identifiers (such as name or SSN).

SAFEGUARDS:

The Census Bureau is committed to respecting respondent privacy and protecting confidentiality. Through the Data Stewardship Program, we have implemented management, operational, and technical controls and practices to ensure high-level data protection to respondents of our censuses and surveys.

- An unauthorized browsing policy protects respondent information from casual or inappropriate use by any person with access to Title 13 protected data.
- All Census Bureau employees, persons with special sworn status, as well as employees of FEDRAMP-approved cloud services who may have incidental access to Title 13 protected data, are subject to the restrictions, penalties, and prohibitions of 13 U.S.C. 9 and 214 as modified by Title 18 U.S.C. 3551, et. seq.; the Privacy Act of 1974 (5 U.S.C. 552a(b)(4); 18 U.S.C. 1905; 26 U.S.C. 7213, 7213A, and 7431; and 42 U.S.C. 1306.
- All Census Bureau employees and persons with special sworn status will be regularly advised of regulations issued pursuant to Title 13 governing the confidentiality of the data, and will be required to complete an annual Data Stewardship Awareness training and those who have access to Federal Tax Information data will be regularly advised of regulations issued pursuant to Title 26 governing the confidentiality of the data, and will be required to complete an annual Title 26 awareness program. The restricted-access IT environment has been established to limit the number of Census Bureau staff with direct access to the personal identifiers in this system to protect the confidentiality of the data and to prevent unauthorized use or access. These safeguards provide a level and scope of security that meet the level and scope of security established by OMB Circular No. A–130, Appendix III, Security of Federal Automated Information Resources.
- All Census Bureau and FEDRAMP-approved computer systems that maintain sensitive information are in compliance with the Federal Information Security Management Act, which includes auditing and controls over access to restricted data.
- The use of unsecured telecommunications to transmit individually identifiable information is prohibited.
- Paper copies that contain sensitive information are stored in secure facilities in a locked drawer or file cabinet behind a closed door.
- Each requested use of the data covered in this SORN will be reviewed by an in-house Project Review Board to ensure that data relating to the project will be used only for authorized purposes. All uses of the data are solely for statistical purposes, which by definition means that uses will not directly affect benefits or enforcement actions for any individual. Only when the Project Review Board has approved a project, will access to information from one or more of the source data sets occur. Data from external sources in approved projects will not be made publicly available.
- Any publications based on the Statistical Administrative Records System will be cleared for release under the direction of the Census Bureau's Disclosure Review Board, which will confirm that all the required disclosure protection procedures have been implemented. No information will be released that identifies any individual.

RETENTION AND DISPOSAL:

Records are to be retained in accordance with General Records Schedule GRS 4.3, and the Census Bureau's records control schedule DAA–0029–2014–0005, Records of the Center for Administrative Records Research and Applications, which are approved by the National Archives and Records Administration (NARA). Records are also retained in accordance with agreements developed with sponsoring agencies or source entities. Federal tax information administrative record data will be retained and disposed of in accordance with Publication 1075, *Tax information Security Guidelines for Federal, State, and Local Agencies and Entities.* The Census Bureau issues an Annual Safeguard Security Report that includes information on the retention and disposal of federal tax information. Pursuant to IRS regulation, Title 26 U.S.C. 6103(p)(4)(F)(ii), data cannot be transferred to NARA.

SYSTEM MANAGER AND ADDRESS:

Associate Director for Research and Methodology, U.S. Census Bureau, 4600 Silver Hill Road, Washington, DC 20233–8000.

NOTIFICATION PROCEDURE:

None.

RECORD ACCESS PROCEDURES:

None.

CONTESTING RECORD PROCEDURES:

None.

RECORD SOURCE CATEGORIES:

Individuals and addresses covered by selected administrative record systems and Census Bureau censuses and surveys including current demographic and economic surveys, quinquennial Economic Censuses, and decennial Censuses of Population and Housing. Additionally, the Census Bureau will also acquire administrative record files from agencies such as the Departments of Agriculture, Education, Health and Human Services, Homeland Security, Housing and Urban Development, Labor, Treasury, Veterans Affairs, the Office of Personnel Management, the Social Security Administration, the Selective Service System, and the U.S. Postal Service, etc. Comparable data may also be sought from state agencies, commercial sources, and Web sites.

EXEMPTIONS CLAIMED FOR SYSTEM:

Pursuant to 5 U.S.C. 552a(k)(4), this system of records is exempted from the notification, access, and contest requirements of the agency procedures (under 5 U.S.C. 552a(c)(3), (d), (e)(1), (e)(4)(G), (H), and (I), and (f)). This exemption is applicable as the data are maintained by the Census Bureau solely as statistical records, as required under Title 13, and are not used in whole or in part in making any determination about an identifiable individual. This exemption is made in accordance with the Department's rules which appear in 15 CFR part 4 Subpart B published in this **Federal Register**.

Michael J. Toland,

Department of Commerce, Deputy Chief FOIA Officer, Department Privacy Act Officer.

[FR Doc. 2016–26517 Filed 11–2–16; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

[Docket No. 160616531–6531–01]

Privacy Act of 1974, Amended System of Records

AGENCY: U.S. Census Bureau, U.S. Department of Commerce.

ACTION: Notice of Amendment, Privacy Act System of Records, COMMERCE/CENSUS–5, Decennial Census Programs.

SUMMARY: In accordance with the Privacy Act of 1974, as amended, and Office of Management and Budget (OMB) Circular A–130, Appendix I, ''Federal Agency Responsibilities for Maintaining Records About Individuals,'' the Department of Commerce (Department) is issuing a notice of intent to amend the system of records under COMMERCE/CENSUS–5, Decennial Census Programs. This amendment would update: The location of the records covered by the system of records; the categories of individuals and records covered by the system of records; the routine uses; the purpose; the system manager and address; and the policies and practices for storage and safeguarding the system of records. This amendment also makes other minor administrative updates. Accordingly, the COMMERCE/CENSUS–5, Decennial Census Program notice published in the **Federal Register** on February 24, 2014 (79 FR 10090), is amended as below. We invite public comment on the system amendment announced in this publication.

DATES: To be considered, written comments must be submitted on or before December 5, 2016. Unless comments are received, the amended system of records will become effective as proposed on December 13, 2016. If comments are received, the Department will publish a subsequent notice in the **Federal Register** within 10 days after the comment period closes, stating that the current system of records will remain in effect until publication of a final action in the **Federal Register**.

ADDRESSES: Please address comments to: Byron Crenshaw, Privacy Compliance Branch, Room 8H021, U.S. Census Bureau, Washington, DC 20233–3700 or by email: (*Byron.Crenshaw@census.gov*).

FOR FURTHER INFORMATION CONTACT: Chief, Privacy Compliance Branch, Policy Coordination Office, Room HQ 8H021, U.S. Census Bureau, Washington, DC 20233–3700.

SUPPLEMENTARY INFORMATION: This update makes eight program-related changes. The first of eight proposed changes to program-related provisions updates the location of the system to account for records maintained by a Federal Risk and Authorization Management Program (FedRAMP)-approved cloud service provider. FedRAMP is a government-wide program that provides a standardized approach to security assessment, authorization, and continuous monitoring for cloud products and services. The second proposed change clarifies the categories of individuals covered by the system. The third proposed change updates the categories of records regarding Decennial Census records and clarifies the collection of paradata. Census Bureau employee characteristics and auxiliary data known as paradata also collected during census and survey interviews, pilot tests, and cognitive interviews, are collected under Title 13, U.S.C. and are covered under this Systems of Record Notice (SORN). Paradata covered under Title 5, U.S.C. are covered under SORN COMMERCE/Census-2, Performance Measurement Records. The fourth proposed change updates the routine uses. The fifth proposed change updates the purpose of the system to provide additional information and detail. The sixth proposed change updates the policies and practices for storing the records to include storage by a cloud service provider. The seventh proposed change updates the policies and practices for safeguarding the records in the system. The eighth proposed change updates the system manager and address. This amendment also provides minor administrative updates. The entire resulting system of records notice, as amended, appears below.

COMMERCE/CENSUS–5

SYSTEM NAME:

Decennial Census Programs

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

U.S. Census Bureau, 4600 Silver Hill Road, Washington, DC 20233–8100; Bureau of the Census, Bowie Computer Center, 17101 Medford Boulevard, Bowie, Maryland 20715; and at a FedRAMP-approved cloud services facility.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

All persons surveyed during the Decennial Census Programs, which include the ongoing American Community Survey (ACS), the Decennial Census of Population and Housing (the Decennial Census), as well as persons participating in the pilot census and survey tests of procedures related to the ACS and the Decennial Census, are covered by the system. Participation in Decennial Census Programs is mandatory. Data collected directly from respondents may be supplemented with data from

administrative record files received from other federal, state, or local agencies. Comparable data may also be obtained from private persons and commercial sources. These are collected and processed under the Statistical Administrative Records System. Please see the COMMERCE/CENSUS–8, Statistical Administrative Records System SORN for more information. Field Representative (FR) and interviewer characteristics as well as paradata collected during the Decennial Census Programs (including the same data obtained during recordings) are covered under SORN COMMERCE/Census-2, Performance Measurement Records.

CATEGORIES OF RECORDS IN THE SYSTEM:

Records collected by the ACS and its pilot surveys may contain information such as: Population information—name, address, email address, telephone number (both landline and cell phone number), age, sex, race, Hispanic origin, relationships, housing tenure, number of persons in the household, as well as more detailed information on topics such as marital status and history, fertility, income, employment, education, health insurance or health coverage plans, disability, grandparents as care-givers, and military status and history; Housing information—year built, structure description, uses, features, amenities, number of rooms, utilities, purchase type (*e.g.,* mortgage or deed of trust), and financial characteristics (*e.g.,* home value, property taxes, etc.). Records collected during the Decennial Census and its pilot censuses may contain information such as: Population information—name, address, email address, telephone number (both landline and cell phone number), age, sex, race, Hispanic origin, relationship, housing tenure, number of persons in the household. In accordance with 13 U.S.C. 6(c), information in the Decennial Census Programs may, under specific circumstances and arrangements, also come from administrative records obtained from federal, states, counties, cities, or other units of government. Comparable data may also be obtained from private persons and commercial sources. For instance, the U.S. Census Bureau works with all Federal agencies to obtain counts from their records of federally affiliated Americans overseas. The U.S. Census Bureau also makes arrangements with certain types of facilities (*e.g.,* prisons, long-term care facilities, colleges) to obtain administrative records data on individuals when direct enumeration of those people is not feasible for safety, health, or other reasons. Additional information may be obtained from systems of records notice COMMERCE/CENSUS–8, Statistical Administrative Records. Pilot censuses, surveys, and research study records may contain information on individuals similar to that included in the ACS and Decennial Census. FR and interviewer characteristics as well as paradata collected during the Decennial Census Programs (including data obtained during recordings) may also be collected. Paradata fall into two categories: (1) Paradata protected by Title 13, U.S.C. (''Title 13''), which are covered under this SORN (*e.g.,* method of interview; time and date stamps; deleted changes; audit trail and trace files; item non-response, refusals, and don't know responses; all Internet paradata, including Internet Protocol (IP) address; Global Positioning System (GPS) coordinates; mobile device ID; etc.) and (2) paradata protected by Title 5, U.S.C. (''Title 5''), which are covered under SORN Census-2, Performance Measurement Records (*e.g.,* hours worked on a case, miles driven on a case, survey response rates, cost information, hourly rates for field staff, FR codes, control numbers, login hours, etc.).

AUTHORITIES FOR MAINTENANCE OF THE SYSTEM:

13 U.S.C. 6(c), 141 and 193 and 18 U.S.C. 2510–2521.

PURPOSE(S):

The purpose of this system is to collect statistical information from respondents for the Decennial Census Programs using responses to questions in order to provide key social, housing, and economic data for the nation. The primary uses of ACS data include: Supporting the federal government in administration of programs; providing public officials, planners, and entrepreneurs with information they can use to assess the past and plan for the future; providing information for community planning for hospitals and schools, supporting school lunch programs, improving emergency services, and building bridges; and informing businesses looking to add jobs and expand to new markets. The primary uses of Decennial Census data include: Apportioning the representation among states as mandated by Article 1, Section 2 of the United States Constitution; drawing congressional and state legislative districts, school districts and voting precincts; enforcing voting rights and civil rights legislation; distributing federal dollars to states; informing federal, tribal, state, and local government planning decisions; informing business and nonprofit organization decisions (*e.g.,* where to locate, size of the market); and providing population benchmarks for nearly every other United States survey. Survey records from the Decennial Census Programs are also maintained to conduct research and analysis with survey and administrative data for projects and to undertake methodological evaluations and enhancements by the U.S. Census Bureau improving data collection and quality control. Also, information collected by the Decennial Census is used to provide official census transcripts of the results to the named person(s), their heirs, or legal representatives as described in the system of records notice, COMMERCE/CENSUS–6, Population Census Personal Service Records for 1910 and all subsequent Decennial Censuses (this does not apply to the ACS and pilot census or survey records).

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

Access to records maintained in the system is restricted to Census Bureau employees and individuals with Special Sworn Status, as defined in Title 13 of the United States Code.

DISCLOSURE TO CONSUMER REPORTING AGENCIES:

None.

None.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records (including, but not limited to, sound and video files of survey and cognitive interviews, and pilot tests) are stored in a secure computerized system and on magnetic media; output data will be either electronic or paper copies (including transcripts of sound files). Paper copies or magnetic media are stored in a secure area within a locked drawer or cabinet. Datasets may be accessed only by authorized personnel. Control lists will be used to limit access to those employees with a need to know; rights will be granted based on job functions. Records may also be stored by or at a secure FedRAMP-approved cloud service provider or facility. FedRAMP is a government-wide program that provides a standardized approach to security assessment, authorization, and continuous monitoring for cloud products and services.

RETRIEVABILITY:

Information collected by the Decennial Census Programs may be retrieved by direct identifiers such as name and address. However, only a limited number of sworn U.S. Census Bureau staff will be permitted to retrieve records containing direct identifiers (such as name or address) for authorized purposes. Staff producing final statistical products will have access only to data sets from which direct identifiers have been deleted and replaced by unique non-identifying codes internal to the U.S. Census Bureau.

SAFEGUARDS:

The U.S. Census Bureau is committed to respecting respondent privacy and protecting confidentiality. Through the Data Stewardship Program, we have implemented management, operational, and technical controls and practices to ensure high-level data protection to respondents of our censuses and surveys.

- A policy against unauthorized policy protects respondent information from casual or inappropriate use by any person with access to Title 13 protected data. Unauthorized browsing is defined as the act of searching or looking through, for other than work-related purposes, protected personal or business-related information that directly or indirectly identifies individual persons or businesses. Unauthorized browsing is prohibited.
- All Census Bureau employees and persons with special sworn status permitted to access the system are subject to the restriction, penalties, and prohibitions of 13 U.S.C. 9 and 214, as modified by 18 U.S.C. 3551 *et seq.;* the Privacy Act of 1974 (5 U.S.C. 552a(b)(4)). Employees of FedRAMP-approved cloud service providers do not have access to Title 13 protected data covered by this system of records. The U.S. Census Bureau's security measures ensure that only a restricted number of authorized people have access to Title 13 protected information and that access is only granted to conduct our work and for no other purposes. Every person who works with the census confidential information collected by the U.S. Census Bureau is sworn for life to uphold the law.
- All U.S. Census Bureau employees and persons with special sworn status will be regularly advised of regulations issued pursuant to Title 13 governing the confidentiality of the data, and will be required to complete an annual Data Stewardship Awareness program.
- All U.S. Census Bureau and FedRAMP-approved computer systems that maintain sensitive information are in compliance with the Federal Information Security Management Act, which includes auditing and controls over access to restricted data. The FedRAMP is a government-wide program that provides a standardized approach to security assessment, authorization, and continuous monitoring for cloud products and services.
- The use of unsecured telecommunications to transmit individually identifiable information is prohibited.
- Paper copies that contain sensitive information are stored in secure facilities in a locked drawer or file cabinet behind a locked door.
- Additional data files containing direct identifiers will be maintained solely for the purpose of data collection activities, such as respondent contact and preloading an instrument for a continued interview, and will not be transferred to, or maintained on, working statistical files.
- Any publications based on this system will be cleared for release under the direction of the U.S. Census Bureau's Disclosure Review Board, which will confirm that all the required disclosure avoidance procedures have been implemented and no information that identifies any individual is released.

RETENTION AND DISPOSAL:

Respondent data collected through the Decennial Census Programs, including personally identifying data, are in some cases captured as images suitable for computer processing. Original paper data sources are destroyed, according to the disposal procedures for Title 13 records, after confirmation of successful electronic data capture and data transmission of the images to U.S. Census Bureau headquarters. For the ACS, personally identifying data are scheduled for permanent retention (excluding sound and video files that are retained in accordance with the General Records Schedule and U.S. Census Bureau records control schedules that are approved by the National Archives and Records Administration (NARA)). For the Decennial Census, a record of individual responses, including all names and other entries provided by the respondent, and all associated address and geographic information for each housing unit or person living in group quarters is scheduled for permanent retention (excluding sound and video files that are retained in accordance with the General Records Schedule and U.S. Census Bureau records control schedules that are approved by the NARA). Pilot and cognitive test data collections, data capture, and data processing records are destroyed when two years old or when no longer needed for U. S. Census Bureau program or evaluation purposes, whichever is later. All records are retained in accordance with the General Records Schedule and U.S. Census Bureau records control schedules that are approved by the NARA (44 U.S.C. 2108).

SYSTEM MANAGER(S) AND ADDRESS:

Associate Director for Decennial Census Programs, U.S. Census Bureau, 4600 Silver Hill Road, Washington, DC 20233–8000.

NOTIFICATION PROCEDURE:

None.

RECORD ACCESS PROCEDURE:

None.

CONTESTING RECORD PROCEDURE:

None.

RECORD SOURCE CATEGORIES:

Information in the Decennial Census Programs may come from administrative records from federal, states, counties, cities, or other units of government such as: The U.S. Department of Defense and the U.S. Office of Personal Management for enumeration of federally affiliated Americans overseas; tribal, State, and local governments for service-based enumeration of persons without permanent shelter and for address and road updates; the Federal Bureau of Prisons for inmate enumeration; the U.S. Postal Service for address updates; as well as the Departments of Agriculture, Education, Health and Human Services, Homeland Security, Housing and Urban Development, Labor, Treasury, Veterans Affairs, the Office of Personnel Management, the Social Security Administration, the Selective Service System, and the U.S. Postal Service. Comparable data may also be obtained from private persons and commercial sources.

EXEMPTIONS CLAIMED FOR SYSTEM:

Pursuant to 5 U.S.C. 552a(k)(4), this system of records is exempted from the otherwise applicable notification, access, and contest requirements of the agency procedures (under 5 U.S.C. 552a(c)(3), (d), (e)(1), (e)(4)(G)–(I) and (f)). This exemption is applicable because the data are maintained by the U.S. Census Bureau solely as statistical records, as required under Title 13, to be used solely as statistical records and are not used in whole or in part in making any determination about an identifiable individual. This exemption is made in

accordance with 15 CFR part 4 subpart B.

Michael J. Toland,

Department of Commerce, Deputy Chief FOIA Officer, Department Privacy Act Officer.

[FR Doc. 2016–26516 Filed 11–2–16; 8:45 am]

BILLING CODE 3510–DT–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–912]

New Pneumatic Off-The-Road Tires From the People's Republic of China: Initiation of Antidumping Duty New Shipper Review; 2015–2016

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

DATES: Effective November 3, 2016.

SUMMARY: On September 20, 2016, the Department of Commerce (''the Department'') received a timely request for a new shipper review (''NSR'') of the antidumping duty (''AD'') order on new pneumatic off-the-road tires (''OTR Tires'') from the People's Republic of China (''PRC''). The Department has determined that the request meets the statutory and regulatory requirements for initiation. The period of review (''POR'') for this NSR is September 1, 2015, through August 31, 2016.

FOR FURTHER INFORMATION CONTACT: Alex Rosen, AD/CVD Operations, Office III, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230; telephone: 202–482–7814.

SUPPLEMENTARY INFORMATION:

Background

The AD order on OTR Tires from the PRC was published in the **Federal Register** on September 4, 2008.[1] On September 20, 2016, pursuant to section 751(a)(2)(B)(i) of the Tariff Act of 1930, as amended (''the Act''), and 19 CFR 351.214(b), the Department received a NSR request from The Carlstar Group LLC (''Carlstar Group''), Carlisle (Meizhou) Rubber Manufacturing Co., Ltd. (''Carlisle Meizhou''), and CTP Distribution (HK) Limited (''CTP'') (collectively, ''Carlstar Companies'').[2] Carlstar Companies certified that CTP is the exporter of the subject merchandise upon which the request is based and that its affiliate, Carlisle Meizhou, is the producer of the subject merchandise.[3]

Pursuant to section 751(a)(2)(B)(i)(I) of the Act and 19 CFR 351.214(b)(2)(i), Carlstar Companies certified that it did not export subject merchandise to the United States during the period of investigation (''POI'').[4] Further, Carlstar Companies certified that it is the producer of the subject merchandise upon which the request is based.[5] In addition, pursuant to section 751(a)(2)(B)(i)(II) of the Act and 19 CFR 351.214(b)(2)(iii)(A), Carlstar Companies certified that, since the initiation of the investigation, it has never been affiliated with any PRC exporter or producer who exported subject merchandise to the United States during the POI, including those respondents not individually examined during the investigation.[6] As required by 19 CFR 351.214(b)(2)(iii)(B), Carlstar Companies also certified that its export activities were not controlled by the government of the PRC.[7]

In addition to the certifications described above, pursuant to 19 CFR 351.214(b)(2)(iv), Carlstar Companies submitted documentation establishing the following: (1) The date on which it first shipped subject merchandise for export to the United States; (2) the volume of its first shipment;[8] and (3) the date of its first sale to an unaffiliated customer in the United States.[9]

Finally, the Department conducted a U.S. Customs and Border Protection (''CBP'') database query and confirmed the price, quantity, date of sale, and date of entry of Carlstar Companies' sales, as well as that the shipment reported by Carlstar had entered the United States for consumption and that liquidation had been properly suspended for antidumping duties.[10] However, the Department has concerns with certain information contained in the CBP entry data, and intends to address these, and any remaining issues, after initiation of this NSR. The continuation of the new shipper review will be contingent upon confirmation of the information reported in the review request.

Period of Review

In accordance with 19 CFR 351.214(g)(1)(i)(A), the POR for a NSR initiated in the month immediately following the anniversary month will be the twelve-month period immediately preceding the anniversary month. Therefore, the POR is September 1, 2015, through August 31, 2016.[11] Based on the information provided by Carlstar Companies, the subject merchandise upon which Carlstar Companies' NSR request is based entered the United States during this twelve-month POR.[12]

Initiation of New Shipper Review

Pursuant to section 751(a)(2)(B) of the Act, 19 CFR 351.214(b), and 19 CFR 351.214(d)(1), and based on the evidence provided by Carlstar Companies, we find that its request meets the threshold requirements for initiation of the NSR for shipments of OTR Tires from the PRC produced by Carlisle Meizhou and exported by CTP.[13] If the information supplied by Carlstar Companies is found to be incorrect or insufficient during the course of this proceeding, the Department may rescind the review for Carlstar Companies or apply facts available pursuant to section 776 of the Act, depending on the facts on record.

Absent a determination that the new shipper review is extraordinarily complicated, the Department intends to issue the preliminary results of this NSR within 180 days from the date of initiation and the final results within 90 days after the date on which the preliminary results are issued.[14]

It is the Department's usual practice, in cases involving non-market economies (''NMEs''), to require that a company seeking to establish eligibility for an antidumping duty rate separate from the NME entity-wide rate provide evidence of *de jure* and *de facto* absence of government control over the company's export activities.[15] Accordingly, we will issue questionnaires to Carlstar Companies that will include a section requesting information concerning CTP's eligibility for a separate rate. The NSR will proceed if the responses provide

[1] *See New Pneumatic Off-The-Road Tires from the People's Republic of China: Antidumping Duty Order,* 73 FR 51624 (September 4, 2008) (''*Order*'').

[2] *See* Letter from Carlstar Companies, ''Entry of Appearance and Request for New Shipper Review: New Pneumatic Off-The-Road Tires from the People's Republic of China,'' dated September 20, 2016 (''NSR Request'').

[3] *Id.,* at 1 and Exhibit 1.

[4] *Id.,* at 3.

[5] *Id.*

[6] *Id.*

[7] *Id.*

[8] *Id.,* at 4, where the Carlstar Companies stated that it had no subsequent shipments.

[9] *Id.,* at Exhibits 2–6.

[10] *See* Memorandum to the File from Alex Rosen, Analyst ''U.S. Customs and Border Protection Import Data,'' dated October 19, 2016.

[11] *See* 19 CFR 351.214(g)(1)(ii)(B).

[12] *See* NSR Request at 3.

[13] *See* Memorandum to the File, from Alex Rosen, Analyst, ''Initiation of Antidumping Duty New Shipper Review: New Pneumatic Off-The-Road Tires from the People's Republic of China New Shipper Initiation Checklist,'' dated concurrently with this notice.

[14] *See* section 751(a)(2)(B)(iv) of the Act and 19 CFR 351.214(i).

[15] *See* Import Administration Policy Bulletin, Number: 05.1. (*http://ia.ita.doc.gov/policy/bull05-1.pdf*).

sufficient indication that CTP is not subject to either *de jure* or *de facto* government control with respect to its exports of subject merchandise.

On February 24, 2016, the President signed into law the Trade Facilitation and Trade Enforcement Act of 2015, H.R. 644, which made several amendments to section 751(a)(2)(B) of the Act. We will conduct this NSR in accordance with section 751(a)(2)(B) of the Act, as amended by the *Trade Facilitation and Trade Enforcement Act of 2015.*[16]

Interested parties requiring access to proprietary information in this NSR should submit applications for disclosure under administrative protective order, in accordance with 19 CFR 351.305 and 19 CFR 351.306.

This initiation and notice are in accordance with section 751(a)(2)(B) of the Act, 19 CFR 351.214, and 19 CFR 351.221(c)(1)(i).

Christian Marsh,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2016–26587 Filed 11–2–16; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

U.S. Department of Commerce Trade Finance Advisory Council

AGENCY: International Trade Administration, U.S. Department of Commerce.

ACTION: Notice of an Open Meeting.

SUMMARY: The U.S. Department of Commerce Trade Finance Advisory Council (TFAC) will hold its inaugural meeting on Friday, November 18, 2016, at the U.S. Department of Commerce Library, in Washington, DC. The meeting is open to the public with registration instructions provided below.

The TFAC was chartered on August 11, 2016, to advise the Secretary in identifying effective ways to help expand access to finance for U.S. exporters, especially small and medium-sized enterprises, and their foreign buyers. At the meeting, members will be sworn-in and will begin a discussion of the work they will undertake during their term. They will also be briefed by officials from the Department of Commerce and other agencies on major issues impacting this area. The final agenda will be posted on the Department of Commerce Web site for the Council at *http://trade.gov/tfac/,* at least one week in advance of the meeting.

DATES: Friday, November 18, 2016, from approximately 9:00 a.m. to 12:00 p.m. Eastern Standard Time (EST).

FOR FURTHER INFORMATION CONTACT: Ericka Ukrow, Designated Federal Officer, Office of Finance and Insurance Industries (OFII), International Trade Administration, U.S. Department of Commerce at (202) 482–0405; email: *Ericka.Ukrow@trade.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On July 25, 2016, the Secretary of Commerce established the TFAC pursuant to discretionary authority and in accordance with the Federal Advisory Committee Act, as amended, 5 U.S.C. App. The TFAC advises the Secretary of Commerce in identifying effective ways to help expand access to finance for U.S. exporters, especially small- and medium-sized enterprises (SMEs) and their foreign buyers. The TFAC also provides a forum to facilitate the discussion between a diverse group of stakeholders such as banks, non-bank financial institutions, other trade finance related organizations, and exporters, to gain a better understanding regarding current challenges facing U.S. exporters in accessing capital.

On November 18, 2016, the TFAC will hold its inaugural meeting. Members will be sworn-in, discuss the Council's operational structure, major challenges impacting the provision of trade finance as well as prospects to foster greater access to private sector financing for U.S. exporters, and key priorities to focus on during their term. Members will also hear from officials from the Department of Commerce and other agencies on the resources available to support our exporters in the trade finance area. The agenda may change to accommodate TFAC requirements. The final agenda will be posted on the Department of Commerce Web site for the Council *http://trade.gov/tfac/* at least a week prior to the meeting.

II. Public Participation

The public is invited to submit written statements for the TFAC's meeting. Statements must be received by 5:00 p.m. EST, November 11, 2016 by either of the following methods: (a) Electronic Submission: Submit statements electronically to Ericka Ukrow, U.S. Department of Commerce Trade Finance Advisory Council Designated Federal Officer, via email to *TFAC@trade.gov* ; or (b) Paper Submissions: Send paper statements to Ericka Ukrow, U.S. Department of Commerce Trade Finance Advisory Council Designated Federal Officer, Room 18002, 1401 Constitution Avenue NW., Washington, DC 20230. Statements will be posted on the TFAC Web site 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 are subject to public disclosure. You should submit only information that you wish to make publicly available.

III. Meeting Minutes

Copies of TFAC meeting minutes will be available within 30 days following the meeting.

Dated: October 27, 2016.

Paul Thanos

Director, Office of Finance and Insurance Industries.

[FR Doc. 2016–26572 Filed 11–2–16; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–979]

Initiation and Preliminary Results of Antidumping Duty Changed Circumstances Review: Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled Into Modules, From the People's Republic of China

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

SUMMARY: The Department of Commerce (the ''Department'') is simultaneously initiating, and issuing the preliminary results, of a changed circumstances review of the antidumping duty (''AD'') order on crystalline silicon photovoltaic cells, whether or not assembled into modules, (''solar cells'') from the People's Republic of China (''PRC'') regarding whether Zhejiang ERA Solar Technology Co., Ltd (''Zhejiang ERA'') is the successor-in-interest to Era Solar Co., Ltd (''Era Solar''). Based on the information on the record, we preliminarily determine that Zhejiang ERA is the successor-in-interest to Era Solar for purposes of the AD order on solar cells from the PRC and, as such, is entitled to Zhejiang ERA's cash

[16] Notably, the *Trade Facilitation and Trade Enforcement Act of 2015* removed from section 751(a)(2)(B) of the Act the provision directing the Department to instruct CBP to allow an importer the option of posting a bond or security in lieu of a cash deposit during the pendency of an NSR.

deposit rate with respect to entries of subject merchandise. Interested parties are invited to comment on these preliminary results.

DATES: Effective November 3, 2016.

FOR FURTHER INFORMATION CONTACT: Jeff Pedersen or Eli Lovely, AD/CVD Operations, Office IV, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–2769 and (2020 482–1593, respectively.

SUPPLEMENTARY INFORMATION:

Background

On December 7, 2012, the Department published the AD order on solar cells from the PRC in the **Federal Register**.[1] On August 31, 2016, Zhejiang ERA requested that the Department initiate an expedited changed circumstances review to determine that Zhejiang ERA is the successor-in-interest to Era Solar for AD purposes.[2] On September 12, 2016, Zhejiang ERA responded to a request for additional information from the Department issued on September 9, 2016.[3] We have received no comments on Zhejiang ERA's CCR Request.

Scope of the Order

The merchandise covered by the *Order* is crystalline silicon photovoltaic cells, whether or not assembled into modules, subject to certain exclusions.[4]

Imports of the subject merchandise are provided for under the following subheadings of the Harmonized Tariff Schedule of the United States (''HTSUS''): 8501.61.0000, 8507.20.80, 8541.40.6020, 8541.40.6030, and 8501.31.8000. While HTSUS subheadings are provided for convenience and customs purposes, the written description of the subject merchandise is dispositive.

Initiation of Changed Circumstances Review

Pursuant to section 751(b)(1) of the Tariff Act of 1930, as amended, (the ''Act'') and 19 CFR 351.216(d), the Department will conduct a changed circumstances review of an order upon receipt of information concerning, or of a request from an interested party for a review of, an order which shows changed circumstances sufficient to warrant a review of the order. In the past, the Department has used changed circumstances reviews to address the applicability of cash deposit rates after there have been changes in the name or structure of a respondent, such as a merger or spinoff (''successor-in-interest,'' or ''successorship,'' determinations). Thus, consistent with Department practice, the information submitted by Zhejiang ERA, which includes information regarding a name change, demonstrates changed circumstances sufficient to warrant a review.[5]

Therefore, in accordance with section 751(b)(1) of the Act and 19 CFR 351.216(d), the Department is initiating a changed circumstances review to determine whether Zhejiang ERA is the successor-in-interest to Era Solar.

Preliminary Determination

When it concludes that expedited action is warranted, the Department may publish the notice of initiation and preliminary results for a changed circumstances review concurrently.[6] The Department has combined the notice of initiation and preliminary results in successor-in-interest cases when sufficient documentation has been provided supporting the request to make a preliminary determination.[7] In this instance, because we have determined that the information necessary to support the request for a preliminary determination is on the record, we find that expedited action is warranted, and we are combining the notice of initiation and the notice of preliminary results in accordance with 19 CFR 351.221(c)(3)(ii).

In determining whether one company is the successor to another for purposes of applying the AD law, the Department examines a number of factors including, but not limited to, changes in: (1) Management, (2) production facilities, (3) suppliers, and (4) customer base.[8] While no one or several of these factors will necessarily provide a dispositive indication of succession, the Department will generally consider one company to be the successor to another company if its resulting operation is essentially the same as that of its predecessor.[9] Thus, if the evidence demonstrates that, with respect to the production and sale of the subject merchandise, the new company operates as the same business entity as the prior company, the Department will assign the new company the cash deposit rate of its predecessor.[10]

In its CCR Request and its Supplemental Response, Zhejiang ERA provided evidence demonstrating that it is essentially the same company as Era Solar.[11] According to the information provided, the principal owners remained the same both pre- and post-name change. Further, although the nine-person board of directors was reduced from nine directors to three directors as a result of changes to Era Solar's legal form, the ultimate owners continued to occupy positions on the board after the name change. With regard to management, eight of the nine managers maintained their positions after the company name change.[12] Regarding its production of the subject merchandise, Zhejiang ERA stated that its production facility is the same as that of Era Solar.[13] Zhejiang ERA also provided documentation showing that there has been no material changes in suppliers of inputs or services related to the production, sale and distribution of the subject merchandise [14] or in the customer base as a result of the name

[1] *See Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled Into Modules, From the People's Republic of China: Amended Final Determination of Sales at Less Than Fair Value, and Antidumping Duty Order,* 77 FR 73018 (December 7, 2012) (''*Order*'').

[2] *See* Letter from Zhejiang ERA to the Department regarding, ''Re. Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled Into Modules from the People's Republic of China: Request for Expedited Changed Circumstances Review'' (August 31, 2016) (''CCR Request'').

[3] *See* Letter from Hangzhou Sunny to the Department, regarding ''Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled Into Modules: Response to Supplemental Questionnaire of Zhejiang ERA Solar Technology Co., Ltd'' (September 12, 2016) (''Supplemental Response'').

[4] For a complete description of the Scope of the *Order, see* Memorandum to Paul Piquado, Assistant Secretary for Enforcement and Compliance, from Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, ''Initiation and Preliminary Results of Changed Circumstances Review: Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled Into Modules, from the People's Republic of China'' (''Preliminary Decision Memorandum''), dated concurrently with, and adopted by, this notice.

[5] *See* 19 CFR 351.216(d).

[6] *See* 19 CFR 351.221(c)(3)(ii).

[7] *See, e.g.,* Notice of Initiation and Preliminary Results of Antidumping Duty Changed Circumstances Review: Certain Softwood Lumber Products from Canada, 70 FR 50299 (August 26, 2005).

[8] *See, e.g., Initiation and Preliminary Results of Antidumping Duty Changed Circumstances Review: Multilayered Wood Flooring From the People's Republic of China,* 79 FR 48117, 48118 (August 15, 2014), unchanged in *Multilayered Wood Flooring From the People's Republic of China: Final Results of Changed Circumstances Review,* 79 FR 58740 (September 30, 2014).

[9] *Id.*

[10] *See Notice of Final Results of Changed Circumstances Review: Polychloroprene Rubber from Japan,* 69 FR 67890 (November 22, 2004) citing, *Brass Sheet and Strip from Canada: Notice of Final Results of Antidumping Duty Administrative Review,* 57 FR 20460 (May 13, 1992); and, *Certain Circular Welded Carbon Steel Pipes and Tubes from Taiwan: Initiation of Antidumping Duty Changed Circumstance Review,* 70 FR 17063 (April 4, 2005).

[11] *See,* generally, CCR Request and Supplemental Response.

[12] *Id.*

[13] *Id.*

[14] *Id.*

change.[15] Based on the foregoing, which is explained in greater detail in the Preliminary Decision Memorandum, we preliminarily determine that Zhejiang ERA is the successor-in-interest to Era Solar and, as such, that it is entitled to Zhejiang ERA's AD cash deposit rate with respect to entries of subject merchandise.

Should our final results remain the same as these preliminary results, effective the date of publication of the final results, we will instruct U.S. Customs and Border Protection to suspend liquidation of entries of subject merchandise exported by Zhejiang ERA at the AD cash deposit rate applicable to Era Solar.

Public Comment

Interested parties may submit case briefs not later than 14 days after the date of publication of this notice.[16] Rebuttal briefs, which must be limited to issues raised in case briefs, may be filed not later than seven days after the due date for case briefs.[17] Parties who submit case briefs or rebuttal briefs in this changed circumstances review are requested to submit with each argument: (1) A statement of the issue and (2) a brief summary of the argument with an electronic version included.[18]

Any interested party may request a hearing within 14 days of publication of this notice.[19] Hearing requests should contain the following information: (1) The party's name, address, and telephone number; (2) the number of participants; and (3) a list of the issues to be discussed. Oral presentations at the hearing will be limited to issues raised in the briefs. If a request for a hearing is made, parties will be notified of the time and date for the hearing to be held at the U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230 in a room to be determined.[20]

All submissions, with limited exceptions, must be filed electronically using Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (''ACCESS'').[21] An electronically filed document must be received successfully in its entirety by 5 p.m. Eastern Time (''ET'') on the due date. Documents excepted from the electronic submission requirements must be filed manually (*i.e.,* in paper form) with the APO/Dockets Unit in Room 18022 and stamped with the date and time of receipt by 5 p.m. ET on the due date.[22]

Unless extended, consistent with 19 CFR 351.216(e), we intend to issue the final results of this changed-circumstances review no later than 270 days after the date on which this review was initiated or within 45 days if all parties agree to the outcome of the review.

We are issuing and publishing this initiation and preliminary results notice in accordance with sections 751(b)(1) and 777(i)(1) of the Act and 19 CFR 351.216 and 351.221(c)(3).

Dated: October 27, 2016.

Paul Piquado,

Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2016–26600 Filed 11–2–16; 8:45 am]

BILLING CODE 3510–DS–P

[15] *Id.*

[16] The Department is exercising its discretion under 19 CFR 351.309(c)(1)(ii) to alter the time limit for the filing of case briefs.

[17] The Department is exercising its discretion under 19 CFR 351.309(d)(1) to alter the time limit for the filing of rebuttal briefs.

[18] *See* 19 CFR 351.309(c)(2) and (d)(2).

[19] The Department is exercising its discretion under 19 CFR 351.310(c) to alter the time limit for requesting a hearing.

[20] *See* 19 CFR 351.310(d).

[21] ACCESS is available to registered users at *https://access.trade.gov* and available to all parties in the Central Records Unit, Room B8024 of the main Department of Commerce building.

[22] *See Antidumping and Countervailing Duty Proceedings: Electronic Filing Procedures; Administrative Protective Order Procedures,* 76 FR 39263 (July 6, 2011).

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XE997

Fisheries of the South Atlantic; South Atlantic Fishery Management Council; Public Meeting

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

ACTION: Notice of public meeting of the South Atlantic Fishery Management Council's (Council) Scientific and Statistical Committee (SSC).

SUMMARY: The Council will hold a meeting of its SSC to review the available data for Spiny Lobster and make recommendations for setting the Overfishing Limit (OFL) and Acceptable Biological Catch (ABC).

DATES: The SSC meeting will be held via webinar on Monday, November 21, 2016, from 9 a.m. to 12 p.m.

ADDRESSES: The meeting will be held via webinar. The webinar is open to members of the public. Those interested in participating should contact Mike Errigo at the Council office (see **FOR FURTHER INFORMATION CONTACT**) to request an invitation providing webinar access information. Please request webinar invitations at least 24 hours in advance of the webinar.

Council address: South Atlantic Fishery Management Council, 4055 Faber Place Drive, Suite 201, N. Charleston, SC 29405.

FOR FURTHER INFORMATION CONTACT: Mike Errigo; 4055 Faber Place Drive, Suite 201, North Charleston, SC 29405; phone (843) 571–4366 or toll free (866) SAFMC–10; fax (843) 769–4520; email: *mike.errigo@safmc.net.*

SUPPLEMENTARY INFORMATION: This meeting is held to review the available data for *Spiny Lobster* and make recommendations for OFL and ABC. The SSC decided at their October 18–20, 2016 meeting in Charleston, SC that they did not have enough information to make recommendations of OFL and ABC for Spiny Lobster and requested a webinar be held to review the available information.

Items to be addressed during this meeting:

Review the available information for *Spiny Lobster* and provide recommendations of OFL and ABC for the Spiny Lobster fishery.

Special Accommodations

The meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to the Council office (see **ADDRESSES**) at least 5 business days prior to the meeting.

Note: The times and sequence specified in this agenda are subject to change.

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

Dated: October 28, 2016.

Tracey L. Thompson,

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

[FR Doc. 2016–26519 Filed 11–2–16; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration (NOAA)

Environmental Assessment (EA) for the Proposed Relocation of the Atmospheric Turbulence and Diffusion Division of the Air Resources Laboratory in Oak Ridge, TN

AGENCY: Office of Oceanic and Atmospheric Research (OAR), National Oceanic and Atmospheric Administration (NOAA), U.S. Department of Commerce (DOC).

ACTION: Notice of intent to prepare an EA; request for comments.

SUMMARY: NOAA announces its intention to prepare an EA in accordance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), for the proposed relocation of NOAA/OAR facilities in Oak Ridge, TN.

DATES: Written comments must be received on or before December 5, 2016.

ADDRESSES: Written comments on suggested alternatives and potential impacts should be sent to Barbara Shifflett, Management and Program Analyst, NOAA/ATDD, PO Box 2456, Oak Ridge, TN 37831. Comments may also be submitted via facsimile to 865–220–1733 or by email to *Barbara.Shifflett@noaa.gov.*

SUPPLEMENTARY INFORMATION: The proposed action would involve relocation of NOAA/OAR offices and laboratories within the Oak Ridge, TN area to a larger, modern facility located in an appropriate research setting. The Atmospheric Turbulence and Diffusion Division (ATDD), located in Oak Ridge, TN, is part of NOAA's Air Resources Laboratory (ARL). Research conducted at this laboratory includes experimental and theoretical research on air quality issues, urban dispersion studies and in-situ testbed development, and land-atmosphere interactions and the interactions with regional water budgets for representative U.S. ecosystems.

The current physical space for ATDD consists of four buildings that together provide office space, laboratory space, staging and assembly and a machine shop. In addition, six shipping/storage containers are used to securely store field equipment and supplies, meteorological instrumentation, and power systems for remote climate stations. The current ATDD facilities are approximately 17,573 square feet which includes office space, auditorium and kitchen space, warehouse and storage space and staging areas. Current space can house up to 36 staff, including full-time employees, visiting scientists and students, and contract employees.

ATDD needs additional space to accommodate offices for staff expansion, visiting scientists and students, as well as space for additional lab work, engineering assembly, sensor calibration and testing, and sensor prototyping and evaluation. NOAA/OAR needs at least 12,500 additional or 30,000 total square feet of space to effectively house personnel and equipment necessary to meet ATDD's mission.

Research programs at ATDD will continue over the next decade and beyond at approximately their current levels, with moderate growth in staffing to accommodate emerging programs associated with water and drought planning, climate testbeds and air-surface exchange research. Partnerships with several universities will continue and new partnerships will be established, with a resulting small influx of students and faculty for short and long-term visits. The need for shop, lab, and storage space for testing and evaluation of new sensor technologies will continue to grow.

Programs are often delayed by having to displace partially completed work from available space to complete a project or repair a system with a more urgent timeline. The existing facility severely limits ATDD's ability to implement a primary NOAA goal of working with private industry, universities, and national and international agencies to create and leverage partnerships for more effective research; we frequently encounter such opportunities, but are limited when offering space to accommodate visitors to work with our existing staff.

ATDD's property has historically been used by scientists as a testbed for many systems prior to their deployment into the field. Given the increase in traffic and commercial development in the local area, the testbed data are suspect with regards to accuracy of measurements and actual reliability.

The purpose of the public scoping process for this EA is to determine relevant issues that will influence the scope of the environmental analysis, including potential alternatives, and the extent to which those issues and impacts will be analyzed in the EA. Federal, state, and local agencies, along with other stakeholders that may be interested in or affected by NOAA's decision on this project are invited to participate in the scoping process and, if eligible, may request or be requested by NOAA to participate as a cooperating agency.

Dated: October 28, 2016.

Jason Donaldson,

Chief Financial Officer, Office of Oceanic and Atmospheric Research, National Oceanic and Atmospheric Administration.

[FR Doc. 2016–26497 Filed 11–2–16; 8:45 am]

BILLING CODE 3510–KD–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XE996

Mid-Atlantic Fishery Management Council (MAFMC); Public Meeting

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

ACTION: Notice; public meeting.

SUMMARY: The Mid-Atlantic Fishery Management Council (MAFMC) will convene a public peer review panel meeting.

DATES: The meeting will be held on Friday, November 18, 2016, from 9 a.m. to 5 p.m. See **SUPPLEMENTARY INFORMATION** for agenda details.

ADDRESSES: The meeting will be held at the DoubleTree by Hilton BWI Airport, 890 Elkridge Landing Rd., Linthicum Heights, MD 21090; telephone: (410) 859–8400.

Council address: Mid-Atlantic Fishery Management Council, 800 N. State Street, Suite 201, Dover, DE 19901; telephone: (302) 674–2331; Web site: *www.mafmc.org.*

FOR FURTHER INFORMATION CONTACT: Christopher M. Moore, Ph.D., Executive Director, Mid-Atlantic Fishery Management Council; telephone: (302) 526–5255.

SUPPLEMENTARY INFORMATION: The MAFMC will convene a peer review panel consisting of members of the MAFMC's Scientific and Statistical Committee (SSC) and other outside experts, to review a summer flounder allocation model project. The MAFMC contracted the development of this project to inform consideration of potential changes to the allocation of annual catch and landings limits between the commercial and recreational sectors of the summer flounder fishery. This analysis aims to determine which allocations would maximize benefits to the commercial and recreational sectors. The results of this project and peer review are scheduled to be presented to the MAFMC in December 2016.

A detailed agenda and background documents will be made available on the Council's Web site (*www.mafmc.org*) prior to the meeting.

Special Accommodations

The meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aid should be directed to M.

Jan Saunders, (302) 526–5251, at least 5 days prior to the meeting date.

Dated: October 28, 2016.

Tracey L. Thompson,

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

[FR Doc. 2016–26518 Filed 11–2–16; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[0648–XF008]

Endangered and Threatened Species; Take of Anadromous Fish

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

ACTION: Applications for two new scientific research permits and 13 permit renewals.

SUMMARY: Notice is hereby given that NMFS has received 15 scientific research permit application requests relating to Pacific salmon, steelhead, eulachon, and green sturgeon. The proposed research is intended to increase knowledge of species listed under the Endangered Species Act (ESA) and to help guide management and conservation efforts. The applications may be viewed online at: *https://apps.nmfs.noaa.gov/preview/preview_open_for_comment.cfm.*

DATES: Comments or requests for a public hearing on the applications must be received at the appropriate address or fax number (see **ADDRESSES**) no later than 5 p.m. Pacific standard time on *December 5, 2016.*

ADDRESSES: Written comments on the applications should be sent to the Protected Resources Division, NMFS, 1201 NE Lloyd Blvd., Suite 1100, Portland, OR 97232–1274. Comments may also be sent via fax to 503–230–5441 or by email to *nmfs.nwr.apps@noaa.gov* (include the permit number in the subject line of the fax or email).

FOR FURTHER INFORMATION CONTACT: Rob Clapp, Portland, OR (ph.: 503–231–2314), Fax: 503–230–5441, email: *Robert.Clapp@noaa.gov*). Permit application instructions are available from the address above, or online at *https://apps.nmfs.noaa.gov.*

SUPPLEMENTARY INFORMATION:

Species Covered in This Notice

The following listed species are covered in this notice:

Chinook salmon (*Oncorhynchus tshawytscha*): Threatened Lower Columbia River (LCR); threatened Puget Sound (PS); threatened Snake River (SR) spring/summer-run; threatened SR fall-run; endangered Upper Columbia River (UCR) spring-run; threatened Upper Willamette River (UWR).

Steelhead (*O. mykiss*): Threatened LCR; threatened Middle Columbia River (MCR); threatened PS; threatened SR; threatened UCR; threatened UWR

Chum salmon (*O. keta*): Threatened Hood Canal Summer-run (HCS); threatened Columbia River (CR).

Coho salmon (*O. kisutch*): Threatened LCR; threatened Oregon Coast (OC) coho.

Sockeye salmon (*O. nerka*): Threatened Ozette Lake (OL); endangered SR.

Eulachon (*Thaleichthys pacificus*): Threatened Southern (S).

Green sturgeon (*Acipenser medirostris*): Threatened Southern (S).

Authority

Scientific research permits are issued in accordance with section 10(a)(1)(A) of the ESA (16 U.S.C. 1531 *et seq.*) and regulations governing listed fish and wildlife permits (50 CFR 222–226). NMFS issues permits based on findings that such permits: (1) Are applied for in good faith; (2) if granted and exercised, would not operate to the disadvantage of the listed species that are the subject of the permit; and (3) are consistent with the purposes and policy of section 2 of the ESA. The authority to take listed species is subject to conditions set forth in the permits.

Anyone requesting a hearing on an application listed in this notice should set out the specific reasons why a hearing on that application would be appropriate (see **ADDRESSES**). Such hearings are held at the discretion of the Assistant Administrator for Fisheries, NMFS.

Applications Received

Permit 1135–9R

The United States Geological Survey (USGS) is seeking to renew, for five years, a research permit that currently allows them to take juvenile LCR steelhead in the Wind River subbasin (Washington). The purpose of the USGS study is to provide information on the growth, survival, habitat use, and life-histories of LCR steelhead. This information would improve understanding of habitat associations and life history strategies for LCR steelhead in the Wind River and that, in turn, would help state, tribal, and Federal efforts to restore LCR steelhead. The USGS proposes to capture juvenile LCR steelhead using backpack electrofishing equipment, hold the fish in aerated buckets, anaesthetize them with MS–222, measure length and weight, tag age-0 and age-1 fish with passive integrated transponders (PIT-tags), and release all fish at the site of collection after they recover from anesthesia. The researchers do not propose to kill any fish but a small number may die as an unintended result of research activities.

Permit 1175–9R

The Gifford Pinchot National Forest (GPNF) is seeking to renew, for five years, a research permit that currently allows them to take juvenile PS Chinook salmon, PS steelhead, MCR steelhead, LCR Chinook salmon, LCR coho salmon, and LCR steelhead in the Middle Columbia-Hood and Puyallup subbasins (Washington). The purpose of this research is to describe fish species presence, distribution, spawning areas, and habitat conditions on lands that the GPNF administers. The GPNF and other agencies would use that information in forest management, habitat restoration, and species recovery efforts. The GPNF proposes to use backpack electrofishing and seines to capture juvenile salmonids, hold fish for short periods in aerated buckets, identify, and then release the fish. The researchers do not propose to kill any fish, but a small number may die as an unintentional result of research activities.

Permit 1345–8R

The Washington State Department of Fish and Wildlife (WDFW) is seeking to renew, for five years, a research permit that currently allows them to take juvenile and adult LCR Chinook salmon, PS Chinook salmon, LCR coho salmon, LCR steelhead, and PS steelhead. The WDFW administers a multitude of water bodies through the state of Washington, and this permit would provide them with coverage throughout Puget Sound and the Lower Columbia River basin. The purpose of the WDFW study is to assess inland game fish communities and thereby improve fishery management. The research would benefit salmonids by helping managers write warm-water fish species harvest regulations that reduce potential impacts on listed salmonids. The WDFW proposes to capture fish using boat electrofishing, fyke nets, and gillnets. After being captured, the listed salmon and steelhead would be placed in aerated live wells, identified, and released. The researchers do not propose to kill any listed fish being

captured, but a small number may die as an unintended result of the activities.

Permit 1386–9R

The Washington Department of Ecology (WDOE) is seeking to renew, for five years, a research permit that currently allows them to take juvenile and adult LCR Chinook salmon, PS Chinook salmon, SR spring/summer-run Chinook salmon, SR fall-run Chinook salmon, UCR spring-run Chinook salmon, CR chum salmon, HC summer-run chum salmon, LCR coho salmon, OL sockeye salmon, LCR steelhead, MCR steelhead, PS steelhead, SR Basin steelhead, and UCR steelhead throughout the state of Washington. The purpose of the research is to investigate the occurrence and concentrations of toxic contaminants in non-anadromous freshwater fish tissue, sediment, and water at sites throughout Washington. The WDOE conducts this research in order to meet Federal and state regulatory requirements. This research would benefit listed species by identifying toxic contaminants in fish and informing pollution control actions. The WDOE proposes to capture fish using various methods including backpack and boat electrofishing, beach seining, block, fyke, and gill netting, and angling. All captured salmon and steelhead would either be released immediately or held temporarily in an aerated live well to help them recover before release. The researchers do not propose to kill any fish but a small number may die as an unintended result of research activities.

Permit 1564–5R

The University of Washington (UW) is seeking to renew, for five years, a research permit that currently allows them to take juvenile PS Chinook salmon and PS steelhead. The purpose of the UW study is to monitor the success of habitat restoration projects in the Duwamish River estuary, the Snohomish River estuary, and Shilshole Bay, Washington, by documenting changes in population characteristics among Chinook salmon in response to estuarine habitat restoration actions. The habitat restoration work would be conducted by several entities, but primarily by the Port of Seattle and the City of Seattle. The habitat restoration projects are designed to improve habitats that Chinook salmon use for rearing and migration. Monitoring the restoration sites would help determine the projects' effectiveness and thereby guide future restoration projects for the benefit of listed salmonids in the area. The UW proposes to capture fish using enclosure nets and beach seines. The captured fish would be held in buckets of aerated water. Juvenile salmonids would be anesthetized, checked for marks and tags, measured, and released. Some individuals would have their stomach contents sampled via non-lethal gastric lavage. The researchers do not propose to kill any listed fish being captured, but a small number may die as an unintended result of the activities.

Permit 1585–4R

The Washington State Department of Natural Resources (WDNR) is seeking to renew, for five years, a research permit that currently allows them to take juvenile PS Chinook salmon, HCS chum salmon, and PS steelhead. The work would be carried out in many central Puget Sound tributaries that originate in the Olympic and Cascade Mountain Ranges in Mason, Kitsap, King, Pierce, Thurston, Snohomish, and Lewis Counties, Washington. The purpose of the WDNR study is to determine fish presence or absence in streams greater than two feet in width between ordinary high water marks and with gradients of less than 20 percent. The information gathered would be used to determine salmonid presence and distribution and thereby inform land management decisions on WDNR holdings. The WDNR would use this information on fish-bearing streams to benefit the species by removing existing man-made fish barriers or possibly replacing them with structures that fish can pass over or through. The WDNR proposes to capture fish using backpack electrofishing equipment. The captured fish would be identified and released back to the pools from which they came. In some cases, the researchers may not actually capture any fish, but would merely note their presence. The researchers do not propose to kill any listed fish being captured, but a small number may die as an unintended result of the activities.

Permit 1587–5R

The USGS is seeking to renew a research permit, for five years, that currently allows them to take juvenile HCS chum salmon, PS Chinook salmon, and PS steelhead. The USGS research may also cause them to take adult S eulachon, for which there are currently no ESA take prohibitions. The work would take place in the northern Puget Sound (San Juan Island and Samish Bay), Whidbey Basin (Skagit Bay, Snohomish River delta), southern Puget Sound (Nisqually Delta), Admiralty Inlet (including Foulweather Bluff, Kilisut Harbor, and Oak Bay), and the Strait of Juan de Fuca. The research would be divided into two projects: (1) Restoration of Puget Sound Deltas and other nearshore restoration sites and (2) Effects of Urbanization on Nearshore Ecosystems. The purpose of the USGS study is to understand large river delta ecosystems and the physio-chemical processes related to nearshore habitat alterations that modify trophic web, community dynamics, and forage fish populations. The USGS would sample once per month in each area from April through September, but extra sampling (1–8 days per quarter) may sometimes be needed. The USGS proposes to capture fish primarily by using lampara nets, but beach seines, dip nets, gill nets, and angling may also be used. The captured fish would be identified to species, weighed, and measured. All listed fish would be immediately processed and released near their capture location. Forage fish would be counted, measured, weighed, and some may be sacrificed for otoliths, genetics, and fish health assays. All sampling plans would be reviewed and approved by the USGS Institutional Animal Care and Use Committee before being implemented. The researchers do not propose to kill any listed fish being captured, but a small number may die as an unintended result of the activities.

Permit 1598–4R

The Washington State Department of Transportation (WSDOT) is seeking to renew, for five years, a research permit that currently allows them to take juvenile PS Chinook salmon, UCR spring-run Chinook salmon, SR spring/summer-run Chinook salmon, SR fall-run Chinook salmon, LCR Chinook salmon, HCS chum salmon, CR chum salmon, LCR coho salmon, OL sockeye salmon, SR sockeye salmon, LCR steelhead, PS steelhead, MCR steelhead, SR steelhead, and UCR steelhead. The WSDOT research may also cause them to take eulachon, for which there are currently no ESA take prohibitions. Sample sites would be located throughout the state of Washington. The purpose of the WSDOT study is to determine the distribution and diversity of anadromous fish species in waterbodies crossed by or adjacent to the state transportation systems (highways, railroads, and/or airports). This information would be used to assess the impacts that projects proposed at those facilities may have on listed species. The research would benefit the listed species by helping WSDOT minimize project impacts on listed fish to the greatest extent possible. Depending on the size of the stream system, the WSDOT proposes to capture fish using dip nets, stick seines, baited gee minnow traps, or backpack

electrofishing. The captured fish would be identified to species and immediately released. The researchers do not propose to kill any listed fish being captured, but a small number may die as an unintended result of the activities.

Permit 16069–2R

The City of Portland (COP) is seeking to renew, for five years, a research permit that currently allows them to take juvenile and adult MCR steelhead, UCR spring Chinook salmon, UCR steelhead, SR spring/summer-run Chinook salmon, SR fall-run Chinook salmon, SR steelhead, SR sockeye salmon, LCR Chinook salmon, LCR coho salmon, LCR steelhead, CR chum salmon, UWR Chinook salmon, UWR steelhead, OC coho salmon, and S green sturgeon in the Columbia and Willamette rivers and tributaries (Oregon). The COP research may also cause them to take adult S eulachon, for which there are currently no ESA take prohibitions. This research is part of the Portland Watershed Management Plan, which aims to improve watershed health in the Portland area. In this program, project personnel sample 37 sites annually across all Portland watersheds for hydrology, habitat, water chemistry, and biological communities. The research would benefit listed salmonids by providing information to assess watershed health, status of critical habitat, effectiveness of watershed restoration actions, and compliance with regulatory requirements. The City of Portland proposes to capture juvenile fish using backpack and boat electrofishing, hold fish in a bucket of aerated water, take caudal fin clips for genetic analysis, and release fish at a point near their capture site that would be chosen to minimize the likelihood of recapture. The researchers would avoid contact with adult fish. The researchers do not propose to kill any fish but a small number may die as an unintended result of research activities.

Permit 16666–2R

The U.S. Fish and Wildlife Service (FWS) is seeking to renew, for five years, a research permit that currently allows them to take juvenile LCR coho salmon and adult LCR Chinook salmon in Abernathy Creek (Washington). The goal of this research is to determine the natural reproductive success and relative fitness of hatchery origin and natural-origin steelhead and assess the overall demographic effects of hatchery fish supplementation in Abernathy Creek relative to two adjacent control streams. The research would benefit listed salmonids by producing data to be used in hatchery and genetic management plans. Steelhead are not listed in these streams, but the FWS have captured juvenile LCR coho salmon and observed adult LCR Chinook salmon in previous years. The FWS proposes capture, handle, and release juvenile LCR coho salmon during backpack electrofishing surveys. The researchers would avoid electrofishing near adult coho and Chinook salmon. The researchers do not expect to kill any listed fish, but a small number may die as an unintended result of the research activities.

Permit 16702–3R

The Northwest Fisheries Science Center (NWFSC) is seeking to renew for five years a research permit that currently allows them to take juvenile PS Chinook salmon and PS steelhead. The NWFSC research may also cause them to take adult S eulachon, for which there are currently no ESA take prohibitions. The survey sites would be located in the Snohomish River estuary. The purpose of the NWFSC study is to monitor habitat use of juvenile PS Chinook salmon in response to estuary restoration at the Qwuloolt restoration site by levee breach and subsequent tidal inundation in late 2015. Specifically, the goals are to identify the life history types present, their spatial and temporal distribution, their feeding ecology, and the interactions with other biota. The research would benefit the listed species by determining if the restoration strategies are effective in restoring fish habitat and populations. Sampling would occur year round; biweekly from February to September and then once a month from October to January. The NWFSC proposes to capture fish using beach seines (mainstem habitat) and fyke traps (tidal channels). The researchers would intentionally kill up to 15 juvenile PS Chinook via a lethal dose of MS–222. Specimens would be taken for stomach, otolith, and other tissue sampling. Any PS Chinook unintentionally killed during the research would be used in lieu of a fish that would otherwise be sacrificed. All other juvenile PS Chinook and all PS steelhead captured would be counted, measured (fork length), and released.

Permit 16866–3R

The Oregon State University (OSU) Department of Fisheries and Wildlife is seeking to renew, for five years, a research permit that currently allows them to take adult and juvenile LCR Chinook salmon, LCR coho salmon, LCR steelhead, CR chum salmon, UWR Chinook salmon, UWR steelhead, MCR steelhead, UCR spring Chinook salmon, UCR steelhead, SR spring/summer-run Chinook salmon, SR fall-run Chinook salmon, and SR steelhead in the Willamette River basin (Oregon). The OSU research may also cause them to take adult S eulachon, for which there are currently no ESA take prohibitions. Objectives of the study are to (1) assess the status of native and non-native fish communities, (2) implement long-term monitoring, (3) compile and summarize existing reports and unpublished data on fish communities in the Willamette River from OSU research, Oregon Department of Fish and Wildlife (ODFW) research, and EPA research, and (4) measure water quality in known cold water refugia to determine their suitability as fish habitat. The study would benefit listed salmonids by providing data for state and Federal collaborators to use in their management and planning of conservation, restoration, and recovery efforts. The OSU researchers propose to capture juvenile salmonids using backpack and boat electrofishing, hold fish in aerated fresh water, and then identify, measure, and release juvenile fish. Adult fish may be encountered but would not be netted. The researchers do not propose to kill any fish but a small number may die as an unintended result of research activities.

Permit 20492

The ODFW is seeking to renew, for five years, a research permit for fisheries research in the Willamette and Columbia basins (Oregon) and on the Oregon coast. ODFW proposes to take juvenile UCR spring-run Chinook salmon, UCR steelhead, SR spring/summer-run Chinook salmon, SR fall-run Chinook salmon, SR Basin steelhead, SR sockeye salmon, MCR steelhead, LCR Chinook salmon, LCR coho salmon, LCR steelhead, CR chum salmon, UWR Chinook salmon, UWR steelhead, and OC coho salmon, and adult S green sturgeon. The ODFW research may also cause them to take adult S eulachon, for which there are currently no ESA take prohibitions. The new permit would cover the following projects: (1) Warm-water and Recreational Game Fish Management, (2) District Fish Population Sampling in the Upper Willamette Basin, and (3) Salmonid Assessment and Monitoring in the Deschutes River. The research would provide information on fish population structure, abundance, genetics, disease occurrences, and species interactions. This information would be used to direct management actions to benefit listed species. Juvenile salmonids would be collected using

boat electrofishing. Some fish would be anesthetized, sampled for length and weight, allowed to recover from the anesthesia, and released. Most salmonids would be allowed to swim away after being electroshocked, or they would be netted and released immediately. The ODFW does not intend to kill any of the fish being captured, but a small number may die as an unintended result of the activities.

Permit 20535

The U.S. Army Corps of Engineers (USACE) is seeking a three-year research permit to annually take juvenile PS Chinook salmon and PS steelhead in the lower Duwamish River (Washington). The USACE research may also cause them to take adult S eulachon, for which there are currently no ESA take prohibitions. The purpose of the USACE study is to collect starry flounder (*Platichthys stellatus*) and shiner surfperch (*Cymatogaster aggregate*) for tissue sampling and PCB congener analysis. The research would benefit the listed species by enhancing the understanding of contaminant partitioning within the food web near the Lower Duwamish Waterway Superfund Site. The USACE proposes to capture fish using beach seines. All listed fish are released would be captured, handled, and released. The researchers do not propose to kill any listed fish being captured, but a small number may die as an unintended result of the activities.

Permit 20659

The FWS is seeking a five-year research permit to annually take juvenile PS Chinook salmon and PS steelhead from Lake Washington and its tributaries (King County, Washington state). The purposes of the FWS study are (1) to test how attracted Chinook salmon are to different types of artificial lighting, and (2) to examine juvenile Chinook salmon abundance and diets at the mouths of two non-natal tributaries in the City of Seattle. The research would benefit the listed species by (1) providing better information to land resource managers on how best to reduce the effects of nighttime artificial lighting on juvenile Chinook salmon while maintaining appropriate lighting for safety considerations and (2) understanding how juvenile Chinook salmon use urban streams during base flow conditions and after rain events. The FWS proposes to capture fish using beach seines. All PS steelhead and the majority of the PS Chinook salmon would be immediately released after capture. A subset of the juvenile PS Chinook would be anesthetized with MS–222, measured for length, undergo gastric lavage (non-natal stream surveys only), and released after they have recovered. The researchers do not propose to kill any listed fish being captured, but a small number may die as an unintended result of the activities.

This notice is provided pursuant to section 10(c) of the ESA. NMFS will evaluate the applications, associated documents, and comments submitted to determine whether the applications meet the requirements of section 10(a) of the ESA and Federal regulations. The final permit decisions will not be made until after the end of the 30-day comment period. NMFS will publish notice of its final action in the **Federal Register**.

Dated: October 31, 2016.

Angela Somma,

Chief, Endangered Species Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2016–26530 Filed 11–2–16; 8:45 am]

BILLING CODE 3510–22–P

COMMISSION OF FINE ARTS

Notice of Meeting

The next meeting of the U.S. Commission of Fine Arts is scheduled for 17 November 2016, at 9:00 a.m. in the Commission offices at the National Building Museum, Suite 312, Judiciary Square, 401 F Street NW., Washington DC 20001–2728. Items of discussion may include buildings, parks and memorials.

Draft agendas and additional information regarding the Commission are available on our Web site: *www.cfa.gov.* Inquiries regarding the agenda and requests to submit written or oral statements should be addressed to Thomas Luebke, Secretary, U.S. Commission of Fine Arts, at the above address; by emailing *cfastaff@cfa.gov;* or by calling 202–504–2200. Individuals requiring sign language interpretation for the hearing impaired should contact the Secretary at least 10 days before the meeting date.

Dated 24 October 2016, in Washington, DC.

Thomas Luebke,

Secretary.

[FR Doc. 2016–26306 Filed 11–2–16; 8:45 am]

BILLING CODE M

DEPARTMENT OF DEFENSE

Office of the Secretary

Judicial Proceedings Since Fiscal Year 2012 Amendments Panel (Judicial Proceedings Panel); Notice of Federal Advisory Committee Meeting

AGENCY: Department of Defense.

ACTION: Notice of meeting.

SUMMARY: The Department of Defense is publishing this notice to announce the following Federal Advisory Committee meeting of the Judicial Proceedings Since Fiscal Year 2012 Amendments Panel (''the Judicial Proceedings Panel'' or ''the Panel''). The meeting is open to the public.

DATES: A meeting of the Judicial Proceedings Panel will be held on Friday, November 18, 2016. The public session will begin at 9:00 a.m. and end at 3:45 p.m.

ADDRESSES: Judicial Proceedings Panel, One Liberty Center, Executive Conference Center, 14th Floor, 875 N. Randolph Street, Arlington, Virginia 22203.

FOR FURTHER INFORMATION CONTACT: Ms. Julie Carson, Judicial Proceedings Panel, One Liberty Center, Suite 150, 875 N. Randolph Street, Arlington, Virginia 22203. Email: *whs.pentagon.em.mbx.judicial-panel@mail.mil.* Phone: (703) 693–3849. Web site: *http://jpp.whs.mil.*

SUPPLEMENTARY INFORMATION: This public meeting is being held under the provisions of the Federal Advisory Committee Act of 1972 (5 U.S.C., Appendix, as amended), the Government in the Sunshine Act of 1976 (5 U.S.C. 552b, as amended), and 41 CFR 102–3.150.

Purpose of the Meeting: In section 576(a)(2) of the National Defense Authorization Act for Fiscal Year 2013 (Pub. L. 112–239), as amended, Congress tasked the Judicial Proceedings Panel to conduct an independent review and assessment of judicial proceedings conducted under the Uniform Code of Military Justice (UCMJ) involving adult sexual assault and related offenses since the amendments made to the UCMJ by section 541 of the National Defense Authorization Act for Fiscal Year 2012 (Pub. L. 112–81; 125 Stat. 1404), for the purpose of developing recommendations for improvements to such proceedings. At this meeting, the Panel will receive a briefing from a representative of the Joint Service Committee on Military Justice on revisions to the Manual for Courts-

Martial and will hold deliberations on the topic of victims' appellate rights. The Panel will end the meeting with a planning session to discuss the way ahead for future JPP meetings and reports.

Agenda

8:30 a.m.–9:00 a.m. Administrative Work (41 CFR 102–3.160, not subject to notice & open meeting requirements)
9:00 a.m.–9:15 a.m. Welcome and Introduction
—Designated Federal Official Opens Meeting
—Remarks of the Chair
9:15 a.m.–10:15 a.m. Joint Service Committee on Military Justice Update on Revisions to the Manual for Courts-Martial
—Representative from the Joint Service Committee on Military Justice
10:15 a.m.–12:15 p.m. Deliberations on Victims' Appellate Rights
—Service representatives and civilian advocates available to answer Panel questions
12:15 p.m.–1:15 p.m. Lunch
1:15 p.m.–2:45 p.m. Deliberations on Victims' Appellate Rights (Continued)
—Service representatives and civilian advocates available to answer Panel questions
2:45 p.m.–3:30 p.m. JPP Planning Session
3:30 p.m.–3:45 p.m. Public Comment
3:45 p.m. Meeting Adjourned

Availability of Materials for the Meeting: A copy of the November 18, 2016 public meeting agenda and any updates or changes to the agenda, including individual speakers not identified at the time of this notice, as well as other materials provided to Panel members for use at the public meeting, may be obtained at the meeting or from the Panel's Web site at *http://jpp.whs.mil.*

Public's Accessibility to the Meeting: Pursuant to 5 U.S.C. 552b and 41 CFR 102–3.140 through 102–3.165, and the availability of space, this meeting is open to the public. Seating is limited and is on a first-come basis. Visitors are required to sign in at the One Liberty Center security desk and must leave government-issued photo identification on file while in the building. Department of Defense Common Access Card (CAC) holders who do not have authorized access to One Liberty Center must provide an alternate form of government-issued photo identification to leave on file with security while in the building. All visitors must pass through a metal detection security screening.

Special Accommodations: Individuals requiring special accommodations to access the public meeting should contact the Judicial Proceedings Panel at *whs.pentagon.em.mbx.judicial-panel@mail.mil* at least five (5) business days prior to the meeting so that appropriate arrangements can be made.

Procedures for Providing Public Comments: Pursuant to 41 CFR 102–3.140 and section 10(a)(3) of the Federal Advisory Committee Act of 1972, the public or interested organizations may submit written comments to the Panel about its mission and topics pertaining to this public session. Written comments must be received by the JPP at least five (5) business days prior to the meeting date so that they may be made available to the Judicial Proceedings Panel for their consideration prior to the meeting. Written comments should be submitted via email to the Judicial Proceedings Panel at *whs.pentagon.em.mbx.judicial-panel@mail.mil* in the following formats: Adobe Acrobat or Microsoft Word. Please note that since the Judicial Proceedings Panel operates under the provisions of the Federal Advisory Committee Act, as amended, all written comments will be treated as public documents and will be made available for public inspection. If members of the public are interested in making an oral statement pertaining to the agenda for the public meeting, a written statement must be submitted as described in this notice along with a request to provide an oral statement. After reviewing the written comments and the oral statement, the Chairperson and the Designated Federal Official will determine who will be permitted to make an oral presentation of their issue during the public comment portion of this meeting. This determination is at the sole discretion of the Chairperson and Designated Federal Official, will depend on the time available and relevance to the Panel's activities for that meeting, and will be on a first-come basis. When approved in advance, oral presentations by members of the public will be permitted from 3:30 p.m. to 3:45 p.m. on November 18, 2016 in front of the Panel members.

Committee's Designated Federal Official: The Panel's Designated Federal Official is Ms. Maria Fried, Department of Defense, Office of the General Counsel, 1600 Defense Pentagon, Room 3B747, Washington, DC 20301–1600.

Dated: October 31, 2016.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2016–26607 Filed 11–2–16; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF EDUCATION

NCER–NPSAS Grants—Connecting Students 2017: Testing the Effectiveness of FAFSA Interventions on College Outcomes; ED–2016–ICCD–0112; Correction

AGENCY: Department of Education.

ACTION: Correction notice.

SUMMARY: On October 21, 2016 the U.S. Department of Education published a 60-day comment period notice in the **Federal Register** (Page 72582, Column 2 and 3; Page 72583, Column 1) seeking public comment for an information collection entitled, ''NCER–NPSAS Grants—Connecting Students 2017: Testing the Effectiveness of FAFSA Interventions on College Outcomes.'' The title and burden hours were incorrect. The correct title is ''NCER–NPSAS Grant Study—Connecting Students with Financial Aid (CSFA) 2017: Testing the Effectiveness of FAFSA Interventions on College Outcomes'', and the burden hours are 6,808.

The Acting Director, Information Collection Clearance Division, Office of the Chief Privacy Officer, Office of Management, hereby issues a correction notice as required by the Paperwork Reduction Act of 1995.

Dated: October 31, 2016.

Kate Mullan,

Acting Director, Information Collection Clearance Division, Office of the Chief Privacy Officer, Office of Management.

[FR Doc. 2016–26568 Filed 11–2–16; 8:45 am]

BILLING CODE P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP17–4–000]

Gulf South Pipeline Company, LP; Notice of Request Under Blanket Authorization

Take notice that on October 21, 2016, Gulf South Pipeline Company, LP (Gulf South), 9 Greenway Plaza, Suite 2800, Houston, Texas 77046 filed in Docket No. CP17–4–000, filed a prior notice request pursuant to sections 157.205

and 157.216 of the Federal Energy Regulatory Commission's regulations under the Natural Gas Act (NGA) and Gulf South's blanket authorizations issued in Docket Nos. CP82–430–000. Gulf South seeks authorization to abandon on compressor units and associated facilities, all as more fully set forth in the application which is on file with the Commission and open to public inspection. The filing may also be viewed on the web 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, (866) 208–3676 or TTY, (202) 502–8659.

Gulf South proposes to abandon facilities at its Napoleonville Compressor Station, located in Assumption Parish, Louisiana. Gulf South proposes to abandon two 1,100 horsepower reciprocating units and abandon appurtenant facilities. Gulf South states the units have been idle since 2006 and are now in need of repair or replacement, it claims that the most prudent course of action is to abandon the units and that the proposed abandonment will not result in a material decrease in service to customers.

Any questions regarding this Application should be directed to Kathy D. Fort, Manager, Certificates and Tariffs, Gulf South Pipeline Company, LP, 9 Greenway Plaza, Suite 2800, Houston, Texas 77046, by phone (270) 688–6825, by fax (713) 479–1745, or by email at *kathy.fort@bwpmlp.com.*

Any person or the Commission's Staff may, within 60 days after the 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 Commission's 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 protest. If a protest is filed and not withdrawn within 30 days after the time allowed for filing a protest, the instant request shall be treated as an application for authorization pursuant to section 7 of the NGA.

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.

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 via the internet in lieu of paper. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site (*www.ferc.gov*) under the ''e-Filing'' link. 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.

Dated: October 28, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–26603 Filed 11–2–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 14510–001]

FFP Project 124, LLC; 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.:* 14510–001.

c. *Date Filed:* August 24, 2016.

d. *Submitted By:* FFP Project 124, LLC.

e. *Name of Project:* Red River Lock and Dam No. 1 Hydroelectric Project.

f. *Location:* On the Red River, at the U.S. Army Corps of Engineers' Red River Lock and Dam No. 1, near the Town of Marksville in Catahoula Parish, Louisiana.

g. *Filed Pursuant to:* 18 CFR 5.3 of the Commission's regulations.

h. *Potential Applicant Contact:* Erik Steimle, Vice President, Development, Rye Development, LLC, 745 Atlantic Avenue, 8th Floor, Boston, MA 02111; (617) 701–3288; email—*erik@ryedevelopment.com.*

i. *FERC Contact:* Allan Creamer at (202) 502–8365; or email at *allan.creamer@ferc.gov.*

j. FFP Project 124, LLC filed its request to use the Traditional Licensing Process on August 24, 2016. FFP Project 124, LLC provided public notice of its request on October 20, 2016. In a letter dated October 26, 2016, the Director of the Division of Hydropower Licensing approved FFP Project 124, LLC's 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/or NOAA Fisheries under section 7 of the Endangered Species Act and the joint agency regulations thereunder at 50 CFR, Part 402; and NOAA Fisheries under section 305(b) of the Magnuson-Stevens Fishery Conservation and Management Act and implementing regulations at 50 CFR 600.920. We are also initiating consultation with the Louisiana State Historic Preservation Officer, 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 FFP Project 124, LLC as the Commission's non-federal representative for carrying out informal consultation pursuant to section 7 of the

Endangered Species Act and section 305(b) of the Magnuson-Stevens Fishery Conservation and Management Act; and consultation pursuant to section 106 of the National Historic Preservation Act.

m. FFP Project 124, LLC 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. 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: October 26, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–26591 Filed 11–2–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 7656–013]

John A. Dodson; Notice of Meeting

a. *Project Name and Number:* Buttermilk Falls Project No. 7656.

b. *Date and Time of Meeting:* November 30, 2016, 2:00 p.m.–3:00 p.m. EST.

c. *Place:* Teleconference.

d. *FERC Contact:* Ashish Desai, *Ashish.Desai@ferc.gov,* (202) 502–8370.

e. *Purpose of Meeting:* Commission staff is holding the teleconference to discuss potentially the rerouting of the penstock, repairing the powerhouse, and the property rights of lands within the project boundary. In addition, staff will discuss the application to transfer the project license from Mr. John A. Dodson to the Village of Highland Falls—High Point Utility.

f. All local, state, and federal agencies, Indian tribes, and other interested parties are invited to participate by phone. Please call Ashish Desai at (202) 502–8370 or email at *Ashish.Desai@ferc.gov* by November 25, 2016 to receive specific instructions on how to participate.

Dated: October 26, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–26590 Filed 11–2–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL17–12–000]

Lee County, Florida; Notice of Petition for Declaratory Order

Take notice that on October 27, 2016, pursuant to Rule 207 of the Federal Energy Regulatory Commission's (Commission) Rules of Practice and Procedure,[1] Lee County, Florida filed a petition for declaratory order confirming that, as a political subdivision of the State of Florida, section 201(f) of the Federal Power Act (FPA), 16 U.S.C. 824(f) exempts it from Commission rate regulation under section 205 and 206 of the FPA, 16 U.S.C. 824(d) and (c), all as more fully explained in the petition.

Any person desiring to intervene or to protest in this proceeding must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. 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 FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

[1] 18 CFR 385.207 (2016).

Persons unable to file electronically should submit an original and 5 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

The filings in the above proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also 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 25, 2016.

Dated: October 28, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–26544 Filed 11–2–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Number: PR16–73–001.

Applicants: Bridgeline Holdings, L.P.

Description: Tariff filing per 284.123(b), (e): Bridgeline Holdings Amended SOC 10–25–16 to be effective 10/1/2016; Filing Type: 1270.

Filed Date: 10/26/2016.

Accession Number: 201610265026.

Comments Due: 5 p.m. ET 11/16/16.

284.123(g) Protests Due: 5 p.m. ET 11/16/16.

Docket Numbers: RP17–63–000.

Applicants: Trailblazer Pipeline Company LLC.

Description: § 4(d) Rate Filing: Neg Rate 2016–10–28 Green Plains to be effective 11/1/2016.

Filed Date: 10/26/16.

Accession Number: 20161026–5035.

Comments Due: 5 p.m. ET 11/7/16.

Docket Numbers: RP17–64–000.

Applicants: DBM Pipeline, LLC.

Description: § 4(d) Rate Filing: Negotiated Rate Filing to be effective 11/1/2016.

Filed Date: 10/26/16.

Accession Number: 20161026–5038.

Comments Due: 5 p.m. ET 11/7/16.

Docket Numbers: RP17–65–000.

Applicants: Natural Gas Pipeline Company of America.

Description: § 4(d) Rate Filing: Shell Energy North Negotiated Rate to be effective 11/1/2016.

Filed Date: 10/26/16.

Accession Number: 20161026–5043.

Comments Due: 5 p.m. ET 11/7/16.

Docket Numbers: RP17–66–000.

Applicants: Rockies Express Pipeline LLC.

Description: § 4(d) Rate Filing: Neg Rate Perm Partial CR ARM to be effective 11/1/2016.

Filed Date: 10/26/16.

Accession Number: 20161026–5050.

Comments Due: 5 p.m. ET 11/7/16.

Docket Numbers: RP17–67–000.

Applicants: Rockies Express Pipeline LLC.

Description: § 4(d) Rate Filing: Neg Rate 2016–10–26 Encana for 10–27 to be effective 10/27/2016.

Filed Date: 10/26/16.

Accession Number: 20161026–5062.

Comments Due: 5 p.m. ET 11/7/16.

Docket Numbers: RP17–68–000.

Applicants: Natural Gas Pipeline Company of America

Description: § 4(d) Rate Filing: Munich RE Trading Negotiated Rate to be effective 11/1/2016.

Filed Date: 10/26/16.

Accession Number: 20161026–5064.

Comments Due: 5 p.m. ET 11/7/16.

Docket Numbers: RP17–69–000.

Applicants: Iroquois Gas Transmission System, L.P.

Description: § 4(d) Rate Filing: 10/26/16 Negotiated Rates—Hartree Partners, LP (RTS) 7090–02 to be effective 11/1/2016.

Filed Date: 10/26/16.

Accession Number: 20161026–5116.

Comments Due: 5 p.m. ET 11/7/16.

Docket Numbers: RP17–70–000.

Applicants: Iroquois Gas Transmission System, L.P.

Description: § 4(d) Rate Filing: 10/26/16 Negotiated Rates—Hartree Partners, LP (RTS) 7090–03 to be effective 11/1/2016.

Filed Date: 10/26/16.

Accession Number: 20161026–5117.

Comments Due: 5 p.m. ET 11/7/16.

Docket Numbers: RP17–71–000.

Applicants: Algonquin Gas Transmission, LLC.

Description: § 4(d) Rate Filing: AGT FRQ 2016 Filing to be effective 12/1/2016.

Filed Date: 10/26/16.

Accession Number: 20161026–5120.

Comments Due: 5 p.m. ET 11/7/16.

Docket Numbers: RP17–72–000.

Applicants: Natural Gas Pipeline Company of America.

Description: § 4(d) Rate Filing: Seven Generations Negotiated Rate to be effective 11/1/2016.

Filed Date: 10/27/16.

Accession Number: 20161027–5000.

Comments Due: 5 p.m. ET 11/8/16.

Docket Numbers: RP17–73–000.

Applicants: Southern LNG Company, L.L.C.

Description: § 4(d) Rate Filing: SLNG Electric Power Cost Adjustment—2016 to be effective 12/1/2016.

Filed Date: 10/27/16.

Accession Number: 20161027–5050.

Comments Due: 5 p.m. ET 11/8/16.

Docket Numbers: RP17–74–000.

Applicants: Viking Gas Transmission Company.

Description: Compliance filing 2015–2016 Gas Sales and Purchases Report.

Filed Date: 10/27/16.

Accession Number: 20161027–5057.

Comments Due: 5 p.m. ET 11/8/16.

Docket Numbers: RP17–75–000.

Applicants: Midwestern Gas Transmission Company.

Description: Compliance filing 2015–2016 Gas Sales and Purchases Report.

Filed Date: 10/27/16.

Accession Number: 20161027–5059.

Comments Due: 5 p.m. ET 11/8/16.

Docket Numbers: RP17–76–000.

Applicants: Midwestern Gas Transmission Company.

Description: Compliance filing 2015–2016 Cashout Report.

Filed Date: 10/27/16.

Accession Number: 20161027–5071.

Comments Due: 5 p.m. ET 11/8/16.

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 date(s). 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: October 27, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–26542 Filed 11–2–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[P–2556–080]

Messalonskee Stream Hydro, LLC: Notice of Application Accepted for Filing and Soliciting Comments, Motions To Intervene, and Protests

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection.

a. *Type of Application:* Temporary Variance of License.

b. *Project No.:* 2556–080.

c. *Date Filed:* October 7, 2016.

d. *Applicant:* Messalonskee Stream Hydro, LLC.

e. *Name of Project:* Messalonskee Hydroelectric Project.

f. *Location:* The project is located on the Messalonskee Stream in Kennebec County, Maine.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791 (a)–825(r).

h. *Applicant Contact:* Andrew Locke, President, Messalonskee Stream Hydro, LLC, 55 Union Street 4th Floor, Boston, MA 02108 (617) 284–6778.

i. *FERC Contact:* Steven Sachs, (202) 502–8666, *Steven.Sachs@ferc.gov.*

j. Deadline for filing comments, motions to intervene, and protests is 14 days from the issuance of this notice by the Commission. The Commission strongly encourages electronic filing. Please file comments, motions to intervene, and protests using the Commission's eFiling system at *http://www.ferc.gov/docs-filing/efiling.asp.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/doc-sfiling/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–2556–080.

k. *Description of Request:* The applicant requests a temporary variance of the Messalonskee Lake elevation requirement as a result of drought conditions. The normal minimum elevation for Messalonskee Lake is 234.4 feet above mean sea level. The applicant states the reservoir surface has already fallen below this level due to low inflow, and proposes the minimum

level be temporarily modified to 232.9 feet above mean sea level until January 1, 2017, or until the reservoir surface rises above its normal minimum elevation.

l. *Locations of the Applications:* A copy of the application is available for inspection and reproduction at the Commission's Public Reference Room, located at 888 First Street NE., Room 2A, Washington, DC 20426, or by calling (202) 502–8371. The filing may also be viewed on the Commission's Web site at *http://www.ferc.gov/docs-filing/elibrary.asp.* Enter the docket number excluding the last three digits in the docket number field to access the document. You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, call 1–866–208–3676 or email *FERCOnlineSupport@ferc.gov*, for TTY, call (202) 502- 8659.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

n. *Comments, Motions To Intervene, or Protests:* Anyone may submit comments, a motion to intervene, or a protest in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, motions to intervene, or protests must be received on or before the specified comment date for the particular application.

o. *Filing and Service of Responsive Documents:* Any filing must (1) bear in all capital letters the title ''COMMENTS'', ''MOTION TO INTERVENE'', or ''PROTEST'' as applicable; (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, motions to intervene, or protests must set forth their evidentiary basis and otherwise comply with the requirements of 18 CFR 4.34(b). All comments, motions to intervene, or protests should relate to project works which are the subject of the temporary variance request. Agencies may obtain copies of the application directly from the applicant. A copy of any protest or motion to intervene must be served upon each representative of the applicant specified in the particular application. If an intervener files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency. A copy of all other filings in reference to this application must be accompanied by proof of service on all persons listed in the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 4.34(b) and 385.2010.

Dated: October 28, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–26546 Filed 11–2–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Commission Staff Attendance

The Federal Energy Regulatory Commission hereby gives notice that members of the Commission's staff may attend the following meetings related to the transmission planning activities of the PJM Interconnection, L.L.C. (PJM):

PJM Planning Committee

November 3, 2016, 9:30 a.m.–12:00 p.m. (EST).

PJM Transmission Expansion Advisory Committee

November 3, 2016, 11:00 a.m.–3:00 p.m. (EST).

The above-referenced meetings will be held at: PJM Conference and Training Center, PJM Interconnection, 2750 Monroe Boulevard, Audubon, PA 19403.

The above-referenced meetings are open to stakeholders.

Further information may be found at *www.pjm.com.*

The discussions at the meetings described above may address matters at issue in the following proceedings:

Docket No. ER16–453, *PJM Interconnection, L.L.C. and Northeast Transmission Development, LLC*

Docket No. ER16–736, *PJM Interconnection, L.L.C.*

Docket No. ER14–972, *PJM Interconnection, L.L.C.*

Docket No. ER14–1485, *PJM Interconnection, L.L.C.*

Docket Nos. ER13–1944, *et al., PJM Interconnection, L.L.C., et al.*

Docket No. ER15–1344, *PJM Interconnection, L.L.C.*

Docket No. ER15–1387, *PJM Interconnection, L.L.C. and Potomac Electric Power Company*

Docket No. ER15–2562, *PJM Interconnection, L.L.C.*

Docket No. ER15–2563, *PJM Interconnection, L.L.C.*

Docket No. EL15–18, *Consolidated Edison Company of New York, Inc.* v. *PJM Interconnection, L.L.C.*

Docket No. EL15–41, *Essential Power Rock Springs, LLC, et al.* v. *PJM Interconnection, L.L.C.*

Docket No. ER15–2114, *PJM Interconnection, L.L.C. and Transource West Virginia, LLC*

Docket No. EL15–79, *TransSource, LLC* v. *PJM Interconnection, L.L.C.*

Docket No. EL15–95, *Delaware Public Service Commission, et al.* v. *PJM Interconnection, L.L.C., et al.*

Docket No. EL15–67, *Linden VFT, LLC* v. *PJM Interconnection, L.L.C.*

Docket No. EL05–121, *PJM Interconnection, L.L.C.*

Docket No. ER13–198, *PJM Interconnection, L.L.C.*

Docket No. ER16–1335, *PJM Interconnection, L.L.C.*

Docket No. ER16–2401, *PJM Interconnection, L.L.C.*

Docket No. ER16–2716, *PJM Interconnection, L.L.C.*

Docket No. ER16–1499, *PJM Interconnection, L.L.C.*

Docket No. ER16–1807, *First Energy Solutions Corp.*

Docket No. EL16–96, *PJM Interconnection, L.L.C.*

Docket No. EL16–71, *Monongahela Power Company et al.*

Docket No. ER16–2539, *PJM Interconnection, L.L.C.*

For more information, contact the following:

Jonathan Fernandez, Office of Energy Market Regulation, Federal Energy Regulatory Commission, (202) 502–6604 *Jonathan.Fernandez@ferc.gov.*

Alina Halay, Office of Energy Market Regulation, Federal Energy Regulatory Commission, (202) 502–6474, *Alina.Halay@ferc.gov.*

Dated: October 26, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–26588 Filed 11–2–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL17–13–000]

American Municipal Power, Inc., Blue Ridge Power Agency, Craig-Botetourt Electric Cooperative, Indiana Michigan Municipal Distributors Association, Indiana Municipal Power Agency, Old Dominion Electric Cooperative, Inc., Wabash Valley Power Association, Inc. v. Appalachian Power Company, Columbus Southern Power Company, Indiana Michigan Power Company, Kentucky Power Company, Kingsport Power Company, Ohio Power Company, Wheeling Power Company, AEP Appalachian Transmission Company, Inc., AEP Indiana Michigan Transmission Company, Inc., AEP Kentucky Transmission Company, Inc., AEP Ohio Transmission Company, Inc., AEP West Virginia Transmission Company, Inc.; Notice of Complaint

Take notice that on October 27, 2016, pursuant to section 206 of the Federal Power Act, 16 U.S.C. 824e and 825e and Rule 206 of the Federal Energy Regulatory Commission's (Commission) Rules of Practice and Procedure, 18 CFR 385.206 (2016), American Municipal Power, Inc., Blue Ridge Power Agency, Craig-Botetourt Electric Cooperative, Indiana Michigan Municipal Distributors Association, Indiana Municipal Power Agency, Old Dominion Electric Cooperative, Inc., and Wabash Valley Power Association, Inc., (Collectively, Joint Complainants) filed a formal complaint against Appalachian Power Company, Columbus Southern Power Company, Indiana Michigan Power Company, Kentucky Power Company, Kingsport Power Company, Ohio Power Company, Wheeling Power Company, AEP Appalachian Transmission Company, Inc.

AEP Indiana Michigan Transmission Company, Inc., AEP Kentucky Transmission Company, Inc., AEP Ohio Transmission Company, Inc., AEP West Virginia Transmission Company, Inc., (AEP East Companies or Respondents), alleging that the 10.99 percent base rate on common equity currently included in the formula transmission rates of the AEP East Companies is unjust and unreasonable, all as more fully explained in the complaint.

Joint Complainants certify that copies of the complaint were served in accordance with Rule 206(c).

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 and 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 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 16, 2016.

Dated: October 28, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–26545 Filed 11–2–16; 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 exempt wholesale generator filings:

Docket Numbers: EG17–17–000.

Applicants: TransCanada Maine Wind Development Inc.

Description: TransCanada Maine Wind Development Inc. Notice of Self-Certification of Exempt Wholesale Generator Status.

Filed Date: 10/28/16.

Accession Number: 20161028–5079.

Comments Due: 5 p.m. ET 11/18/16.

Docket Numbers: EG17–18–000.

Applicants: Innovative Solar 47, LLC.

Description: Notice of Self-Certification of Exempt Wholesale Generator Status of Innovative Solar 47, LLC.

Filed Date: 10/28/16.

Accession Number: 20161028–5153.

Comments Due: 5 p.m. ET 11/18/16.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER16–2524–001.

Applicants: Entergy Louisiana, LLC.

Description: Tariff Amendment: EES Corrected LBA Agreements to be effective 9/1/2016.

Filed Date: 10/28/16.

Accession Number: 20161028–5000.

Comments Due: 5 p.m. ET 11/18/16.

Docket Numbers: ER16–2725–000.

Applicants: PSEG Energy Solutions LLC.

Description: Amendment to September 30, 2016 PSEG Energy Solutions LLC tariff filing.

Filed Date: 10/27/16.

Accession Number: 20161027–5228.

Comments Due: 5 p.m. ET 11/17/16.

Docket Numbers: ER17–202–000.

Applicants: Monterey CA, LLC.

Description: Tariff Cancellation: Cancellation to be effective 11/1/2016.

Filed Date: 10/27/16.

Accession Number: 20161027–5170.

Comments Due: 5 p.m. ET 11/17/16.

Docket Numbers: ER17–203–000.

Applicants: Southern California Edison Company.

Description: Compliance filing: SCE Combined Compliance Filing to be effective 10/14/2016.

Filed Date: 10/27/16.

Accession Number: 20161027–5181.

Comments Due: 5 p.m. ET 11/17/16.

Docket Numbers: ER17–204–000.

Applicants: Quantum Power Corp.

Description: Baseline eTariff Filing: Market Based Rate Tariff Baseline Filing to be effective 1/1/2017.

Filed Date: 10/28/16.

Accession Number: 20161028–5041.

Comments Due: 5 p.m. ET 11/18/16.

Docket Numbers: ER17–205–000.

Applicants: Upper Michigan Energy Resources Corporation.

Description: § 205(d) Rate Filing: UMERC to MSCPA FERC Rate Schedule No 8 to be effective 1/1/2017.

Filed Date: 10/28/16.

Accession Number: 20161028–5047.

Comments Due: 5 p.m. ET 11/18/16.

Docket Numbers: ER17–206–000.

Applicants: Upper Michigan Energy Resources Corporation.

Description: § 205(d) Rate Filing: UMERC to ATC Common Facilities Agreement Rate Schedule No 9 to be effective 1/1/2017.

Filed Date: 10/28/16.
Accession Number: 20161028–5050.
Comments Due: 5 p.m. ET 11/18/16.
Docket Numbers: ER17–207–000.
Applicants: California Power Exchange Corporation.
Description: § 205(d) Rate Filing: Rate Filing for Rate Period 30 to be effective 1/1/2017.
Filed Date: 10/28/16.
Accession Number: 20161028–5051.
Comments Due: 5 p.m. ET 11/18/16.
Docket Numbers: ER17–208–000.
Applicants: Public Service Company of Colorado.
Description: § 205(d) Rate Filing: 2016–10–28 Att O–PSCo Tbls 4, 5, 22–TOIF Filing to be effective 1/1/2017.
Filed Date: 10/28/16.
Accession Number: 20161028–5056.
Comments Due: 5 p.m. ET 11/18/16.
Docket Numbers: ER17–209–000.
Applicants: Upper Michigan Energy Resources Corporation.
Description: § 205(d) Rate Filing: UMERC to ATC Project Services Agreement Rate Schedule No 10 to be effective 1/1/2017.
Filed Date: 10/28/16.
Accession Number: 20161028–5089.
Comments Due: 5 p.m. ET 11/18/16.
Docket Numbers: ER17–210–000.
Applicants: Sabine Cogen, LP.
Description: § 205(d) Rate Filing: Reactive Rate Schedule and Request for Expedited Consideration to be effective 12/1/2016.
Filed Date: 10/28/16.
Accession Number: 20161028–5102.
Comments Due: 5 p.m. ET 11/18/16.
Docket Numbers: ER17–211–000.
Applicants: Mid-Atlantic Interstate Transmission, LL, PJM Interconnection, L.L.C.
Description: § 205(d) Rate Filing: MAIT submits OATT revisions re: MAIT, Penelec and MetEd Formula Rate/Protocols to be effective 1/1/2017.
Filed Date: 10/28/16.
Accession Number: 20161028–5109.
Comments Due: 5 p.m. ET 11/18/16.
Docket Numbers: ER17–212–000.
Applicants: Upper Michigan Energy Resources Corporation.
Description: § 205(d) Rate Filing: UMERC to Crystal Falls Rate Schedule 4 to be effective 1/1/2017.
Filed Date: 10/28/16.
Accession Number: 20161028–5110.
Comments Due: 5 p.m. ET 11/18/16.
Docket Numbers: ER17–213–000.
Applicants: Midcontinent Independent System Operator, Inc.
Description: § 205(d) Rate Filing: 2016–10–28_Module D Clean-up Filing to be effective 12/28/2016.
Filed Date: 10/28/16.
Accession Number: 20161028–5134.
Comments Due: 5 p.m. ET 11/18/16.
Docket Numbers: ER17–214–000.
Applicants: PJM Interconnection, L.L.C., Mid-Atlantic Interstate Transmission, LLC.
Description: § 205(d) Rate Filing: Revisions to OATT and OA re: MAIT Integration to be effective 1/1/2017.
Filed Date: 10/28/16.
Accession Number: 20161028–5135.
Comments Due: 5 p.m. ET 11/18/16.
Docket Numbers: ER17–215–000.
Applicants: Midcontinent Independent System Operator, Inc., Great River Energy, South Mississippi Electric Power Association.
Description: Compliance filing: 2016–10–28_Compliance filing to address ROE Order to be effective 9/28/2016.
Filed Date: 10/28/16.
Accession Number: 20161028–5140.
Comments Due: 5 p.m. ET 11/18/16.
Docket Numbers: ER17–216–000.
Applicants: PJM Interconnection, L.L.C., Mid-Atlantic Interstate Transmission, LLC.
Description: § 205(d) Rate Filing: Revisions to CTOA adding MAIT as Transmission Owner to be effective 1/1/2017.
Filed Date: 10/28/16.
Accession Number: 20161028–5145.
Comments Due: 5 p.m. ET 11/18/16.
Docket Numbers: ER17–217–000.
Applicants: Jersey Central Power & Light, PJM Interconnection, L.L.C.
Description: § *205(d) Rate Filing: JCPL submits revisions to OATT re: Attachment H Formula Rate/Protocol to be effective 1/1/2017.*
Filed Date: 10/28/16.
Accession Number: 20161028–5151.
Comments Due: 5 p.m. ET 11/18/16.
Docket Numbers: ER17–218–000.
Applicants: California Independent System Operator Corporation.
Description: § 205(d) Rate Filing: 2016–10–28 Modify Definition Load Serving Entity to be effective 1/1/2017.
Filed Date: 10/28/16.
Accession Number: 20161028–5152.
Comments Due: 5 p.m. ET 11/18/16.
Docket Numbers: ER17–219–000.
Applicants: PacifiCorp.
Description: § 205(d) Rate Filing: OATT Revised Sections (Ancillary Services) to be effective 1/1/2017.
Filed Date: 10/28/16.
Accession Number: 20161028–5155.
Comments Due: 5 p.m. ET 11/18/16.
Docket Numbers: ER17–220–000.
Applicants: Duke Energy Carolinas, LLC.
Description: § 205(d) Rate Filing: Amendment to DEC-Duke Cities NITSAs to be effective 10/1/2016.
Filed Date: 10/28/16.
Accession Number: 20161028–5158.
Comments Due: 5 p.m. ET 11/18/16.
Docket Numbers: ER17–221–000.
Applicants: Southwest Power Pool, Inc.
Description: § 205(d) Rate Filing: 607R29 Westar Energy, Inc. NITSA NOA to be effective 1/1/2017.
Filed Date: 10/28/16.
Accession Number: 20161028–5162.
Comments Due: 5 p.m. ET 11/18/16.
Docket Numbers: ER17–222–000.
Applicants: Palmco Power PA, LLC.
Description: § 205(d) Rate Filing: Modify Market-Based Rate Tariff to be effective 11/2/2016.
Filed Date: 10/28/16.
Accession Number: 20161028–5175.
Comments Due: 5 p.m. ET 11/18/16.
Docket Numbers: ER17–223–000.
Applicants: Metropolitan Edison Company, Pennsylvania Electric Company, PJM Interconnection, L.L.C.
Description: Tariff Cancellation: Notice of Cancellation of Service Agreement No. 4181 to be effective 1/1/2017.
Filed Date: 10/28/16.
Accession Number: 20161028–5204.
Comments Due: 5 p.m. ET 11/18/16.
Docket Numbers: ER17–224–000.
Applicants: PJM Interconnection, L.L.C.
Description: *Tariff Cancellation: Notice of Cancellation of WMPA, SA No. 3261, Queue No. W3–045 to be effective 10/28/2016.*
Filed Date: 10/28/16.
Accession Number: 20161028–5210.
Comments Due: 5 p.m. ET 11/18/16.

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: October 28, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–26541 Filed 11–2–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. PF16–9–000]

Spire STL Pipeline Company, LLC; Notice of Intent To Prepare an Environmental Assessment for the Planned Spire STL Pipeline Project, Request for Comments on Environmental Issues, and Notice of Public Scoping Sessions

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 Spire STL Pipeline Project (Project) involving construction and operation of facilities by Spire STL Pipeline Company, LLC (Spire) in Scott, Greene, and Jersey Counties, Illinois and St. Charles and St. Louis Counties, Missouri. 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 November 25, 2016.

If you sent comments on the Project to the Commission before the opening of this docket on July 22, 2016, you will need to file those comments in Docket No. PF16–9–000 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 planned project and encourage them to comment on their areas of concern.

If you are a landowner receiving this notice, a pipeline company representative may contact you about the acquisition of an easement to construct, operate, and maintain the planned facilities. The company would seek to negotiate a mutually acceptable agreement. However, if the Commission approves the Project, that approval conveys with it the right of eminent domain. Therefore, if easement negotiations fail to produce an agreement, the pipeline company could initiate condemnation proceedings where compensation would be determined in accordance with state law.

A fact sheet prepared by the FERC entitled ''An Interstate Natural Gas Facility On My Land? What Do I Need To Know?'' is available for viewing on the FERC Web site (*www.ferc.gov*). This fact sheet addresses a number of typically asked questions, including the use of eminent domain and how to participate in the Commission's proceedings.

Public Participation

For your convenience, there are four methods you can use to submit your comments to the Commission. The Commission will provide equal consideration to all comments received, whether filed in written form or provided verbally. The Commission encourages electronic filing of comments and has expert staff available to assist you at (202) 502–6652 or *ferconlinesupport@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 (PF16–9–000) with your submission: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Room 1A, Washington, DC 20426.

(4) In lieu of sending written or electronic comments, the Commission invites you to attend one of the public scoping sessions its staff will conduct in the Project area, scheduled as follows.

Date and time	Location
Monday, November 14, 2016, 4:00–8:00 p.m. ...	North County Recreation Complex 2577 Redman Rd., St. Louis, MO 63136.
Tuesday, November 15, 2016, 4:00–8:00 p.m. ..	Elsah Township Community Building 14690 Fessler Rd., Dow, IL 62022. (at Fessler Rd. and Highway 3).
Wednesday, November 16, 2016, 4:00–8:00 p.m.	Knights of Columbus Hall 1/2 mile south of Town of Carrollton on US 67 Highway, Carrollton, IL 62016. (at U.S. 67 and Jack Pine Rd., behind the Dollar General).

The primary goal of these scoping sessions is to have you identify the specific environmental issues and concerns that should be considered in the EA to be prepared for this Project. Individual verbal comments will be taken on a one-on-one basis with a court reporter. This format is designed to receive the maximum amount of verbal comments, in a convenient way during the timeframe allotted.

Each scoping session is scheduled from 4:00 p.m. to 8:00 p.m. Central Standard Time. You may arrive at any time after 4:00 p.m. There will not be a formal presentation by Commission staff when the session opens. If you wish to speak, the Commission staff will hand out numbers in the order of your arrival; distribution of numbers will be discontinued at 7:30 p.m.

Your verbal scoping comments will be recorded by the court reporter (with FERC staff or representative present) and become part of the public record for this proceeding. Transcripts will be publicly available on FERC's eLibrary system (see below for instructions on using eLibrary). If a significant number of people are interested in providing verbal comments in the one-on-one settings, a time limit of 5 minutes may be implemented for each commentor.

It is important to note that verbal comments hold the same weight as written or electronically submitted comments. Although there will not be a formal presentation, Commission staff will be available throughout the scoping

session to answer your questions about the environmental review process. Representatives from Spire will also be present to answer project-specific questions.

Please note this is not your only public input opportunity; please refer to the review process flow chart in appendix 1.[1]

Summary of the Planned Project

Spire plans to construct and operate a pipeline to transport natural gas from the Rockies Express Pipeline LLC pipeline in Scott County, Illinois to an interconnect with Laclede Gas Company's Line 880. The Project would consist of the following facilities in Illinois and Missouri:

- Approximately 57.4 miles of new 24-inch-diameter pipeline in Scott, Greene, and Jersey Counties, Illinois and St. Charles and St. Louis Counties, Missouri;
- purchase of and modification of 7.6 miles of the existing 20-inch-diameter Line 880 pipeline in St. Louis County, Missouri;
- three new meter and regulating stations in Scott County, Illinois and St. Louis County, Missouri;
- modifications at the existing Redman Delivery Station in St. Louis County; Missouri; and
- appurtenant underground and aboveground facilities.

According to Spire, the Project would be designed to transport about 400,000 dekatherms per day of natural gas service. The general location of the Project facilities is shown in appendix 2.

Land Requirements for Construction

Construction of the planned facilities would disturb about 920.3 acres of land for the new pipeline, modifications to the existing Line 880, and aboveground facilities. Spire would maintain about 352.2 acres for permanent operation of the Spire Project's facilities following construction; the remaining acreage would be restored and revert to former uses. Modifications at the existing Redman Delivery Station would occur within the boundary of the facility.

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 [2] 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 be addressed 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 planned project under these general headings: Geology and soils; land use; water resources, fisheries, and wetlands; cultural resources; socioeconomics; vegetation and wildlife, including migratory birds; air quality and noise; endangered and threatened species; public safety; and cumulative impacts.

We will also evaluate possible alternatives to the planned Project or portions of the Project, and make recommendations on how to lessen or avoid impacts on the various resource areas.

Although no formal application has been filed, we have already initiated our NEPA review under the Commission's pre-filing process. The purpose of the pre-filing process is to encourage early involvement of interested stakeholders and to identify and resolve issues before the FERC receives an application. As part of our pre-filing review, we have begun to contact some federal and state agencies to discuss their involvement in the scoping process and the preparation of the EA.

The EA will present our independent analysis of the issues and 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 we make 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 related to this Project to formally cooperate with us in the preparation of the EA.[3] 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. Currently, the U.S. Army Corps of Engineers and Illinois Department of Agriculture have expressed their intention to participate as cooperating agencies in the preparation of the EA to satisfy their NEPA responsibilities related to this Project.

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 Offices (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.[4] We will define the project-specific Area of Potential Effects (APE) in consultation with the SHPOs 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, meter and regulating 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; environmental and public interest groups; 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

[1] The appendices referenced in this notice will not appear in the **Federal Register**. Copies of the 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 page 7 of this notice.

[2] ''We,'' ''us,'' and ''our'' refer to the environmental staff of the Commission's Office of Energy Projects.

[3] The Council on Environmental Quality regulations addressing cooperating agency responsibilities are at Title 40, Code of Federal Regulations, Part 1501.6.

[4] The Advisory Council on Historic Preservation 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.

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 planned project.

Copies of the EA 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 (see appendix 3).

Becoming an Intervenor

Once Spire files its application with the Commission, 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. Motions to intervene are more fully described at *http://www.ferc.gov/resources/guides/how-to/intervene.asp.* Instructions for becoming an intervenor are in the ''Document-less Intervention Guide'' under the ''e-filing'' link on the Commission's Web site. Please note that the Commission will not accept requests for intervenor status at this time. You must wait until the Commission receives a formal application for the Project.

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 (*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 field (*i.e.,* PF16–9). 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) 502–6652. 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: October 26, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–26592 Filed 11–2–16; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2015–0762; FRL–9953–06]

Registration Review; Conventional, Biopesticide and Antimicrobial Pesticides Dockets Opened for Review and Comment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: With this document, EPA is opening the public comment period for several registration reviews for the list of chemicals identified in the table in Unit III. Registration review is EPA's periodic review of pesticide registrations to ensure that each pesticide continues to satisfy the statutory standard for registration, that is, the pesticide can perform its intended function without unreasonable adverse effects on human health or the environment. Registration review dockets contain information that will assist the public in understanding the types of information and issues that the Agency may consider during the course of registration reviews. Through this program, EPA is ensuring that each pesticide's registration is based on current scientific and other knowledge, including its effects on human health and the environment. This document also announces that the Agency has closed the registration review case for bromine chloride (case 5008) and that it will not be opening registration review dockets for the following cases: Xylene (aromatic solvents, case 3020); butafenacil (case 7261), naptalam (case 0183); spiroxamine (case 7040); polyethoxylated alcohols & polyethoxylated aliphatic alcohols (case 3119); and carbofuran (case 0101).

DATES: Comments must be received on or before January 3, 2017.

ADDRESSES: Submit your comments identified by the docket identification (ID) number for the specific pesticide of interest provided in the table in Unit III.A., by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.
- *Mail:* 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.*

FOR FURTHER INFORMATION CONTACT: *For pesticide specific information contact:* The person identified as a contact in the table in Unit III.A. Also include the docket ID number listed in the table in Unit III.A. for the pesticide of interest.

For general information contact: Richard Dumas, Pesticide Re-Evaluation Division (7508P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 308–8015; fax number: (703) 308–8090; email address: *dumas.richard@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

This action is directed to the public in general, and may be of interest to a wide range of stakeholders including environmental, human health, farmworker, and agricultural advocates; the chemical industry; pesticide users; and members of the public interested in the sale, distribution, or use of pesticides. Since others also may be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action.

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

1. *Submitting CBI.* Do not submit this information to EPA through *regulations.gov* or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then

identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at *http://www.epa.gov/dockets/comments.html.*

3. *Environmental justice.* EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of any group, including minority and/or low income populations, in the development, implementation, and enforcement of environmental laws, regulations, and policies. To help address potential environmental justice issues, the Agency seeks information on any groups or segments of the population who, as a result of their location, cultural practices, or other factors, may have atypical or disproportionately high and adverse human health impacts or environmental effects from exposure to the pesticides discussed in this document, compared to the general population.

II. Authority

EPA is initiating its reviews of the pesticides identified in this document pursuant to section 3(g) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136a(g)) and the Procedural Regulations for Registration Review at 40 CFR part 155, subpart C. Section 3(g) of FIFRA provides, among other things, that the registrations of pesticides are to be reviewed every 15 years. Under FIFRA, a pesticide product may be registered or remain registered only if it meets the statutory standard for registration given in FIFRA section 3(c)(5) (7 U.S.C. 136a(c)(5)). When used in accordance with widespread and commonly recognized practice, the pesticide product must perform its intended function without unreasonable adverse effects on the environment; that is, without any unreasonable risk to man or the environment, or a human dietary risk from residues that result from the use of a pesticide in or on food.

III. Registration Reviews

A. What action is the agency taking?

As directed by FIFRA section 3(g), EPA is reviewing the pesticide registrations identified in the table in this unit to assure that they continue to satisfy the FIFRA standard for registration—that is, they can still be used without unreasonable adverse effects on human health or the environment. A pesticide registration review begins when the Agency establishes a docket for the pesticide registration review case and opens the docket for public review and comment. At present, EPA is opening registration review dockets for the cases identified in the following table.

TABLE—REGISTRATION REVIEW DOCKETS OPENING

Registration review case name and number	Docket ID number	Contact
4-Aminopyridine, 0015	EPA–HQ–OPP–2016–0030	Moana Appleyard, *appleyard.moana@epa.gov*, (703) 308–8175.
Aliphatic Alcohols (C6–C16), 4004	EPA–HQ–OPP–2016–0261	Andrew Reighart, *reighart.andrew@epa.gov*, (703) 347–0469.
Aliphatic Solvents, 3004	EPA–HQ–OPP–2015–0767	Veronica Dutch, *dutch.veronica@epa.gov*, (703) 308–8585.
Alkyl Dimethyl Benzyl Ammonium Chloride (ADBAC), 0350.	EPA–HQ–OPP–2015–0737	Rachel Ricciardi, *ricciardi.rachel@epa.gov*, (703) 347–0465. Maria Piansay, *piansay.maria@epa.gov*, (703) 308–8063.
Bacillus thuringiensis Plant-incorporated Protectants in Cotton-Lepidopteran Pests, 6504.	EPA–HQ–OPP–2016–0475	Alan Reynolds, *reynolds.alan@epa.gov*, (703) 605–0515.
Butoxypolypropylene Glycol, 3123	EPA–HQ–OPP–2016–0048	Veronica Dutch, *dutch.veronica@epa.gov*, (703) 308–8585.
Chlormequat Chloride, 7069	EPA–HQ–OPP–2015–0816	Jordan Page, *page.jordan@epa.gov*, (703) 347–0467.
Dicloran (DCNA), 0113	EPA–HQ–OPP–2016–0141	James Parker, *parker.james@epa.gov*, (703) 306–0469.
Didecyl Dimethyl Ammonium Chloride (DDAC), 3003	EPA–HQ–OPP–2015–0740	Rachel Ricciardi, *ricciardi.rachel@epa.gov*, (703) 347–0465. Maria Piansay, *piansay.maria@epa.gov*, (703) 308–8063.
Dodine and Dodecylguanidine hydrochloride (DGH), 0161.	EPA–HQ–OPP–2015–0477	Wilhelmena Livingston, *livingston.wilhelmena@epa.gov*, (703) 308–8025. Stephen Savage, *savage.stephen@epa.gov*, (703) 347–0345.
Flumethrin, 7456	EPA–HQ–OPP–2016–0031	Maria Piansay, *piansay.maria@epa.gov*, (703) 308–8063.
Formaldehyde and Paraformaldehyde, 0556	EPA–HQ–OPP–2015–0739	Sandra O'Neill, *oneill.sandra@epa.gov*, (703) 347–0141.
Mefluidide and Salts, 2370	EPA–HQ–OPP–2015–0786	Susan Bartow, *bartow.susan@epa.gov*, (703) 603–0065.
Metaflumizone, 7446	EPA–HQ–OPP–2016–0417	Nathan Sell, *sell.nathan@epa.gov*, (703) 347–8020.
Naphthalene, 0022	EPA–HQ–OPP–2016–0113	Miguel Zavala, *zavala.miguel@epa.gov*, (703) 347–0504.
Napropamide, 2450	EPA–HQ–OPP–2016–0019	Linsey Walsh, *walsh.linsey@epa.gov*, (703) 347–8030.
Para-dichlorobenzene, 3058	EPA–HQ–OPP–2016–0117	Miguel Zavala, *zavala.miguel@epa.gov*, (703) 347–0504.
Peroxyoctanoic Acid, 5081	EPA–HQ–OPP–2016–0341	Stephen Savage, *savage.stephen@epa.gov*, (703) 347–0345.
Phosphorous Acids and Salts, 6035	EPA–HQ–OPP–2016–0488	Menyon Adams, *wadams.menyon@epa.gov*, (703) 347–8496.
Phytophthora palmivora, 4105	EPA–HQ–OPP–2016–0451	Kathleen Martin, *martin.kathleen@epa.gov*, (703) 308–2857.

TABLE—REGISTRATION REVIEW DOCKETS OPENING—Continued

Registration review case name and number	Docket ID number	Contact
Pyrasulfotole, 7272	EPA–HQ–OPP–2016–0391	Marquea D. King, *king.marquea@epa.gov*, (703) 305–7432.
Tembotrione, 7273	EPA–HQ–OPP–2016–0063	Linsey Walsh, *walsh.linsey@epa.gov*, (703) 347–8030.

This document also announces the closure of the registration review case for bromine chloride (case 5008 and Docket ID Number: EPA–HQ–OPP–2009–0025) because all of the registrations in the U.S. have been canceled. In addition, EPA is announcing that it will not be opening a docket for the following cases: xylene (aromatic solvents, case 3020), butafenacil (case 7261), naptalam (case 0183), spiroxamine (case 7040), and polyethoxylated alcohols & polyethoxylated aliphatic alcohols (case 3119). These pesticide active ingredients are not included in any products currently registered under FIFRA section 3 and FIFRA section 24(c). Furthermore, EPA is announcing that it will not be opening the docket for carbofuran (case 0101) because there are no active end-use product registrations.

B. Docket Content

1. *Review dockets.* The registration review dockets contain information that the Agency may consider in the course of the registration review. The Agency may include information from its files including, but not limited to, the following information:

- An overview of the registration review case status.
- A list of current product registrations and registrants.
- **Federal Register** notices regarding any pending registration actions.
- **Federal Register** notices regarding current or pending tolerances.
- Risk assessments.
- Bibliographies concerning current registrations.
- Summaries of incident data.
- Any other pertinent data or information.

Each docket contains a document summarizing what the Agency currently knows about the pesticide case and a preliminary work plan for anticipated data and assessment needs. Additional documents provide more detailed information. During this public comment period, the Agency is asking that interested persons identify any additional information they believe the Agency should consider during the registration reviews of these pesticides. The Agency identifies in each docket the areas where public comment is specifically requested, though comment in any area is welcome.

2. *Other related information.* More information on these cases, including the active ingredients for each case, may be located in the registration review schedule on the Agency's Web site at *https://www.epa.gov/pesticide-reevaluation/registration-review-schedules.* Information on the Agency's registration review program and its implementing regulation may be seen at *http://www.epa.gov/pesticide-reevaluation/registration-review-process.*

3. *Information submission requirements.* Anyone may submit data or information in response to this document. To be considered during a pesticide registration review, the submitted data or information must meet the following requirements:

- To ensure that EPA will consider data or information submitted, interested persons must submit the data or information during the comment period. The Agency may, at its discretion, consider data or information submitted at a later date.
- The data or information submitted must be presented in a legible and useable form. For example, an English translation must accompany any material that is not in English and a written transcript must accompany any information submitted as an audiographic or videographic record. Written material may be submitted in paper or electronic form.
- Submitters must clearly identify the source of any submitted data or information.
- Submitters may request the Agency to reconsider data or information that the Agency rejected in a previous review. However, submitters must explain why they believe the Agency should reconsider the data or information in the pesticide registration review.

As provided in 40 CFR 155.58, the registration review docket for each pesticide case will remain publicly accessible through the duration of the registration review process; that is, until all actions required in the final decision on the registration review case have been completed.

Authority: 7 U.S.C. 136 *et seq.*

Dated: October 14, 2016.

Yu-Ting Guilaran,

Director, Pesticide Re-evaluation Division, Office of Pesticide Programs.

[FR Doc. 2016–26620 Filed 11–2–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OEI–2016–0235; FRL–9954–87–OLEM]

Privacy Act; System of Records; Amendment of the EPA Personnel Emergency Contact Files, EPA–44

AGENCY: Environmental Protection Agency.

ACTION: Notice.

SUMMARY: Pursuant to the provisions of the Privacy Act of 1974 the U.S. Environmental Protection Agency's (EPA) Office of Land and Emergency Management, Office of Emergency Management is giving notice that it proposes to amend the EPA Personnel Emergency Contact files system of records. The system is being amended to change (1) the system name to Mass Alert and Notification System (MANS); (2) the categories of individuals covered by the system; and (3) categories of records in the system. This system of records will contain information collected from EPA personnel, contractors, grantees, consultants, and other support staff, including volunteers, who have an active EPA identification badge or are in the process of obtaining an EPA identification badge, for the purposes of providing emergency alerts and notifications and conducting accountability activities in support of affected persons following an emergency. Records may also be used for mass alert and notification system tests, drills, and exercises.

DATES: Persons wishing to comment on this system of records notice must do so by December 13, 2016. If no comments are received, the system of records notice will become effective by December 13, 2016.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OEI–2016–0235, by one of the following methods:

- *www.regulations.gov:* Follow the online instructions for submitting comments.
- *Email: oei.docket@epa.gov.*
- *Fax:* 202–566–1752.
- *Mail:* OEI Docket, Environmental Protection Agency, Mailcode: 2822T, 1200 Pennsylvania Ave. NW., Washington, DC 20460.
- *Hand Delivery:* OEI Docket, EPA/DC, EPA West Building, Room 3334, 1301 Constitution Ave. NW., Washington, DC. Such deliveries are only accepted during the Docket's normal hours of operations, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–HQ–OEI–2016–0235. 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 for which disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *www.regulations.gov.* The *www.regulations.gov* Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to EPA without going through *www.regulations.gov* your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket visit the EPA Docket Center homepage at *http://www.epa.gov/epahome/dockets.htm.*

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 for which 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 OEI Docket, EPA/DC, EPA West Building, Room 3334, 1301 Constitution Ave. NW., Washington. DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OEI Docket is (202) 566–1752.

FOR FURTHER INFORMATION CONTACT: Joe Vescio, National Continuity of Operations Manager, at (202) 564–2522.

SUPPLEMENTARY INFORMATION:

I. General Information

The U.S. Environmental Protection Agency (EPA) proposes to amend the EPA Personnel Emergency Contact Files system of records notice to more accurately reflect its scope and to address changes related to the expanded categories of individuals and records in the system. The EPA Personnel Emergency Contact Files system of records has been renamed Mass Alert and Notification System (MANS). This system of records contain personally identifiable information collected from EPA personnel, contractors, grantees, consultants, and other support staff, including volunteers, who have an active EPA identification badge or are in the process of obtaining an EPA identification badge, for the purposes of providing emergency alerts and notifications and conducting accountability of affected persons following an emergency. The privacy of the individual is affected by 1) rapidly and effectively disseminating emergency alerts and notifications, and 2) conducting personnel accountability activities following an emergency and having the ability to contact emergency personnel identified in case of an emergency pertaining to the employee. With this system of records modification, the MANS may also be used for mass alert and notification test, drill, and exercise evolutions.

The EPA will pre-populate MANS with government-furnished contact information, including first name, last name, middle initial, office location, scope of the record subject's responsibilities, work email address, work telephone number, work mobile telephone number, work short message service (SMS) (texting), and work telephone typewriter, teletypewriter or text phone/Telecommunications Device for the Deaf (TTY/TDD). Records are from various communications mediums such as telephones, emails and SMS. With this system of records modification, record subjects will have the option to voluntarily and securely add their own personal contact information, and information for their emergency contact person including home address, personal email address(es), home telephone number(s) and personal mobile telephone number(s), short message service (SMS) (texting), telephone typewriter, teletypewriter or text phone/Telecommunications Device for the Deaf (TTY/TDD) by establishing a personal account on the MANS web-portal.

Information maintained pursuant to this System of Records Notice (SORN) will be managed and maintained by the Office of Emergency Management in accordance with the Privacy Act. In order to protect the privacy of record subjects, only EPA personnel administering the MANS and contractor support staff (governed by the Privacy Act compliance terms in their contract) will have access to the MANS and government-furnished source data. EPA MANS Administrators will be required to present log-in credentials (*i.e.,* username and password) in order to access MANS; these individuals have the appropriate security clearances and a role-based need to access records in the system. Electronic data are stored on servers that are maintained in locked facilities with secure access control.

Dated: October 12, 2016.

Ann Dunkin,

Chief Information Officer.

EPA–44

SYSTEM NAME

Mass Alert and Notification System.

SYSTEM LOCATION

Each Headquarters Office, 1200 Pennsylvania Ave. NW., Washington DC 20460, WJC North Building, or Regional Office may maintain emergency contact records.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM

42 U.S.C. 5121 *et seq.;* Executive Order 12656 (Nov. 18, 1989); Federal Continuity Directive 1 (2012)

PURPOSE(S)

To contact EPA personnel, contractors, grantees, consultants, and other support staff, including volunteers, who have an active EPA identification badge or are in the process of obtaining an EPA identification badge, for the purposes of providing emergency alerts and notifications and conducting accountability activities in support of affected persons following an

emergency, or, as a means to account for EPA employees, contractors, grantees, consultants, and any other support staff personnel following an emergency event. Records may also be used for mass alert and notification system test, drill, and exercise evolutions. This system will provide EPA with the ability to rapidly and effectively disseminate emergency alerts and notification information. In addition, it will provide the opportunity to identify emergency contacts in case of an incident that involves an employee.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM

EPA personnel, contractors, grantees, consultants, and any other support staff personnel, including volunteers.

CATEGORIES OF RECORDS IN THE SYSTEM

The EPA will pre-populate MANS with the following government-furnished contact information: First name, last name, middle initial, office location, scope of the record subject's responsibilities, work email address, work telephone number and work mobile telephone number, work short message service (SMS) (texting) and work telephone typewriter, teletypewriter or text phone/Telecommunications Device for the Deaf (TTY/TDD). Records are from various communications mediums such as telephones, emails and SMS. Record subjects will also have the option to voluntarily and securely add their own personal contact information, and emergency contact(s), including home address, personal email address(es), home telephone number(s) and personal mobile telephone number(s), short message service (SMS) (texting), telephone typewriter, teletypewriter or text phone/Telecommunications Device for the Deaf (TTY/TDD) by establishing a personal account on the MANS web-portal.

RECORD SOURCE CATEGORIES

Records contained in this system of records are obtained from:

Individuals about whom the records will pertain and existing EPA systems of records including the following:

EPA–19 EPA Identification Card Record

EPA–62 EPA Personnel Access and Security System (EPASS)

EPA–1–R HRLOB

EPA–32 EPA Telecommunication Detail Records

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES

General routine uses A, E, F, G, H, K and L. apply to this system. Records may also be disclosed to Federal, State, local, foreign, tribal, or other public authorities or to federal contracting companies or individuals involved with an emergency (or related exercise) that may require EPA assistance.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM

STORAGE

In an electronic database.

RETRIEVABILITY

Information will be retrieved primarily by employee name. Information may also be retrieved by any collected data element.

SAFEGUARDS

Records are maintained in a secure, password protected computer system. All records are maintained in secure, access-controlled areas or buildings.

RETENTION AND DISPOSAL

Records stored in this system are subject to EPA's records schedule 1012, Information Technology Management. Records are kept as long as the record subject is affiliated with EPA.

SYSTEM MANAGER(S) AND ADDRESS

Director, Office of Emergency Management, Environmental Protection Agency, William Jefferson Clinton North Building, 1200 Pennsylvania Avenue NW., Mail Code 5104A, Washington, DC 20460. EPA coordinators in Regions and other offices may also be responsible for records.

RECORD ACCESS PROCEDURES

Request for access must be made in accordance with the procedures described in EPA's Privacy Act regulations at 40 CFR part 16. Requesters will be required to provide adequate identification, such as a driver's license, employee identification card, or other identifying document. Additional identification procedures may be required in some instances.

CONTESTING RECORDS PROCEDURES

Requests for correction or amendment must identify the record to be changed and the corrective action sought. EPA Privacy Act regulations are set out in 40 CFR part 16.

NOTIFICATION PROCEDURE

Any individual who wants to know whether this system of records contains a record about him or her, who wants access to his or her record, or who wants to contest the contents of a record, should make a written request to the Agency Privacy Officer at *Earle.judy@epa.gov* or by mail at EPA FOIA Office, Attn: Privacy Act Officer, MC 2822T, 1200 Pennsylvania Avenue NW., Washington, DC 20460.

SYSTEM EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT

None.

[FR Doc. 2016–26487 Filed 11–2–16; 8:45 am]

BILLING CODE P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OGC–2016–0623; FRL–9954–93–OGC]

Proposed Consent Decree, Clean Air Act Citizen Suit

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of proposed consent decree; request for public comment.

SUMMARY: In accordance with section 113(g) of the Clean Air Act, as amended (''CAA'' or the ''Act''), notice is hereby given of a proposed consent decree to address a lawsuit filed by Citizens for Clean Air and Sierra Club (''Plaintiffs'') in the United States District Court for the Western District of Washington: *Citizens for Clean Air, et al.* v. *McCarthy, et al.* No. 2:16–cv–00857–JCC (W.D. WA.). On June 14, 2016, Plaintiffs filed a lawsuit alleging that Gina McCarthy, in her official capacity as Administrator of the United States Environmental Protection Agency (''EPA'') and Dennis McLerran, in his official capacity as Regional Administrator of the United States Environmental Protection Agency, Region 10 (collectively, ''EPA''), failed to perform duties mandated by CAA to take final action to approve, disapprove, or conditionally approve, in whole or in part, the Fairbanks North Star Borough Moderate Area Attainment Plan for attainment of the 2006 24-hour fine particulate matter (''$PM_{2.5}$'') NAAQS, which Alaska submitted to EPA in two parts on December 31, 2014 and January 29, 2015. The proposed consent decree would establish deadlines for EPA to take certain specified actions related to the Alaska submissions.

DATES: Written comments on the proposed consent decree must be received by December 5, 2016.

ADDRESSES: Submit your comments, identified by Docket ID number EPA–HQ–OGC–2016–0623, online at *www.regulations.gov.* For comments submitted at *www.regulations.gov,* follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *www.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 generally will not consider comments or comment contents located outside of the primary submission (*i.e.* on the web, cloud, or other file sharing system). For additional submission methods, please contact the person identified in the ''For Further Information Contact'' section. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Geoffrey L. Wilcox, Air and Radiation Law Office (2344A), Office of General Counsel, U.S. Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460; telephone: (202) 564–5601; fax number: (202) 564–5603; email address: *wilcox.geoffrey@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Additional Information About the Proposed Consent Decree

On June 14, 2016, Plaintiffs filed a lawsuit alleging that EPA has a mandatory duty to take final action to approve, disapprove, or conditionally approve, in whole or in part, the Fairbanks North Star Borough Moderate Area Attainment Plan for the 2006 24-hour $PM_{2.5}$ NAAQS. Alaska made this SIP submission to EPA in two parts on December 31, 2014 and January 29, 2015. EPA found the submission complete pursuant to CAA section 110(k)(1)(B), 42 U.S.C. 7410(k)(1)(B), on February 18, 2015. Section 110(k)(2) requires EPA to take action on a SIP submission within one year of the date it is complete.

The proposed consent decree would resolve a lawsuit filed by the Plaintiffs seeking to compel EPA to take actions required under CAA section 110(k)(2)–(4) with respect to the Fairbanks North Star Borough Moderate Area Attainment Plan. Under the terms of the proposed consent decree, EPA must take proposed action on the SIP submission no later than January 19, 2017, and must take final action thereon no later than August 28, 2017. See the proposed consent decree for the specific details.

For a period of thirty (30) days following the date of publication of this notice, the Agency will accept written comments relating to the proposed consent decree from persons who are not named as parties or intervenors to the litigation in question. EPA or the Department of Justice may withdraw or withhold consent to the proposed consent decree if the comments disclose facts or considerations that indicate that such consent is inappropriate, improper, inadequate, or inconsistent with the requirements of the Act. Unless EPA or the Department of Justice determines that consent to this proposed consent decree should be withdrawn, the terms of the consent decree will be affirmed.

II. Additional Information About Commenting on the Proposed Consent Decree

A. How can I get a copy of the proposed consent decree?

The official public docket for this action (identified by EPA–HQ–OGC–2016–0623) contains a copy of the proposed consent decree. The official public docket is available for public viewing at the Office of Environmental Information (OEI) Docket in the EPA Docket Center, EPA West, Room 3334, 1301 Constitution Ave. NW., Washington, DC. The EPA Docket Center 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 OEI Docket is (202) 566–1752.

An electronic version of the public docket is available through *www.regulations.gov.* You may use *www.regulations.gov* to submit or view public comments, access the index listing of the contents of the official public docket, and access those documents in the public docket that are available electronically. Once in the system, key in the appropriate docket identification number then select ''search''.

It is important to note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing online at *www.regulations.gov* without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. Information claimed as CBI and other information whose disclosure is restricted by statute is not included in the official public docket or in the electronic public docket. EPA's policy is that copyrighted material, including copyrighted material contained in a public comment, will not be placed in EPA's electronic public docket but will be available only in printed, paper form in the official public docket. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the EPA Docket Center.

B. How and to whom do I submit comments?

You may submit comments as provided in the **ADDRESSES** section. Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked ''late.'' EPA is not required to consider these late comments.

If you submit an electronic comment, EPA recommends that you include your name, mailing address, and an email address or other contact information in the body of your comment and with any disk or CD ROM you submit. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. Any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket. 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.

Use of the *www.regulations.gov* Web site to submit comments to EPA electronically is EPA's preferred method for receiving comments. The electronic public docket system is an ''anonymous access'' system, which means EPA will not know your identity, email address, or other contact information unless you provide it in the body of your comment. In contrast to EPA's electronic public docket, EPA's electronic mail (email) system is not an ''anonymous access'' system. If you send an email comment directly to the Docket without going through *www.regulations.gov,* your email address is automatically captured and included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

Gautam Srinivasan,

Deputy Associate General Counsel.

[FR Doc. 2016–26617 Filed 11–2–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OARM–2016–0210; FRL–9954–90–OARM]

National and Governmental Advisory Committees to the U.S. Representative to the Commission for Environmental Cooperation

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of advisory committee meeting.

SUMMARY: Under the Federal Advisory Committee Act, Public Law 92–463, the Environmental Protection Agency (EPA) gives notice of a meeting of the National Advisory Committee (NAC) and Governmental Advisory Committee (GAC) to the U.S. Representative to the North American Commission for Environmental Cooperation (CEC). The National and Governmental Advisory Committees advise the EPA Administrator in her capacity as the U.S. Representative to the CEC Council. The committees are authorized under Articles 17 and 18 of the North American Agreement on Environmental Cooperation (NAAEC), North American Free Trade Agreement Implementation Act, Public Law 103–182, and as directed by Executive Order 12915, entitled ''Federal Implementation of the North American Agreement on Environmental Cooperation.'' The NAC is composed of 16 members representing academia, environmental non-governmental organizations, and private industry. The GAC consists of 14 members representing state, local, and tribal governments. The committees are responsible for providing advice to the U.S. Representative on a wide range of strategic, scientific, technological, regulatory, and economic issues related to implementation and further elaboration of the NAAEC.

The purpose of the meeting is to provide advice on issues related to the CEC's 2016–17 Draft Operational Plan, youth engagement, and other trade and environment issues in North America. The meeting will also include a public comment session. The agenda, meeting materials, and general information about the NAC and GAC will be available at *http://www2.epa.gov/faca/nac-gac.*

DATES: The National and Governmental Advisory Committees will hold an open meeting on Wednesday, November 16, 2016 from 9:00 a.m. to 5:00 p.m., and Thursday, November 17, 2016 from 9:00 a.m. until 3:00 p.m.

ADDRESSES: The meeting will be held at the U.S. EPA, Conference Room 1117A, located in the William Jefferson Clinton East Building, 1200 Pennsylvania Ave. NW., Washington, DC 20004. Telephone: 202–564–2294. The meeting is open to the public, with limited seating on a first-come, first-served basis.

FOR FURTHER INFORMATION CONTACT: Oscar Carrillo, Designated Federal Officer, *carrillo.oscar@epa.gov,* 202–564–0347, U.S. EPA, Federal Advisory Committee Management Division (1601–M), 1200 Pennsylvania Avenue NW., Washington, DC 20004.

SUPPLEMENTARY INFORMATION: Requests to make oral comments, or provide written comments to the NAC/GAC should be sent to Oscar Carrillo at *carrillo.oscar@epa.gov* by Tuesday, November 8, 2016. The meeting is open to the public, with limited seating on a first-come, first-served basis. Members of the public wishing to participate in the teleconference should contact Oscar Carrillo at *carrillo.oscar@epa.gov* or (202) 564–0347 by Nov. 8, 20116.

Meeting Access: For information on access or services for individuals with disabilities, please contact Oscar Carrillo at 202–564–0347 or *carrillo.oscar@epa.gov.* To request accommodation of a disability, please contact Oscar Carrillo, preferably at least 10 days prior to the meeting, to give EPA as much time as possible to process your request.

Dated: October 25, 2016.

Oscar Carrillo,

Designated Federal Officer.

[FR Doc. 2016–26611 Filed 11–2–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPPT–2016–0111; FRL–9950–33]

Agency Information Collection Activities; Proposed Renewal of an Existing Collection (EPA ICR No. 2487.02 and OMB Control No. 2070–0189); Comment Request

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA), this document announces that EPA is planning to submit an Information Collection Request (ICR) to the Office of Management and Budget (OMB). The ICR, entitled: ''Safer Choice Logo Redesign Consultations'' and identified by EPA ICR No. 2487.02 and OMB Control No. 2070–0189, represents the renewal of an existing ICR that is scheduled to expire on February 28, 2017. Before submitting the ICR to OMB for review and approval, EPA is soliciting comments on specific aspects of the proposed information collection that is summarized in this document. The ICR and accompanying material are available in the docket for public review and comment.

DATES: Comments must be received on or before January 3, 2017.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPPT–2016–0111, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.
- *Mail:* Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.*

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

FOR FURTHER INFORMATION CONTACT: *For technical information contact:* Wen Chen, Chemistry, Economics & Sustainable Strategies Division (7406–M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (202) 564–8849; email address: *wen.chen@epa.gov.*

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

SUPPLEMENTARY INFORMATION:

I. What information is EPA particularly interested in?

Pursuant to PRA section 3506(c)(2)(A) (44 U.S.C. 3506(c)(2)(A)), EPA specifically solicits comments and information to enable it to:

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

2. Evaluate the accuracy of the Agency's estimates of the burden of the proposed collection of information, including the validity of the methodology and assumptions used.

3. Enhance the quality, utility, and clarity of the information to be collected.

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses. In particular, EPA is requesting comments from very small businesses (those that employ less than 25) on examples of specific additional efforts that EPA could make to reduce the paperwork burden for very small businesses affected by this collection.

II. What information collection activity or ICR does this action apply to?

Title: Safer Choice Logo Redesign Consultations.

ICR number: EPA ICR No. 2487.02.

OMB control number: OMB Control No. 2070–0189.

ICR status: This ICR is currently scheduled to expire on February 28, 2017. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information, unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the Code of Federal Regulations (CFR), after appearing in the **Federal Register** when approved, are listed in 40 CFR part 9, are displayed either by publication in the **Federal Register** or by other appropriate means, such as on the related collection instrument or form, if applicable. The display of OMB control numbers for certain EPA regulations is consolidated in 40 CFR part 9.

Abstract: This information collection supports the consultation process by which the U.S. Environmental Protection Agency (EPA) will refine and enhance its logo redesign and education approach for the Safer Choice Product Recognition Program (Safer Choice program), formerly known as the Design for the Environment Program. The Safer Choice program recognizes products where all ingredients meet EPA's stringent requirements for human health and the environment as found in the Safer Choice Standard. Under the encouragement of the current program, leading companies have already made great progress in developing safer, highly effective chemical products. Since the program's inception in 1997, formulators have been using the program as a portal to OPPT's unique chemical expertise, information resources, and guidance on greener chemistry. Safer Choice partners enjoy Agency recognition, including the use of the Safer Choice label on qualifying products.

The Safer Choice program adopted a new logo in March 2015 in response to stakeholder feedback. Following the launch of the new logo, EPA will conduct consumer surveys to gauge consumer recognition of the new logo and understand how the new logo and educational activities are diffusing over time and changing purchasing decisions. This ICR will enable Safer Choice to collect feedback from consumers through focus groups and online surveys and integrate it into the program, which will help to strengthen the visibility of the logo and program, improve product recognition among formulators and partners, and further promote chemical safety.

Responses to the collection of information are voluntary. Respondents may claim all or part of a notice confidential. EPA will disclose information that is covered by a claim of confidentiality only to the extent permitted by, and in accordance with, the procedures in TSCA section 14 and 40 CFR part 2.

Burden statement: The annual public reporting and recordkeeping burden for this collection of information is estimated to range between 0.17 hours and 2.0 hours per response depending upon the nature of the respondent. Burden is defined in 5 CFR 1320.3(b).

The ICR, which is available in the docket along with other related materials, provides a detailed explanation of the collection activities and the burden estimate that is only briefly summarized here:

Respondents/Affected Entities: Entities potentially affected by this ICR are individual adult consumers who are members of the general population.

Estimated total number of potential respondents: 2,330.

Frequency of response: On occasion.

Estimated total average number of responses for each respondent: 1.0.

Estimated total annual burden hours: 777 hours.

Estimated total annual costs: $29,513. This includes an estimated burden cost of $29,513 and an estimated cost of $0 for capital investment or maintenance and operational costs.

III. Are there changes in the estimates from the last approval?

There is a decrease of 1,220 hours in the total estimated respondent burden compared with that identified in the ICR currently approved by OMB. This decrease reflects a reduction in the total number of responses because EPA will conduct fewer consumer online surveys. This change is an adjustment.

IV. What is the next step in the process for this ICR?

EPA will consider the comments received and amend the ICR as appropriate. The final ICR package will then be submitted to OMB for review and approval pursuant to 5 CFR 1320.12. EPA will issue another **Federal Register** document pursuant to 5 CFR 1320.5(a)(1)(iv) to announce the submission of the ICR to OMB and the opportunity to submit additional comments to OMB. If you have any questions about this ICR or the approval process, please contact the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

Authority: 44 U.S.C. 3501 *et seq.*

Dated: October 27, 2016.

James Jones,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

[FR Doc. 2016–26619 Filed 11–2–16; 8:45 am]

BILLING CODE 6560–50–P

FARM CREDIT ADMINISTRATION

Farm Credit Administration Board; Sunshine Act; Regular Meeting

AGENCY: Farm Credit Administration.

SUMMARY: Notice is hereby given, pursuant to the Government in the Sunshine Act, of the regular meeting of the Farm Credit Administration Board (Board).

DATES: The regular meeting of the Board will be held at the offices of the Farm Credit Administration in McLean, Virginia, on November 10, 2016, from 9:00 a.m. until such time as the Board concludes its business.

ADDRESSES: Farm Credit Administration, 1501 Farm Credit Drive, McLean, Virginia 22102–5090. Submit attendance requests via email to *VisitorRequest@FCA.gov.* See **SUPPLEMENTARY INFORMATION** for further information about attendance requests.

FOR FURTHER INFORMATION CONTACT: Dale L. Aultman, Secretary to the Farm Credit Administration Board, (703) 883–4009, TTY (703) 883–4056.

SUPPLEMENTARY INFORMATION: Parts of this meeting of the Board will be open to the public (limited space available), and parts will be closed to the public. Please send an email to *VisitorRequest@FCA.gov* at least 24 hours before the

meeting. In your email include: name, postal address, entity you are representing (if applicable), and telephone number. You will receive an email confirmation from us. Please be prepared to show a photo identification when you arrive. If you need assistance for accessibility reasons, or if you have any questions, contact Dale L. Aultman, Secretary to the Farm Credit Administration Board, at (703) 883–4009. The matters to be considered at the meeting are:

Open Session

A. *Approval of Minutes*
- October 13, 2016

B. *Report*
- Update on the Farm Credit System's Young, Beginning and Small Farmer Reporting

Closed Session *

- Office of Secondary Market Oversight Quarterly Report

Dated: November 1, 2016.

Dale L. Aultman,

Secretary, Farm Credit Administration Board.

*Session Closed-Exempt pursuant to 5 U.S.C. 552b(c)(8) and (9).

[FR Doc. 2016–26700 Filed 11–1–16; 4:15 pm]

BILLING CODE 6705–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0262]

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 3, 2017. 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 to *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.: 3060–0262.

Title: Section 90.179, Shared Use of Radio Stations.

Form No.: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit, non-for-profit institutions, and state, local and tribal government.

Number of Respondents and Responses: 43,000 respondents, 43,000 responses.

Estimated Time per Response: .25 up to .75 hours.

Frequency of Response: Recordkeeping requirement and On occasion reporting requirement.

Obligation To Respond: Required to obtain or retain benefits. The statutory authority for this collection is contained in 47 U.S.C. 154(i), 161, 303(g), 303(r) and 332(c)(7).

Total Annual Burden: 43,000 hours.

Annual Cost Burden: None.

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 Commission was directed by the United States Congress, in the Balanced Budget Act of 1997, to dedicate 2.4 MHz of electromagnetic spectrum in the 746–806 MHz band for public safety services. Section 90.179 requires that Part 90 licensees that share use of their private land mobile radio facility on non-profit, cost-sharing basis to prepare and keep a written sharing agreement as part of the station records. Regardless of the method of sharing, an up-to-date list of persons who are sharing the station and the basis of their eligibility under Part 90 must be maintained. The requirement is necessary to identify users of the system should interference problems develop. This information is used by the Commission to investigate interference complaints and resolve interference and operational complaints that may arise among the users.

Federal Communications Commission.

Marlene H. Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2016–26552 Filed 11–2–16; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0519]

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 3, 2017. 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 to *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 Number: 3060–0519.

Title: Rules and Regulations Implementing the Telephone Consumer Protection Act (TCPA) of 1991, CG Docket No. 02–278. Form Number: N/A. Type of Review: Revision of a currently approved collection. Respondents: Business or other for-profit entities; Individuals or households; Not-for-profit institutions.

Number of Respondents and Responses: 36,548 respondents; 147,434,797 responses.

Estimated Time per Response: .004 hours (15 seconds) to 1 hour.

Frequency of Response: Recordkeeping requirement; Annual, on occasion and one-time reporting requirements; Third party disclosure requirement.

Obligation To Respond: Required to obtain or retain benefits. The statutory authority for the information collection requirements is found in the Telephone Consumer Protection Act of 1991 (TCPA), Public Law 102–243, December 20, 1991, 105 Stat. 2394, which added Section 227 of the Communications Act of 1934, [47 U.S.C. 227] Restrictions on the Use of Telephone Equipment.

Total Annual Burden: 666,598 hours. Total Annual Cost: $2,745,000.

Nature and Extent of Confidentiality: Confidentiality is an issue to the extent that individuals and households provide personally identifiable information, which is covered under the FCC's system of records notice (SORN), FCC/CGB–1, ''Informal Complaints and Inquiries.'' As required by the Privacy Act, 5 U.S.C. 552a, the Commission also published a SORN, FCC/CGB–1 ''Informal Complaints, Inquiries, and Requests for Dispute Assistance'', in the **Federal Register** on August 15, 2014 (79 FR 48152) which became effective on September 24, 2014. A system of records for the do-not-call registry was created by the Federal Trade Commission (FTC) under the Privacy Act. The FTC originally published a notice in the **Federal Register** describing the system. *See* 68 FR 37494, June 24, 2003. The FTC updated its system of records for the do-not-call registry in 2009. *See* 74 FR 17863, April 17, 2009.

Privacy Impact Assessment: Yes.

Needs and Uses: The reporting requirements included under this OMB Control Number 3060–0519 enable the Commission to gather information regarding violations of Section 227 of the Communications Act, the Do-Not-Call Implementation Act (Do-Not-Call Act), and the Commission's implementing rules. If the information collection were not conducted, the Commission would be unable to track and enforce violations of Section 227 of the Communications Act, the Do-Not-Call Act, or the Commission's implementing rules. The Commission's implementing rules provide consumers with protections from many unwanted telephone solicitations and other commercial calls.

The National Do-Not-Call Registry supplements the company-specific do-not-call rules for those consumers who wish to continue requesting that particular companies not call them. Any company that is asked by a consumer, including an existing customer, not to call again must honor that request for five (5) years.

A provision of the Commission's rules, however, allows consumers to give specific companies permission to call them through an express written agreement. Nonprofit organizations are exempt from the Do-Not-Call Registry requirements.

On September 21, 2004, the Commission released the *Safe Harbor Order* establishing a limited safe harbor in which callers will not be liable for placing autodialed and prerecorded message calls to numbers ported from a wireline service to a wireless service within the previous 15 days. The Commission also amended its existing National Do-Not-Call Registry safe harbor to require telemarketers to scrub their lists against the Registry every 31 days.

On June 17, 2008, in accordance with the Do-Not-Call Improvement Act of 2007, the Commission revised its rules to minimize the inconvenience to consumers of having to re-register their preferences not to receive telemarketing calls and to further the underlying goal of the National Do-Not-Call Registry to protect consumer privacy rights. The Commission released a *Report and Order* in CG Docket No. 02–278, FCC 08–147, amending the Commission's rules under the TCPA to require sellers and/or telemarketers to honor registrations with the National Do-Not-Call Registry so that registrations would not automatically expire based on the then-current five year registration period. Specifically, the Commission modified § 64.1200(c)(2) of its rules to require sellers and/or telemarketers to honor numbers registered on the Registry indefinitely or until the number is removed by the database administrator or the registration is cancelled by the consumer.

On February 15, 2012, the Commission released a *Report and Order* in CG Docket No. 02–278, FCC 12–21, revising its rules to: (1) Require prior express written consent for all autodialed or prerecorded telemarketing calls to wireless numbers and for all prerecorded telemarketing calls to residential lines; (2) eliminate the established business relationship exception to the consent requirement for prerecorded telemarketing calls to residential lines; (3) require telemarketers to include an automated, interactive opt-out mechanism in all prerecorded telemarketing calls, to allow consumers more easily to opt out of future robocalls during a robocall itself; and (4) require telemarketers to comply with the 3% limit on abandoned calls during each calling campaign, in order to discourage intrusive calling campaigns. Finally, the Commission also exempted from the Telephone Consumer Protection Act requirements prerecorded calls to residential lines made by health care-related entities governed by the Health Insurance Portability and Accountability Act of 1996.

On August 11, 2016, the Commission released a *Report and Order* in CG Docket No. 02–278, FCC 16–99, adopting rules to implement the TCPA amendments Congress enacted in Section 301 of the Bipartisan Budget Act of 2015. The Commission adopted rules implementing the law's exception from the prior express consent requirement for autodialed or prerecorded calls to wireless numbers ''solely to collect a debt owed to or guaranteed by the United States,'' and placing limits on the number and duration of autodialed or prerecorded calls to wireless numbers ''to collect a debt owed or guaranteed by the United States.'' Federal government callers and contractors making these calls on behalf of the federal government, without prior express consent of the called party, may call the person or persons responsible for paying the debt at one of three phone numbers specified in the rules, may call three times during a 30-day period, may call between 8:00 a.m. and 9:00 p.m. local

time at the debtor's location, may not call once the debtor requests that the calls cease, and must transfer the stop-call request to the new servicer if the debt servicer changes. Callers must notify debtors of their right to request that no further autodialed or prerecorded calls be made to the debtor for the life of the debt. Prerecorded calls may not exceed 60 seconds, excluding required disclosures and stop-calling instructions. Text messages are limited to 160 characters, including required disclosures, which may be sent in a separate text message. Calls may be made (1) once the debt is delinquent and, (2) if the debt is not yet delinquent, then after one of the following events and in the 30 days before one of the following events: the end of a grace, deferment, or forbearance period; expiration of an alternative payment arrangement; or occurrence of a similar time-sensitive event or deadline affecting the amount or timing of payments due.

Federal Communications Commission.

Marlene H. Dortch,

Secretary. Office of the Secretary.

[FR Doc. 2016–26551 Filed 11–2–16; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–XXXX and 3060–XXXX]

Information Collection Being Submitted for Review and Approval to the Office of Management and Budget

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995, the Federal Communications Commission (FCC or Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collections. Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees. The FCC may not conduct or sponsor a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

DATES: Written comments should be submitted on or before December 5, 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 contacts below as soon as possible.

ADDRESSES: Direct all PRA comments to Kimberly R. Keravuori, OMB, via email *Kimberly_R_Keravuori@omb.eop.gov;* and to Nicole Ongele, FCC, via email *PRA@fcc.gov* and to *Nicole.Ongele@fcc.gov*. Include in the comments the OMB control number as shown in the ''Supplementary Information'' section below.

FOR FURTHER INFORMATION CONTACT: For additional information or copies of the information collection, contact Nicole Ongele at (202) 418–2991. To view a copy of this information collection request (ICR) submitted to OMB: (1) Go to the Web page <*http://www.reginfo.gov/public/do/PRAMain*>, (2) look for the section of the Web page called ''Currently Under Review,'' (3) click on the downward-pointing arrow in the ''Select Agency'' box below the ''Currently Under Review'' heading, (4) select ''Federal Communications Commission'' from the list of agencies presented in the ''Select Agency'' box, (5) click the ''Submit'' button to the right of the ''Select Agency'' box, (6) when the list of FCC ICRs currently under review appears, look for the OMB control number of this ICR and then click on the ICR Reference Number. A copy of the FCC submission to OMB will be displayed.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–XXXX.

Title: Inmate Calling Services Data Collection, One-Time Data Collection.

Form Number: FCC Form 2300.

Type of Review: New collection.

Respondents: Business or other for-profit.

Number of Respondents and Responses: 15 respondents; 15 responses.

Estimated Time per Response: 100 hours.

Frequency of Response: One-time reporting requirement.

Obligation To Respond: Mandatory. Statutory authority for this information collection is contained in 47 U.S.C. 1, 4(i), 4(j), 201, 276, and 303(r) of the Communications Act of 1934, as amended, 47 U.S.C. 151, 154(i)–(j), 201, 276 and 303(r).

Total Annual Burden: 1,500 hours.

Total Annual Cost: No cost.

Privacy Act Impact Assessment: No impact(s).

Nature and Extent of Confidentiality: The Commission anticipates providing confidential treatment for proprietary information submitted by inmate calling service (ICS) providers. Parties that comply with the terms of a protective order for the proceeding will have an opportunity to comment on the data.

Needs and Uses: Section 201 of the Communications Act of 1934 Act (Act), as amended, 47 U.S.C. 201, requires that ICS providers' interstate rates and practices be just and reasonable. Section 276 of the Act, 47 U.S.C. 276, requires that payphone service providers (including those, such as ICS providers, that serve correctional institutions) be fairly compensated. The Commission's Second Report and Order and Third Further Notice of Proposed Rulemaking (FNPRM) requires that all ICS providers comply with a one-time mandatory data collection. ICS providers must submit data on the costs of providing—and the demand for—interstate, international, and intrastate ICS. The data collection requires ICS providers to submit data on ICS calls, various ICS costs, company and contract information, information about facilities served, ICS revenues, ancillary fees, and mandatory taxes and fees. ICS providers are also required to apportion direct costs for each cost category and to explain how joint and common costs are apportioned among the facilities they serve and the services they provide. The data will be used to enable the Commission to assess the costs related to ICS and ensure that ICS rates and fees related to ICS rates remain just, reasonable, and fair, as required by sections 201 and 276 of the Act.

The Commission's Wireline Bureau staff will develop a standardized template for the submission of data and provide instructions to simplify compliance with and reduce the burdens of the data collection. The template will also include filing instructions and text fields for respondents to use to explain portions of their filings, as needed. *See* FCC Form 2300. Providers are encouraged to file their data electronically via the Commission's Electronic Comment Filing System (ECFS).

OMB Control Number: 3060–XXXX.

Title: Inmate Calling Services Data Collection; Annual Reporting, Certification, and Consumer Disclosure Requirements.

Form Number: FCC Form 2301.

Type of Review: New collection.

Respondents: Business or other for-profit.

Number of Respondents and Responses: 15 respondents; 15 responses.

Estimated Time per Response: 5 hours–60 hours.

Frequency of Response: Annual reporting and certification requirements; third party disclosure requirement.

Obligation To Respond: Mandatory. Statutory authority for this information collection is contained in 47 U.S.C. 1, 4(i), 4(j), 201, 225, 276, and 303(r) of the Communications Act of 1934, as amended, 47 U.S.C. 151, 154(i)–(j), 201, 225, 276 and 303(r).

Total Annual Burden: 1,200 hours.

Total Annual Cost: No cost.

Privacy Act Impact Assessment: No impact(s).

Nature and Extent of Confidentiality: The Commission anticipates providing confidential treatment for proprietary information submitted by providers of inmate calling services (ICS). Parties that comply with the terms of a protective order for the proceeding will have an opportunity to comment on the data.

Needs and Uses: Section 201 of the Communications Act of 1934 Act (Act), as amended, 47 U.S.C. 201, requires that ICS providers' rates and practices be just and reasonable. Section 276 of the Act, 47 U.S.C. 276, requires that payphone service providers (including those that serve correctional institutions such as ICS providers) be fairly compensated. The Commission's Second Report and Order and Third Further Notice of Proposed Rulemaking (*Second Report and Order*), WC Docket No., FCC 15–136, requires that ICS providers file annual reports with the Commission, including certifications that the reported data are complete and accurate. The annual reporting and certification rules require ICS providers to file, among other things: data regarding their ICS rates and minutes of use by facility and size of facility; current ancillary service charge amounts and the instances of use of each; and the monthly amount of any site commission payments. The Commission also requires an officer of each ICS provider annually to certify the accuracy of the data submitted and the provider's compliance with the *Second Report and Order.* The consumer disclosure rule requires ICS providers to inform customers of their rates and charges. The data will assist the Commission in, among other things, ensuring compliance with the *Second Report and Order* and monitoring the effectiveness of the ICS reforms adopted therein. The data will be used to enable the Commission to assess the costs related to ICS and ensure that ICS rates and ancillary service charges related to ICS rates remain just, reasonable, and fair, as required by sections 201 and 276 of the Act.

The Commission's Wireline Bureau staff will develop a standardized template for the submission of data and provide instructions to simplify compliance with and reduce the burdens of the data collection. The template will also include filing instructions and text fields for respondents to use to explain portions of their filings, as needed. *See* FCC Form 2301. Providers are encouraged to file their data electronically via the Commission's Electronic Comment Filing System (ECFS).

Federal Communications Commission.

Marlene H. Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2016–26554 Filed 11–2–16; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Healthcare Infection Control Practices Advisory Committee (HICPAC)

In accordance with section 10(a) (2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC), National Center for Emerging and Zoonotic Infectious Diseases (NCEZID) announces a meeting of the aforementioned committee:

Times and Dates:

9:00 a.m.–5:00 p.m., EST, December 1, 2016

9:00 a.m.–12:00 p.m., EST, December 2, 2016

Place: Centers for Disease Control and Prevention, Global Communications Center, Building 19, Auditorium B, 1600 Clifton Road NE., Atlanta, Georgia, 30329; Call-in number: 866–707–0452; Passcode: 78829617.

Status: Open to the public, in-person capacity is limited by the space available and 100 lines on the call-in number. Time will be available for public comment. The public is welcome to submit written comments in advance of the meeting. Comments should be submitted in writing by email to the contact person listed below. The deadline for receipt of written public comments is November 18, 2016. All requests must contain the name, address, and organizational affiliation of the speaker, as well as the topic being addressed. Written comments should not exceed one single-spaced typed page in length and delivered in 3 minutes or less. Please note that the public comment period may end before the time indicated, following the last call for comments. Members of the public who wish to provide public comments should plan to attend the public comment session in-person at the start time listed. Written comments received in advance of the meeting will be included in the official record of the meeting.

Purpose: The Committee is charged with providing advice and guidance to the Director, Division of Healthcare Quality Promotion, the Director, National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), the Director, CDC, the Secretary, Health and Human Services regarding (1) the practice of healthcare infection prevention and control; (2) strategies for surveillance, prevention, and control of infections, antimicrobial resistance, and related events in settings where healthcare is provided; and (3) periodic updating of CDC guidelines and other policy statements regarding prevention of healthcare-associated infections and healthcare-related conditions.

Matters for Discussion: The agenda will include updates on CDC's activities for prevention of healthcare associated infections (HAIs), updates on antimicrobial stewardship, an update on infection prevention in long term care facilities, an update on Draft Infection Control Guidelines, and an update from the workgroup for considerations on endoscope reprocessing.

Agenda items are subject to change as priorities dictate.

Contact person for More Information: Erin Stone, M.S., HICPAC, Division of Healthcare Quality Promotion, NCEZID, CDC, 1600 Clifton Road NE., Mailstop A–07, Atlanta, Georgia 30329. Telephone (404) 639–4045. Email: *hicpac@cdc.gov.*

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and

Prevention and the Agency for Toxic Substances and Disease Registry.

Claudette Grant,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2016–26570 Filed 11–2–16; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–17–17CA]; Docket No. CDC–2016–0105]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing efforts to reduce public burden and maximize the utility of government information, 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. This notice invites comment on a proposed information collection project entitled ''Positive Health Check Evaluation Trial.'' CDC is requesting a three-year approval for a data collection effort designed to evaluate effectiveness of the Positive Health Check (PHC) online tool created by RTI and CDC. This CDC and Research Triangle Institute (RTI) developed tool delivers tailored evidence based prevention messages to HIV positive patients, on improving clinical outcomes and retention in care of HIV positive patients with unsuppressed viral loads. This data collection is also designed to assess the feasibility of implementing the intervention in clinics and the cost of the intervention.

DATES: Written comments must be received on or before January 3, 2017.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2016–0105 by any of the following methods:

- *Federal eRulemaking Portal: Regulations.gov*. Follow the instructions for submitting comments.
- *Mail:* Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS–D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to *Regulations.gov*, including any personal information provided. For access to the docket to read background documents or comments received, go to *Regulations.gov*.

Please note: All public comment should be submitted through the Federal eRulemaking portal (*Regulations.gov*) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact the Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS–D74, Atlanta, Georgia 30329; phone: 404–639–7570; Email: *omb@cdc.gov*.

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. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

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 of the proposed 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. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. 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.

Proposed Project

Positive Health Check Evaluation Trial—New—National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

HIV transmission continues to be an urgent public health challenge in the United States. According to CDC, approximately 1.2 million people are living with HIV, with close to 50,000 new cases each year. Antiretroviral therapy (ART) suppresses the plasma HIV viral load (VL) and people living with HIV (PLWH) who are treated with ART—compared with those who are not—have a substantially reduced risk of transmitting HIV sexually, through drug sharing, or from mother to child. However, it is estimated that only 19% to 28% of people who are infected with HIV in the United States have an undetectable HIV VL. To enhance HIV prevention efforts, implementable, effective, scalable interventions are needed that focus on enhancing prevention and care to improve the health of and reduce HIV transmission risk among PLWH. The Positive Health Check (PHC) intervention is based on earlier computer-based interventions that were proven efficacious for HIV prevention.

The PHC intervention approach is innovative in multiple ways. First, it uses an interactive video doctor to deliver tailored messages that meet specific patient needs related to adherence, sexual risk reduction, engagement in care, mother-to-child transmission, and drug use. Second, this intervention is designed specifically to support patient behavior change by providing useful tips to practice between visits. These tips are patient driven and populated on a handout while patients use the PHC intervention, thereby increasing engagement and the likelihood of success. Third, PHC supports patient-provider communication by also generating a set

of questions that patients would like to ask their provider. These behavior change tips and questions are also populated on a Patient Handout that patients may share with their provider. As such, PHC supports patients and providers during their clinical encounter and promotes communication. Finally, the PHC intervention has been designed from the onset for wide-scale dissemination. Its flexible digital strategy provides access on multiple devices and platforms. This approach makes PHC an important intervention strategy to improve public health in communities that have a high incidence of HIV infection.

This data collection has four primary aims: (1) Implement a randomized trial to test the efficacy of the PHC intervention for improving clinical health outcomes, specifically viral load and retention in care; (2)conduct a feasibility assessment to determine strategies to facilitate implementation and integration of PHC into HIV primary care clinics; (3) collect and document data on the cost of PHC intervention implementation; and (4) document the standard of care at each participating clinic. The awardee of this cooperative agreement is RTI. RTI has subcontracted with four clinical sites to implement the trial. The sub-contractors are the Atlanta VA Medical Center (Atlanta, Georgia), Hillsborough County Health Department (Tampa, Florida), Rutgers Infectious Disease Practice (Newark, New Jersey), and Crescent Care (New Orleans, Louisiana). The four clinical sites are well suited for this work, given the high rates of patients with elevated viral loads.

During the 24-month implementation period, 1,010 patients will be enrolled into the trial (505 intervention arm and 505 control arm) across the four clinics to evaluate the effectiveness of the PHC intervention. To assess the effectiveness of the PHC intervention, patients randomized to the intervention arm will provide their responses to the patient tailoring questions embedded within the intervention and all enrolled patients will consent to have their de-identified clinical values be made available via passive data collection via the electronic medical record. In addition to the main trial, three to five key staff at each clinic site will be selected to participate in the PHC feasibility assessment which includes an online survey and qualitative interviews.

Finally, clinic staff who participate in the implementation of the PHC intervention will provide data on the cost of implementing the PHC intervention. It is estimated that the total burden hours for all data collection activities is 315.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total response burden (in hours)
Persons eligible for study	PHC intervention trial consent	505	1	5/60	42
	Staff online survey consent	20	1	5/60	2
Enrolled participants	PHC tailoring questions	505	3	5/60	126
	Online clinic staff survey	20	3	15/60	15
	Clinic staff qualitative interview	20	3	40/60	40
	Non-research labor cost questionnaire	12	3	75/60	45
	PHC labor cost questionnaire	12	3	75/60	45
Total					315

Leroy A. Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2016–26501 Filed 11–2–16; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[CDC–2013–0021; Docket Number NIOSH–245, 245–A]

Issuance of Final Guidance Publication

AGENCY: National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of issuance of final guidance publication.

SUMMARY: NIOSH announces the availability of the following final publication: ''Criteria for a Recommended Standard: Occupational Exposure to Diacetyl and 2,3-pentanedione'' [DHHS(NIOSH) Publication Number 2016–111].

DATES: The final criteria document was published October 31, 2016.

ADDRESSES: This document may be obtained at the following link: *http://www.cdc.gov/niosh/docs/2016–111.*

FOR FURTHER INFORMATION CONTACT: Lauralynn McKernan, NIOSH/Division of Surveillance, Hazard Evaluations and Field Studies, 1090 Tusculum Avenue, MS R–12, Cincinnati, OH 45226. 513–533–8542 (not a toll free number).

SUPPLEMENTARY INFORMATION: On July 25, 2011, NIOSH published a notice of public meeting and request for comments on the draft ''Criteria for a Recommended Standard: Occupational Exposure to Diacetyl and 2,3-pentanedione.'' in the **Federal Register** (76 FR 44338). On October 18, 2011, NIOSH published an extension of comment period (76 FR 64353). On April 11, 2012, NIOSH published an expanded charge for peer reviewers (77 FR 21777) and then on December 26, 2013, NIOSH published another notice (78 FR 78363) for review of revised Chapters 6 and 8 of the Criteria document. All comments received were reviewed and accepted where appropriate. Comments for Docket 245 are available at: *http://www.cdc.gov/niosh/docket/archive/docket245.html.* Comments for Docket 245–A can be found in the docket at: *www.regulations.gov*, Docket No. CDC–2013–0021.

Dated: October 28, 2016.

John Howard,

Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.

[FR Doc. 2016–26507 Filed 11–2–16; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Committee on Breast Cancer in Young Women (ACBCYW)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC), announces the following meeting of the aforementioned committee:

Time and Date: 1:00 p.m.–5:00 p.m. EST, December 13, 2016.

Place: This meeting will be held via Teleconference and web access. Teleconference and web access login information is as follows:

Toll-Free Telephone: 1–888–566–6510, Participant passcode: 3895011.

Net Conference and Web Url: *https://www.mymeetings.com/nc/join/.* Conference number: PWXW1545545, Audience passcode: 3895011.

Participants can join the event directly at: *https://www.mymeetings.com/nc/join.php?i=PWXW1545545&p=3895011&t=c.*

WebEx Required Download: Participants must have the WebEx Event Manager installed prior to joining the web portion of the meeting.

Status: Open to the public, limited only by the audio phone lines and net conference access available.

Purpose: The committee provides advice and guidance to the Secretary, HHS; the Assistant Secretary for Health; and the Director, CDC, regarding the formative research, development, implementation and evaluation of evidence-based activities designed to prevent breast cancer (particularly among those at heightened risk) and promote the early detection and support of young women who develop the disease. The advice provided by the Committee will assist in ensuring scientific quality, timeliness, utility, and dissemination of credible appropriate messages and resource materials.

Matters for Discussion: The agenda will include discussions on the current and emerging topics related to breast cancer in young women. These will include public health communication, breast cancer in young women digital and social media campaigns, and CDC updates. Committee workgroups will report findings to the committee.

Agenda items are subject to change as priorities dictate.

Online Registration Required: All ACBCYW Meeting participants must register for the meeting online at least 3 business days in advance at *http://www.cdc.gov/cancer/breast/what_cdc_is_doing/meetings.htm.* Please complete all the required fields before submitting your registration and submit no later than December 8, 2016.

Contact Person for More Information: Temeika L. Fairley, Ph.D., Designated Federal Officer, National Center for Chronic Disease Prevention and Health Promotion, CDC, 5770 Buford Hwy, NE., Mailstop K52, Atlanta, Georgia 30341, Telephone (770) 488–4518, Fax (770) 488–4760. Email: *acbcyw@cdc.gov.*

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention, and Agency for Toxic Substances and Disease Registry.

Claudette Grant,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2016–26569 Filed 11–2–16; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–17–17BZ]; Docket No. CDC–2016–0104]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing efforts to reduce public burden and maximize the utility of government information, 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. This notice invites comment on a proposed information collection project entitled ''Project Pride.'' This project is funded by CDC at 12 health departments in the United States. The health departments will report standardized program monitoring and evaluation (M&E) data to CDC. CDC is requesting approval to collect standardized HIV prevention program evaluation data from funded health departments.

DATES: Written comments must be received on or before January 3, 2017.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2017–0104 by any of the following methods:

- *Federal eRulemaking Portal: Regulations.gov*. Follow the instructions for submitting comments.
- *Mail:* Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS–D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to *Regulations.gov*, including any personal information provided. For access to the docket to read background documents or comments received, go to *Regulations.gov*.

Please note: All public comment should be submitted through the Federal eRulemaking portal (*Regulations.gov*) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact the Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS–D74, Atlanta, Georgia 30329; phone: 404–639–7570; Email: *omb@cdc.gov.*

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. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

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 of the proposed 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. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. 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.

Proposed Project

Project PrIDE—New—National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

State, local and territorial health departments in the U.S. are implementing high impact HIV prevention programs to reduce new HIV infections among populations of gay, bisexual, and other men who have sex with men (MSM) and transgender persons. Additional effort is needed to realize the benefits of new prevention strategies that have the potential to significantly reduce new HIV infections and increase viral suppression among MSM and transgender persons.

Pre-exposure prophylaxis (PrEP) is a potent new prevention tool for MSM without HIV but who are at substantial risk of acquiring HIV infection. The daily use of oral, antiretroviral medication (PrEP) with co-formulated tenofovir disoproxil fumarate and emtricitabine (marketed as Truvada®) is proven to significantly reduce the risk of HIV acquisition among sexually active adults. In July 2012, the US Food and Drug Administration approved an HIV prevention indication for Truvada, and in May 2014 CDC published Public Health Service clinical practice guidelines for provision of PrEP to persons at substantial risk of HIV acquisition through sexual or injection routes of transmission as part of a package of HIV prevention clinical services. It is critical for health departments to address barriers to and facilitate broader awareness, support and capacity for the scale-up of PrEP services for MSM and transgender persons at high risk for HIV infection, particularly persons of color, recognizing that the population with the highest incidence of HIV in the U.S. is young African American MSM.

Another potent prevention tool involves antiretroviral medication to suppress HIV–1 viral load, improve health outcomes and reduce transmission risk among people living with HIV (PLWH). The importance of antiretroviral treatment has increased focus on interventions and public health strategies designed to link, engage and re-engage persons living with HIV in health care, with the ultimate outcome of suppressing HIV viral load, decreasing morbidity and increasing survival. To increase viral suppression, more people who are diagnosed with HIV will need to be retained in HIV medical care and receive antiretroviral treatment. There is a need for health departments to implement public health strategies for improving linkage, engagement and re-engagement of MSM and transgender persons who are not in care.

Data to Care is a public health strategy for identifying these individuals. Data to Care is based on the use of surveillance data to intervene directly in disease control. Data to Care programs use laboratory reports received by a health department's HIV surveillance program, and a range of other data sources as markers of HIV care, and analyze these reports to confidentially identify HIV-diagnosed individuals who are not engaged in HIV medical care or have not achieved viral suppression. Several state health departments have taken steps toward initiating a Data to Care program, and a few have reported successful implementation of Data to Care activities. It is important that these efforts be expanded and that other state, local and territorial health departments scale up and implement this promising public health strategy to improve outcomes along the HIV continuum of care and prevent new HIV infections.

The purpose of this project is to support 12 health departments in the United States to implement PrEP and Data to Care demonstration projects for 200 clients annually, prioritizing MSM and transgender persons at high risk of HIV infection, particularly persons of color.

Health departments that are involved in this project will be required to prioritize their services to these populations. Services may also be provided for persons at substantial risk for HIV (for PrEP) or persons who have HIV and are not virally suppressed or have ongoing risk behavior (for Data to Care) who are not MSM or transgender.

CDC HIV program grantees will collect, enter or upload, and report budget data, information on the HIV prevention and care services, and client demographic characteristics with an estimated of 1,104 burden hours.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
Clients	Data Elements	2,400	1	25/60	1,000
Health Departments	Data Management	12	2	20/60	8
Health Departments	Performance Progress Report	12	1	8	96
Total					1,104

Leroy A. Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2016–26500 Filed 11–2–16; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Board on Radiation and Worker Health (ABRWH or Advisory Board), National Institute for Occupational Safety and Health (NIOSH)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), and pursuant to the requirements of 42 CFR 83.15(a), the Centers for Disease Control and Prevention (CDC), announces the following meeting of the aforementioned committee:

Times and Dates: 8:15 a.m.–5:00 p.m., Mountain Time, November 30, 2016; 8:15 a.m.–10:00 a.m., Mountain Time, December 1, 2016.

Public Comment Time and Date: 5:00 p.m.–6:00 p.m.*, Mountain Time, November 30, 2016.

* Please note that the public comment period may end before the time indicated, following the last call for comments. Members of the public who wish to provide public comments should plan to attend the public comment session at the start time listed.

Place: Hilton Santa Fe Historic Plaza, 100 Sandoval Street, Santa Fe, New Mexico 87501; Phone: (505) 986–6416; Fax: (505) 986–6439.

Status: Open to the public, limited only by the space available. The meeting space accommodates approximately 100 people. The public is also welcome to listen to the meeting by joining the teleconference at USA toll-free, dial-in number, 1–866–659–0537 and the pass code is 9933701.

Live Meeting Connection: https://www.livemeeting.com/cc/cdc/join?id=Z9K2DF&role=attend&pw=ABRWH; Meeting ID: Z9K2DF; Entry Code: ABRWH.

Background: The Advisory Board was established under the Energy Employees Occupational Illness Compensation Program Act of 2000 to advise the President on a variety of policy and technical functions required to implement and effectively manage the new compensation program. Key functions of the Advisory Board include providing advice on the development of probability of causation guidelines which have been promulgated by the Department of Health and Human Services (HHS) as a final rule, advice on methods of dose reconstruction which have also been promulgated by HHS as a final rule, advice on the scientific validity and quality of dose estimation and reconstruction efforts being performed for purposes of the compensation program, and advice on petitions to add classes of workers to the Special Exposure Cohort (SEC).

In December 2000, the President delegated responsibility for funding, staffing, and operating the Advisory Board to HHS, which subsequently delegated this authority to the CDC. NIOSH implements this responsibility for CDC. The charter was issued on August 3, 2001, renewed at appropriate intervals, rechartered on March 22, 2016 pursuant to Executive Order 13708, and will expire on September 30, 2017.

Purpose: This Advisory Board is charged with (a) providing advice to the Secretary, HHS, on the development of guidelines under Executive Order 13179; (b) providing advice to the Secretary, HHS, on the scientific validity and quality of dose reconstruction efforts performed for this program; and (c) upon request by the Secretary, HHS, advising the Secretary on whether there is a class of employees at any Department of Energy facility who were exposed to radiation but for whom it is not feasible to estimate their radiation dose, and on whether there is reasonable likelihood that such radiation doses may have endangered the health of members of this class.

Matters for Discussion: The agenda for the Advisory Board meeting includes: NIOSH Program Update; Department of Labor Program Update; Department of Energy Program Update; Dose Reconstruction Report to the Secretary; SEC Petitions Update; Site Profile review for Hooker Electrochemical (Niagara, New York); SEC petitions for: Area IV of Santa Susana Field Laboratory (1965–1988; Ventura County, California), Carborundum Company (1943–1976; Niagara Falls, New York), Savannah River Site (1973–2007; Aiken, South Carolina), and Los Alamos National Laboratory (1996–2005; Los Alamos, New Mexico); and Board Work Sessions.

The agenda is subject to change as priorities dictate.

In the event an individual cannot attend, written comments may be submitted to the contact person below well in advance of the meeting. Any written comments received will be provided at the meeting in accordance with the redaction policy provided below.

Policy on Redaction of Board Meeting Transcripts (Public Comment):

(1) If a person making a comment gives his or her personal information, no attempt will be made to redact the name; however, NIOSH will redact other personally identifiable information, such as contact information, social security numbers, case numbers, etc., of the commenter.

(2) If an individual in making a statement reveals personal information (*e.g.,* medical or employment information) about themselves that information will not usually be redacted. The NIOSH Freedom of Information Act (FOIA) coordinator will, however, review such revelations in accordance with the Federal Advisory Committee Act and if deemed appropriate, will redact such information.

(3) If a commenter reveals personal information concerning a living third party, that information will be reviewed by the NIOSH FOIA coordinator, and upon determination, if deemed appropriated, such information will be redacted, unless the disclosure is made by the third party's authorized representative under the Energy Employees Occupational Illness Compensation Program Act (EEOICPA) program.

(4) In general, information concerning a deceased third party may be disclosed; however, such information will be redacted if (a) the disclosure is made by an individual other than the survivor claimant, a parent, spouse, or child, or the authorized representative of the deceased third party; (b) if it is unclear whether the third party is living or deceased; or (c) the information is unrelated or irrelevant to the purpose of the disclosure.

The Board will take reasonable steps to ensure that individuals making public comment are aware of the fact that their comments (including their name, if provided) will appear in a transcript of the meeting posted on a public Web site. Such reasonable steps include: (a) A statement read at the start of each public comment period stating that transcripts will be posted and names of speakers will not be redacted; (b) A printed copy of the statement mentioned in (a) above will be displayed on the table where individuals sign up to make public comments; (c) A statement such as outlined in (a) above will also appear with the agenda for a Board Meeting when it is posted on the NIOSH Web site; (d) A statement such as in (a) above will appear in the **Federal Register**

Notice that announces Board and Subcommittee meetings.

Contact Person for More Information: Theodore Katz, Designated Federal Officer, NIOSH, CDC, 1600 Clifton Road NE., MS E–20, Atlanta, Georgia 30329, telephone: (513)533–6800, toll free: 1–800–CDC–INFO, email: *dcas@cdc.gov*.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** Notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Claudette Grant,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2016–26571 Filed 11–2–16; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[CFDA Number: 93.564]

Announcement of the Award of a Single-Source Program Expansion Supplement Grant to the Washington State Department of Social and Health Services in Lacey, WA

AGENCY: Office of Child Support Enforcement, ACF, HHS.

ACTION: Notice of the award of a single-source program expansion supplement grant to the Washington State Department of Social and Health Services in Lacey, WA, to support the development of additional dissemination tools such as reports and web-based trainings on the lessons learned and early findings from the Evaluation of Behavioral Interventions for Child Support Services of the Behavioral Interventions for Child Support Services (BICS) Demonstration.

SUMMARY: The Administration for Children and Families (ACF), Office of Child Support Enforcement (OCSE), Division of Program Innovation, announces the award of a single-source program expansion supplement grant in the amount of $200,000 to the Washington State Department of Social and Health Services in Lacey, WA, to support the development of additional dissemination tools such as reports and web-based trainings on the lessons learned and early findings from the Evaluation of Behavioral Interventions for Child Support Services of the Behavioral Interventions for Child Support Services (BICS) Demonstration.

DATES: The period of support for this supplement is September 30, 2016 through September 29, 2017.

FOR FURTHER INFORMATION CONTACT: Michael Hayes, Senior Programs Manager, Office of Child Support Enforcement, 330 C Street SW., 5th Floor, Washington, DC 20201. Telephone: 202–401–5651; Email: *Michael.Hayes@acf.hhs.gov*.

SUPPLEMENTARY INFORMATION: In FY 2014, OCSE competitively awarded a cooperative agreement to the Washington State Department of Social and Health Services to conduct a 5-year evaluation of OCSE's national demonstration called Behavioral Interventions for Child Support Services (BICS).

This supplement will allow the Washington State Department of Social and Health Services to develop additional dissemination tools such as reports and web-based trainings on the lessons learned and early findings from the evaluation of Behavioral Interventions for Child Support Services Demonstration.

The cost of the BICS evaluation is higher than originally budgeted because the process mapping and project design phase has been significantly slower than anticipated for the grantees. This led to the need for increased technical assistance to the BICS grantees by the evaluation grantee. Additionally, as a result of the mapping and design phase, OCSE anticipates an increased number of interesting findings that will be of benefit to the greater child support field.

The supplemental funds will allow Washington State Department of Social and Health Services to provide increased technical assistance to the BICS demonstration sites, and support the development of additional dissemination tools such as reports and web-based trainings on the lessons learned and early findings from the Evaluation of BICS.

Specifically, the Washington State Department of Social and Health Services will explore the development of innovative, user-friendly tools such as podcasts and infographics that will provide research findings and learning to the child support community in a way that is easily accessible to interested program administrators and policy officials. These tools will also continue to build the evidence-base in what works in the delivery of child support services.

Statutory Authority: Section 1115 of the Social Security Act authorizes funds for experimental, pilot, or demonstration projects that are likely to assist in promoting the objectives of Part D of Title IV.

Christopher Beach,

Senior Grants Policy Specialist, Division of Grants Policy, Office of Administration.

[FR Doc. 2016–26563 Filed 11–2–16; 8:45 am]

BILLING CODE 4184–42–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[CFDA Number: 93.564]

Announcement of the Award of a Single-Source Expansion Supplement Grant to the Wisconsin Department for Children and Families in Madison, WI

AGENCY: Office of Child Support Enforcement, ACF, HHS.

ACTION: Notice of the award of a single-source expansion supplement grant to the Wisconsin Department of Children and Families to support the evaluation of the Child Support Noncustodial Parent Employment Demonstration.

SUMMARY: The Administration for Children and Families (ACF), Office of Child Support Enforcement, Division of Program Innovation announces the award of a cooperative agreement in the amount of $200,000 to the Wisconsin Department for Children and Families in Madison, WI to support the evaluation of the Child Support Noncustodial Parent Employment Demonstration.

In FY 2012, the Office of Child Support Enforcement (OCSE) competitively awarded a cooperative agreement to the Wisconsin Department of Children and Families to conduct a 5-year evaluation of OCSE's national demonstration called Child Support Noncustodial Parent Employment Demonstration (CSPED) under Funding Opportunity Announcement (FOA) number HHS–2012–ACF–OCSE–FD–0537. Under this FOA, a total of $4.5 million of 1115 funds were made available to the Wisconsin Department of Children and Families to conduct this evaluation.

The award of $200,000 the Wisconsin Department of Children and Families is required to cover the unanticipated costs of conducting the CSPED evaluation. The CSPED evaluation includes an impact evaluation using random assignment, an implementation study and a benefit-cost analysis. The evaluator is also providing evaluation-related technical assistance to the grantees implementing CSPED. A baseline and 12 month follow-up survey

are being conducted. Administrative data from multiple sources are also being collected and evaluated. A grants management information system was developed for grantees to use to conduct random assignment, enroll individuals into the project, and document service delivery.

DATES: The period of support for this supplement is September 30, 2016 through September 29, 2017.

FOR FURTHER INFORMATION CONTACT: Elaine Sorensen, Office of Child Support Enforcement, 330 C Street SW., 5th Floor, Washington, DC 20201. Telephone: 202–401–5099; Email: *Elaine.sorensen@acf.hhs.gov.*

SUPPLEMENTARY INFORMATION: Given the importance of child support outcomes for the evaluation of CSPED, OCSE has asked the Wisconsin Department of Children and Families to expand the child support outcomes included in the evaluation, requiring additional collection of child support administrative data and additional analyses of these data. In addition, the Wisconsin Department of Children and Families provided OCSE with preliminary impact findings using child support administrative data, which uncovered further unexpected complications with the child support administrative data. OCSE has asked the Wisconsin Department of Children and Families to go back and collect additional child support administrative data to further understand these complications and report their findings to OCSE. Finally, given the strong focus on child support outcomes for this evaluation, OCSE has asked the evaluator to add a second impact report that focuses exclusively on child support outcomes.

Statutory Authority: Section 1115 of the Social Security Act authorizes funds for experimental, pilot, or demonstration projects that are likely to assist in promoting the objectives of Part D of Title IV.

Christopher Beach,

Certifying Official, Senior Grants Policy Specialist, Division of Grants Policy, Office of Administration.

[FR Doc. 2016–26560 Filed 11–2–16; 8:45 am]

BILLING CODE 4184–42–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0403]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Protection of Human Subjects: Informed Consent; Institutional Review Boards

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by December 5, 2016.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0755. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, Three White Flint North 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Protection of Human Subjects: Informed Consent; Institutional Review Boards OMB Control Number 0910–0755—Extension

Part 50 (21 CFR part 50) applies to all clinical investigations regulated by FDA under sections 505(i) and 520(g) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(i) and 360j(g), respectively), as well as clinical investigations that support applications for research or marketing permits for products regulated by FDA, including foods and dietary supplements that bear a nutrient content claim or a health claim, infant formulas, food and color additives, drugs for human use, medical devices for human use, biological products for human use, and electronic products. Compliance with part 50 is intended to protect the rights and safety of subjects involved in investigations filed with FDA under sections 403, 406, 409, 412, 413, 502, 503, 505, 510, 513–516, 518–520, 721, and 801 of the FD&C Act (21 U.S.C. 343, 346, 348, 350a, 350b, 352, 353, 355, 360, 360c–360f, 360h–360j, 379e, and 381, respectively) and sections 351 and 354–360F of the Public Health Service Act.

With few exceptions, no investigator may involve a human being as a subject in FDA-regulated research unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative (see § 50.20). In seeking informed consent, each subject must be provided with certain elements of informed consent. Those elements are listed in § 50.25. Informed consent shall be documented in writing as described in § 50.27.

An institutional review board (IRB) may approve emergency research without requiring the informed consent of all research subjects provided the IRB finds and documents that certain criteria are met as required in § 50.24. We estimate that about eight times per year an IRB is requested to review emergency research under § 50.24. We estimate, of the 8 yearly requests for IRB review under § 50.24, a particular IRB will take about an hour during each of three separate fully convened IRB meetings to review the request under § 50.24 (one meeting occurring after community consultation). The total annual reporting burden for IRB review of emergency research under § 50.24 is estimated at 24 hours (see table 1).

The information requested in the regulations for exception from the general requirements for informed consent for medical devices (21 CFR 812.47), and the information requested in the regulations for exception from the general requirements of informed consent in § 50.23, paragraphs (a) through (c) and (e), is currently approved under OMB control number 0910–0586. The information requested in the investigational new drug (IND) regulations concerning exception from informed consent for emergency research under § 50.24 is currently approved under OMB control number 0910–0014. In addition, the information requested in the regulations for IND safety reporting requirements for human drug and biological products and safety reporting requirements for bioavailability and bioequivalence studies in humans (21 CFR 320.31(d)

and 21 CFR 312.32(c)(1)(ii) and (iv)) is currently approved under OMB control number 0910–0672.

Some clinical investigations involving children, although otherwise not approvable, may present an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children (see § 50.54). Certain clinical investigations involving children may proceed if the IRB finds and documents that the clinical investigation presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children and when the Commissioner of Food and Drugs, after consultation with a panel of experts in pertinent disciplines and following opportunity for public review and comment, makes a determination that certain conditions are met (see § 50.54(b)).

The information requested for clinical investigations in children of FDA-regulated products is covered by the collections of information in the IND regulations (part 312 (21 CFR part 312)), the investigational device exemption (IDE) regulations (part 812 (21 CFR part 812)), the IRB regulations (§ 56.115 (21 CFR 56.115)), the food additive petition and nutrient content claim petition regulations (21 CFR 101.69 and 101.70), and the infant formula regulations (parts 106 and 107 (21 CFR parts 106 and 107)), all of which are approved by OMB. Specifically, the information collected under the IND regulations is currently approved under OMB control number 0910–0014. The information collected under the IDE regulations is currently approved under OMB control number 0910–0078. The information collected under the IRB regulations is currently approved under OMB control number 0910–0130. The information collected in food additive and nutrient content claim petitions is currently approved under OMB control number 0910–0381 (general requirements) and 0910–0016 (Form FDA 3503). The information collected under the infant formula regulations is currently approved under OMB control number 0910–0256 (general requirements) and 0910–0188 (infant formula recalls).

Part 56 (21 CFR part 56) contains the general standards for the composition, operation, and responsibility of an IRB that reviews clinical investigations regulated by FDA under sections 505(i) and 520(g) of the FD&C Act, as well as clinical investigations that support applications for research or marketing permits for products regulated by FDA, including foods and dietary supplements that bear a nutrient content claim or a health claim, infant formulas, food and color additives, drugs for human use, medical devices for human use, biological products for human use, and electronic products. Compliance with part 56 is intended to protect the rights and welfare of human subjects involved in such investigations.

The information collected under the IRB regulations ''Protection of Human Subjects—Recordkeeping and Reporting Requirements for Institutional Review Boards (part 56),'' including the information collection activities in the provisions in § 56.108(a)(1) and (b), is currently approved under OMB control number 0910–0130. The information collected under the regulations for the registration of IRBs in § 56.106 is currently approved under OMB control number 0990–0279. The information collected for IRB review and approval for the IDE regulations (part 812) is currently approved under OMB control number 0910–0078. The information collected for premarket approval of medical devices (part 814 (21 CFR part 814)) is currently approved under OMB control number 0910–0231. The information collected under the regulations for IRB requirements for humanitarian use devices (part 814, subpart H) is currently approved under OMB control number 0910–0332. The information collected under the regulations for IRB review and approval of INDs (part 312) is currently approved under OMB control number 0910–0014.

This collection of information is limited to certain provisions in part 50, subpart B (Informed Consent of Human Subjects), and part 56 (Institutional Review Boards), currently approved under OMB control number 0910–0755.

This proposed extension applies to the following collections of information in part 50: §§ 50.24 (*Exception from informed consent requirements for emergency research*), 50.25 (*Elements of informed consent*), and 50.27 (*Documentation of informed consent*).

In part 56, this proposed extension applies to the following collections of information: § 56.109(d) (written statement about research when documentation of informed consent is waived); § 56.109(e) (IRB written notification to approve or disapprove research); § 56.109(f) (continuing review of research); § 56.109(g) (IRB written statements to the sponsor about required public disclosures related to emergency research under § 50.24); § 56.113 (*Suspension or termination of IRB approval of research*); § 56.120(a) (IRB response to lesser administrative actions for noncompliance); and, § 56.123 (*Reinstatement of an IRB or an institution*).

In § 56.109(d), if an IRB has waived documentation of consent for research that: (1) Presents no more than minimal risk of harm to subjects and (2) involves no procedures for which consent is normally required outside of the research context, the IRB may nevertheless require the investigator to provide a written statement about the research to the subjects. We estimate that each IRB will review about two minimal risk FDA-regulated studies each year. Because the studies are minimal risk, the review can be fairly straightforward, and the written statement for the subjects would be brief. We estimate that IRB review of each written statement could be completed in less than 30 minutes (0.5 hours).

In § 56.109(f), the amount of time an IRB spends on the continuing review of a particular study will vary depending on the nature and complexity of the research, the amount and type of new information presented to the IRB, and whether the investigator is seeking approval of substantive changes to the research protocol or informed consent document. For many studies, continuing review can be fairly straightforward, and the IRB should be able to complete its deliberations and approve the research within a brief period of time.

In § 56.109(g), an IRB is required to provide the sponsor of a study involving an exception from informed consent for emergency research under § 50.24 with a written statement of information that has been publicly disclosed to the communities in which the investigation will be conducted and from which the subjects will be drawn. Public disclosure prior to initiation of the investigation would include the plans for the investigation and its risks and expected benefits. There must also be public disclosure of sufficient information following completion of the clinical investigation to apprise the community and researchers of the study, including the demographic characteristics of the research population, and its results. (See § 50.24(a)(7)(ii) and (iii)). The purpose of the IRB's written statements is to make the sponsor aware that public disclosure has occurred, so that the sponsor can provide copies of the information that has been disclosed to FDA, as required by §§ 312.54(a) and 812.47(a).

We estimate that about eight requests to review emergency research under § 50.24 are submitted each year, and the IRBs that review those studies would prepare two public disclosure reports: One prior to initiation of the research and one following the study's

completion. We estimate that it will take an IRB approximately 1 hour to prepare a written statement to the study sponsor describing each public disclosure, for a total of 2 hours per study. The total annual third party disclosure burden for IRBs to fulfill this requirement related to emergency research under § 50.24 is estimated at 16 hours (see table 2).

When an IRB or institution violates the regulations, FDA issues to the IRB or institution a noncompliance letter (see § 56.120(a)). The IRB or institution must respond to the noncompliance letter describing the corrective actions that will be taken by the IRB or institution. FDA estimates about seven IRBs or institutions will be issued a noncompliance letter annually. We estimate that the IRB's or institution's response will take about 10 hours to prepare, with an estimated total annual burden of 70 hours.

In 2016, FDA disqualified one IRB under § 56.121. To date, no IRB or institution has been reinstated or applied for reinstatement under § 56.123. For this reason, we estimate the annual reporting burden for one respondent only. We estimate a 5-hour burden per response, with an estimated total annual burden of 5 hours.

The regulatory provisions in parts 50 and 56 currently approved under this collection of information, OMB control number 0910–0755, and for which this extension is requested, are shown in table 1.

In the **Federal Register** of July 19, 2016 (81 FR 46935), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
56.109(d) Written statement about minimal risk research when documentation of informed consent is waived.	2,520	2	5,040	.5 (30 minutes)	2,520
56.109(e) IRB written notification to approve or disapprove research; 56.109(f) Continuing review; 50.25 Elements of informed consent; and 50.27 Documentation of informed consent.	2,520	40	100,800	1	100,800
50.24 Exception from informed consent requirements for emergency research.	8	3	24	1	24
56.113 Suspension or termination of IRB approval of research.	2,520	1	2,520	.5 (30 minutes)	1,260
56.120(a) IRB response to lesser administrative actions for noncompliance.	7	1	7	10	70
56.123 Reinstatement of an IRB or an institution	1	1	1	5	5
Total	.....	.....	.....	.....	104,679

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
56.109(g) IRB written statement about public disclosures to sponsor of emergency research under 50.24	8	2	16	1	16

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: October 28, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–26528 Filed 11–2–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–1486]

Authorizations of Emergency Use of In Vitro Diagnostic Devices for Detection of Zika Virus; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of two Emergency Use Authorizations (EUAs) (the Authorizations) for in vitro diagnostic devices for detection of the Zika virus in response to the Zika virus outbreak in the Americas. FDA issued these Authorizations under the Federal Food, Drug, and Cosmetic Act (the FD&C Act), as requested by Vela Diagnostics USA, Inc. and ARUP Laboratories. The Authorizations contain, among other things, conditions on the emergency use of the authorized in vitro diagnostic devices. The Authorizations follow the February 26, 2016, determination by the Secretary of Health and Human Services (HHS) that there is a significant potential for a public health emergency that has a significant potential to affect national security or the health and

security of U.S. citizens living abroad and that involves Zika virus. On the basis of such determination, the Secretary of HHS declared on February 26, 2016, that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection of Zika virus and/or diagnosis of Zika virus infection, subject to the terms of any authorization issued under the FD&C Act. The Authorizations, which include an explanation of the reasons for issuance, are reprinted in this document.

DATES: The Authorization for Vela Diagnostics USA, Inc. is effective as of September 23, 2016; the Authorization for ARUP Laboratories is effective as of September 28, 2016.

ADDRESSES: Submit written requests for single copies of the EUAs to the Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4338, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the Authorizations may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the Authorizations.

FOR FURTHER INFORMATION CONTACT: Michael Mair, Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4336, Silver Spring, MD 20993–0002, 301–796–8510 (this is not a toll free number).

SUPPLEMENTARY INFORMATION:

I. Background

Section 564 of the FD&C Act (21 U.S.C. 360bbb–3) as amended by the Project BioShield Act of 2004 (Pub. L. 108–276) and the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (Pub. L. 113–5) allows FDA to strengthen the public health protections against biological, chemical, nuclear, and radiological agents. Among other things, section 564 of the FD&C Act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product in certain situations. With this EUA authority, FDA can help assure that medical countermeasures may be used in emergencies to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by biological, chemical, nuclear, or radiological agents when there are no adequate, approved, and available alternatives.

Section 564(b)(1) of the FD&C Act provides that, before an EUA may be issued, the Secretary of HHS must declare that circumstances exist justifying the authorization based on one of the following grounds: (1) A determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a biological, chemical, radiological, or nuclear agent or agents; (2) a determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to U.S. military forces of attack with a biological, chemical, radiological, or nuclear agent or agents; (3) a determination by the Secretary of HHS that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of U.S. citizens living abroad, and that involves a biological, chemical, radiological, or nuclear agent or agents, or a disease or condition that may be attributable to such agent or agents; or (4) the identification of a material threat by the Secretary of Homeland Security under section 319F–2 of the Public Health Service (PHS) Act (42 U.S.C. 247d–6b) sufficient to affect national security or the health and security of U.S. citizens living abroad.

Once the Secretary of HHS has declared that circumstances exist justifying an authorization under section 564 of the FD&C Act, FDA may authorize the emergency use of a drug, device, or biological product if the Agency concludes that the statutory criteria are satisfied. Under section 564(h)(1) of the FD&C Act, FDA is required to publish in the **Federal Register** a notice of each authorization, and each termination or revocation of an authorization, and an explanation of the reasons for the action. Section 564 of the FD&C Act permits FDA to authorize the introduction into interstate commerce of a drug, device, or biological product intended for use when the Secretary of HHS has declared that circumstances exist justifying the authorization of emergency use. Products appropriate for emergency use may include products and uses that are not approved, cleared, or licensed under sections 505, 510(k), or 515 of the FD&C Act (21 U.S.C. 355, 360(k), and 360e) or section 351 of the PHS Act (42 U.S.C. 262). FDA may issue an EUA only if, after consultation with the HHS Assistant Secretary for Preparedness and Response, the Director of the National Institutes of Health, and the Director of the Centers for Disease Control and Prevention (to the extent feasible and appropriate given the applicable circumstances), FDA [1] concludes: (1) That an agent referred to in a declaration of emergency or threat can cause a serious or life-threatening disease or condition; (2) that, based on the totality of scientific evidence available to FDA, including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe that: (A) The product may be effective in diagnosing, treating, or preventing (i) such disease or condition; or (ii) a serious or life-threatening disease or condition caused by a product authorized under section 564, approved or cleared under the FD&C Act, or licensed under section 351 of the PHS Act, for diagnosing, treating, or preventing such a disease or condition caused by such an agent; and (B) the known and potential benefits of the product, when used to diagnose, prevent, or treat such disease or condition, outweigh the known and potential risks of the product, taking into consideration the material threat posed by the agent or agents identified in a declaration under section 564(b)(1)(D) of the FD&C Act, if applicable; (3) that there is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating such disease or condition; and (4) that such other criteria as may be prescribed by regulation are satisfied.

No other criteria for issuance have been prescribed by regulation under section 564(c)(4) of the FD&C Act. Because the statute is self-executing, regulations or guidance are not required for FDA to implement the EUA authority.

II. EUA Requests for In Vitro Diagnostic Devices for Detection of the Zika Virus

On February 26, 2016, the Secretary of HHS determined that there is a significant potential for a public health emergency that has a significant potential to affect national security or the health and security of U.S. citizens living abroad and that involves Zika virus. On February 26, 2016, under section 564(b)(1) of the FD&C Act, and on the basis of such determination, the Secretary of HHS declared that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection of Zika virus and/or diagnosis of Zika virus infection, subject to the terms of any authorization issued under section 564 of the FD&C Act. Notice of the

[1] The Secretary of HHS has delegated the authority to issue an EUA under section 564 of the FD&C Act to the Commissioner of Food and Drugs.

determination and declaration of the Secretary was published in the **Federal Register** on March 2, 2016 (81 FR 10878). On September 1, 2016, Vela Diagnostics USA Inc., requested, and on September 23, 2016, FDA issued, an EUA for the *Sentosa* SA ZIKV RT–PCR Test, subject to the terms of the Authorization. On September 26, 2016, ARUP Laboratories requested, and on September 28, 2016, FDA issued an EUA for the Zika Virus Detection by RT–PCR test, subject to the terms of the Authorization.

III. Electronic Access

An electronic version of this document and the full text of the Authorizations are available on the Internet at *http://www.regulations.gov*.

IV. The Authorizations

Having concluded that the criteria for issuance of the Authorizations under section 564(c) of the FD&C Act are met, FDA has authorized the emergency use of two in vitro diagnostic devices for detection of Zika virus subject to the terms of the Authorizations. The Authorizations in their entirety (not including the authorized versions of the fact sheets and other written materials) follows and provides an explanation of the reasons for issuance, as required by section 564(h)(1) of the FD&C Act:

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

September 23, 2016

Donald Henton
Director Regulatory Affairs North America
Vela Diagnostics USA, Inc.
353C US Route 46 West, Suite 250
Fairfield, NJ 07004

Dear Mr. Henton:

This letter is in response to your request that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for emergency use of Vela Diagnostics USA, Inc.'s ("Vela")[1] *Sentosa*® SA ZIKV RT-PCR Test for the qualitative detection of RNA from Zika virus in human serum, EDTA plasma, and urine (collected alongside a patient-matched serum or plasma specimen) from individuals meeting Centers for Disease Control and Prevention (CDC) Zika virus clinical criteria (e.g., clinical signs and symptoms associated with Zika virus infection) and/or CDC Zika virus epidemiological criteria (e.g., history of residence in or travel to a geographic region with active Zika transmission at the time of travel, or other epidemiological criteria for which Zika virus testing may be indicated), by laboratories in the United States (U.S.) that are certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity tests, or by similarly qualified non-U.S. laboratories, pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 360bbb-3).[2] Test results are for the identification of Zika virus RNA. Zika virus RNA is generally detectable in these specimens during the acute phase of infection and, according to the updated CDC Guidance for U.S. Laboratories Testing for Zika Virus Infection,[3] up to 14 days in serum and urine (possibly longer in urine), following onset of symptoms, if present. Positive results are indicative of current infection.

On February 26, 2016, pursuant to section 564(b)(1)(C) of the Act (21 U.S.C. § 360bbb-3(b)(1)(C)), the Secretary of Health and Human Services (HHS) determined that there is a significant potential for a public health emergency that has a significant potential to affect national security or the health and security of U.S. citizens living abroad and that involves Zika virus.[4] Pursuant to section 564(b)(1) of the Act (21 U.S.C. § 360bbb-3(b)(1)), and on the basis

[1] At the time of authorization, Vela, as the EUA holder, is responsible for satisfying the Conditions of Authorization for the *Sentosa*® SA ZIKV RT-PCR Test, which is manufactured by Vela Operations (Singapore).
[2] For ease of reference, this letter will refer to "laboratories in the United States (U.S.) that are certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, to perform high complexity tests, or by similarly qualified non-U.S. laboratories" as "authorized laboratories."
[3] Available at http://www.cdc.gov/zika/laboratories/lab-guidance.html (last updated on September 1, 2016).
[4] As amended by the Pandemic and All Hazards Preparedness Reauthorization Act, Pub. L. No. 113-5, under section 564(b)(1)(C) of the Act, the Secretary may make a determination of a public health emergency, or of significant potential for a public health emergency.

of such determination, the Secretary of HHS then declared that circumstances exist justifying the authorization of the emergency use of *in vitro* diagnostic tests for detection of Zika virus and/or diagnosis of Zika virus infection, subject to the terms of any authorization issued under 21 U.S.C. § 360bbb-3(a).[5]

Having concluded that the criteria for issuance of this authorization under section 564(c) of the Act (21 U.S.C. § 360bbb-3(c)) are met, I am authorizing the emergency use of the *Sentosa*® SA ZIKV RT-PCR Test (as described in the Scope of Authorization section of this letter (Section II)) in individuals meeting CDC Zika virus clinical criteria (e.g., clinical signs and symptoms associated with Zika virus infection) and/or CDC Zika virus epidemiological criteria (e.g., history of residence in or travel to a geographic region with active Zika transmission at the time of travel, or other epidemiological criteria for which Zika virus testing may be indicated) (as described in the Scope of Authorization section of this letter (Section II)) for the detection of Zika virus infection by authorized laboratories, subject to the terms of this authorization.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of the *Sentosa*® SA ZIKV RT-PCR Test for the detection of Zika virus and diagnosis of Zika virus infection in the specified population meets the criteria for issuance of an authorization under section 564(c) of the Act, because I have concluded that:

1. The Zika virus can cause Zika virus infection, a serious or life-threatening disease or condition to humans infected with the virus;

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that the *Sentosa*® SA ZIKV RT-PCR Test, when used with the specified instrument(s) and in accordance with the Scope of Authorization, may be effective in detecting Zika virus and diagnosing Zika virus infection, and that the known and potential benefits of the *Sentosa*® SA ZIKV RT-PCR Test for detecting Zika virus and diagnosing Zika virus infection outweigh the known and potential risks of such product; and

3. There is no adequate, approved, and available alternative to the emergency use of the *Sentosa*® SA ZIKV RT-PCR Test for detecting Zika virus and diagnosing Zika virus infection.[6]

II. Scope of Authorization

I have concluded, pursuant to section 564(d)(1) of the Act, that the scope of this authorization is limited to the use of the authorized *Sentosa*® SA ZIKV RT-PCR Test by authorized laboratories for the detection of RNA from Zika virus and diagnosis of Zika virus infection in individuals meeting CDC Zika virus clinical criteria (e.g., clinical signs and symptoms associated with Zika virus infection) and/or CDC Zika virus epidemiological criteria (e.g., history of residence in or travel to a geographic region with active Zika transmission at the time of travel, or other epidemiological criteria for which Zika virus testing may be indicated).

[5] HHS. *Determination and Declaration Regarding Emergency Use of in Vitro Diagnostic Tests for Detection of Zika Virus and/or Diagnosis of Zika Virus Infection*. 81 Fed. Reg. 10878 (March 2, 2016).

[6] No other criteria of issuance have been prescribed by regulation under section 564(c)(4) of the Act.

The Authorized *Sentosa*® SA ZIKV RT-PCR Test

The *Sentosa*® SA ZIKV RT-PCR Test is a real-time reverse transcription polymerase chain reaction (RT-PCR) assay for the qualitative detection of RNA from Zika virus in human serum, EDTA plasma, urine (collected alongside a patient-matched serum or plasma specimen) and other authorized specimen types.

To perform the *Sentosa*® SA ZIKV RT-PCR Test, nucleic acids are isolated and purified from the sample using a magnetic bead based extraction method. Nucleic acid extraction is performed using the *Sentosa*® SX Virus Total Nucleic Acid Kit v2.0, or other authorized extraction methods. The Extraction Control is added to each sample prior to extraction.

Nucleic acid extraction and PCR set-up procedures are automated using the *Sentosa*® SX101 instrument, or other authorized instrument(s).

The purified nucleic acid is reverse transcribed into cDNA, which is then amplified. The ZIKV master mix, which contains reagents and enzymes for reverse transcription and specific amplification of the Zika virus targeted region, is added. This is followed by the detection of the target of interest on the Applied Biosystems® 7500 Fast Dx Real-Time PCR instrument (ABI 7500 Fast Dx), the *Sentosa*® SA201, or other authorized instrument, for reverse transcription and PCR amplification.

The *Sentosa*® SA ZIKV RT-PCR Test uses the following materials, or other authorized materials or ancillary products:

- Enzyme Mix
- Zika Virus Primer/Probe Mix
- Extraction Control Primer/Probe Mix
- Extraction Control
- Positive Control
- Negative Control (nuclease free water)

The *Sentosa*® SA ZIKV RT-PCR Test requires the following control materials, or other authorized control materials, to be included in each run; all controls listed below must generate expected results in order for a test to be considered valid, as outlined in the *Sentosa*® SA ZIKV RT-PCR Test Instructions for Use:

- Negative Control: Contains nuclease-free water. Controls for reagent and/or environmental contamination for the target channel and is used throughout the extraction and PCR set-up for each run.

- Positive Control: Contains *in vitro* transcribed Zika RNA. Monitors for substantial reagent failure and is used throughout the extraction and PCR set-up for each run.

- Extraction Control: Contains linearized plasmid DNA. Confirms the validity of the extraction process and identifies potential PCR inhibition; it is used throughout the extraction and PCR set-up for each sample.

To produce a valid run the test controls must meet the performance specifications outlined in the Instructions for Use.

The *Sentosa*® SA ZIKV RT-PCR Test also requires the use of additional materials and ancillary reagents commonly used in clinical laboratories and that are described in the authorized *Sentosa*® SA ZIKV RT-PCR Test Instructions for Use.

The above described *Sentosa*® SA ZIKV RT-PCR Test, when labeled consistently with the labeling authorized by FDA entitled "Instructions for Use: *Sentosa*® SA ZIKV RT-PCR Test and the Product Insert (available at http://www.fda.gov/MedicalDevices/Safety/EmergencySituations/ucm161496.htm), which may be revised by Vela in consultation with the Division of Microbiology Devices (DMD)/Office of In Vitro Diagnostics and Radiological Health (OIR)/Center for Devices and Radiological Health (CDRH), is authorized to be distributed to and used by authorized laboratories under this EUA, despite the fact that it does not meet certain requirements otherwise required by federal law.

The above described *Sentosa*® SA ZIKV RT-PCR Test is authorized to be accompanied by the following information pertaining to the emergency use, which is authorized to be made available to healthcare providers and patients, including pregnant women:

- Fact Sheet for Healthcare Providers: Interpreting *Sentosa*® SA ZIKV RT-PCR Test Results
- Fact Sheet for Patients: Understanding Results from the *Sentosa*® SA ZIKV RT-PCR Test

As described in Section IV below, Vela and its authorized distributors are also authorized to make available additional information relating to the emergency use of the authorized *Sentosa*® SA ZIKV RT-PCR Test that is consistent with, and does not exceed, the terms of this letter of authorization.

I have concluded, pursuant to section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of the authorized *Sentosa*® SA ZIKV RT-PCR Test in the specified population, when used for detection of Zika virus and to diagnose Zika virus infection and used consistently with the Scope of Authorization of this letter (Section II), outweigh the known and potential risks of such a product.

I have concluded, pursuant to section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that the authorized *Sentosa*® SA ZIKV RT-PCR Test may be effective in the detection of Zika virus and diagnosis of Zika virus infection, when used consistently with the Scope of Authorization of this letter (Section II), pursuant to section 564(c)(2)(A) of the Act.

FDA has reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I above, and concludes that the authorized *Sentosa*® SA ZIKV RT-PCR Test, when used for detection of Zika virus and to diagnose Zika virus infection in the specified population (as described in the Scope of Authorization of this letter (Section II)), meets the criteria set forth in section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of the authorized *Sentosa*® SA ZIKV RT-PCR Test under this EUA must be consistent with, and may not exceed, the terms of this letter, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section IV). Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination described above and the Secretary of HHS's corresponding declaration under section 564(b)(1), the *Sentosa*® SA ZIKV RT-PCR Test described above is authorized to detect Zika virus and diagnose Zika virus infection in individuals meeting CDC Zika virus clinical criteria (e.g., clinical signs and symptoms associated with Zika virus infection) and/or CDC Zika virus epidemiological criteria (e.g., history of residence in or travel to a geographic region with active Zika virus transmissions at the time of travel, or other epidemiological criteria for which Zika virus testing may be indicated).

This EUA will cease to be effective when the HHS declaration that circumstances exist to justify the EUA is terminated under section 564(b)(2) of the Act or when the EUA is revoked under section 564(g) of the Act.

III. Waiver of Certain Requirements

I am waiving the following requirements for the *Sentosa*® SA ZIKV RT-PCR Test during the duration of this EUA:

- Current good manufacturing practice requirements, including the quality system requirements under 21 CFR Part 820 with respect to the design, manufacture, packaging, labeling, storage, and distribution of the *Sentosa*® SA ZIKV RT-PCR Test.

- Labeling requirements for cleared, approved, or investigational devices, including labeling requirements under 21 CFR 809.10 and 21 CFR 809.30, except for the intended use statement (21 CFR 809.10(a)(2), (b)(2)), adequate directions for use (21 U.S.C. 352(f)), (21 CFR 809.10(b)(5), (7), and (8)), any appropriate limitations on the use of the device including information required under 21 CFR 809.10(a)(4), and any available information regarding performance of the device, including requirements under 21 CFR 809.10(b)(12).

IV. Conditions of Authorization

Pursuant to section 564 of the Act, I am establishing the following conditions on this authorization:

Vela Diagnostics USA, Inc. and Its Authorized Distributor(s)

A. Vela and its authorized distributor(s) will distribute the authorized *Sentosa*® SA ZIKV RT-PCR Test with the authorized labeling only to authorized laboratories. Changes to the authorized labeling may be made by Vela in consultation with, and require concurrence of, DMD/OIR/CDRH.

B. Vela and its authorized distributor(s) will provide to authorized laboratories the

authorized the *Sentosa*® SA ZIKV RT-PCR Test Fact Sheet for Healthcare Providers and the authorized *Sentosa*® SA ZIKV RT-PCR Test Fact Sheet for Patients.

C. Vela and its authorized distributor(s) will make available on their websites the authorized *Sentosa*® SA ZIKV RT-PCR Test Fact Sheet for Healthcare Providers and the authorized *Sentosa*® SA ZIKV RT-PCR Test Fact Sheet for Patients.

D. Vela and its authorized distributor(s) will inform authorized laboratories and relevant public health authority(ies) of this EUA, including the terms and conditions herein.

E. Vela and its authorized distributor(s) will ensure that the authorized laboratories using the authorized *Sentosa*® SA ZIKV RT-PCR Test have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.[7]

F. Through a process of inventory control, Vela and its authorized distributor(s) will maintain records of device usage.

G. Vela and its authorized distributor(s) will collect information on the performance of the test. Vela will report to FDA any suspected occurrence of false positive and false negative results and significant deviations from the established performance characteristics of the test of which Vela becomes aware.

H. Vela and its authorized distributor(s) are authorized to make available additional information relating to the emergency use of the authorized *Sentosa*® SA ZIKV RT-PCR Test that is consistent with, and does not exceed, the terms of this letter of authorization.

Vela Diagnostics USA, Inc.

I. Vela will notify FDA of any authorized distributor(s) of the *Sentosa*® SA ZIKV RT-PCR Test, including the name, address, and phone number of any, authorized distributor(s).

J. Vela will provide its authorized distributor(s) with a copy of this EUA, and communicate to its authorized distributor(s) any subsequent amendments that might be made to this EUA and its authorized accompanying materials (e.g., Fact Sheets, Instructions for Use).

K. Vela may request changes to the authorized *Sentosa*® SA ZIKV RT-PCR Test Fact Sheet for Healthcare Providers and the authorized *Sentosa*® SA ZIKV RT-PCR Test Fact Sheet for Patients. Such requests will be made by Vela in consultation with, and require concurrence of, DMD/OIR/CDRH.

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[7] For questions related to reporting Zika test results to relevant public health authorities, it is recommended that Vela, other authorized distributor(s), and authorized laboratories consult with the applicable country, state or territory health department(s). According to CDC, Zika virus disease is a nationally notifiable condition (see http://www.cdc.gov/zika/).

L. Vela may request the addition of other instruments for use with the authorized *Sentosa*® SA ZIKV RT-PCR Test. Such requests will be made by Vela in consultation with, and require concurrence of, DMD/OIR/CDRH.

M. Vela may request the addition of other extraction methods for use with the authorized *Sentosa*® SA ZIKV RT-PCR Test. Such requests will be made by Vela in consultation with, and require concurrence of, DMD/OIR/CDRH.

N. Vela may request the addition of other specimen types for use with the authorized *Sentosa*® SA ZIKV RT-PCR Test. Such requests will be made by Vela in consultation with, and require concurrence of, DMD/OIR/CDRH.

O. Vela may request the addition of other control materials for use with the authorized *Sentosa*® SA ZIKV RT-PCR Test. Such requests will be made by Vela in consultation with, and require concurrence of, DMD/OIR/CDRH.

P. Vela may request the addition and/or substitution of other ancillary reagents and materials for use with the authorized *Sentosa*® SA ZIKV RT-PCR Test. Such requests will be made by Vela in consultation with, and require concurrence of, DMD/OIR/CDRH.

Q. Vela will assess traceability[8] of the *Sentosa*® SA ZIKV RT-PCR Test with FDA-recommended reference material(s). After submission to FDA and DMD/OIR/CDRH's review of and concurrence with the data, Vela will update its labeling to reflect the additional testing.

R. Vela, assuming the medical device reporting responsibilities of the manufacturer of the *Sentosa*® SA ZIKV RT-PCR Test, will track adverse events and report to FDA under 21 CFR Part 803.

Authorized Laboratories

S. Authorized laboratories will include with reports of the results of the *Sentosa*® SA ZIKV RT-PCR Test the authorized Fact Sheet for Healthcare Providers and the authorized Fact Sheet for Patients. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.

T. Authorized laboratories will perform the *Sentosa*® SA ZIKV RT-PCR Test on the Applied Biosystems® 7500 Fast Dx Real-Time PCR instrument, the *Sentosa*® SA201 instrument, or other authorized instruments.

U. Authorized laboratories will perform the *Sentosa*® SA ZIKV RT-PCR Test using nucleic acid extraction and PCR set-up procedures automated by the *Sentosa*® SX101 instrument, or other authorized instruments.

[8] Traceability refers to tracing analytical sensitivity/reactivity back to a FDA recommended reference material.

V. Authorized laboratories will perform the *Sentosa*® SA ZIKV RT-PCR Test using the *Sentosa*® SX Virus Total Nucleic Acid Kit v2.0 for nucleic acid extraction, or with other authorized extraction methods.

W. Authorized laboratories will perform the *Sentosa*® SA ZIKV RT-PCR Test on human serum, EDTA plasma, or urine (collected alongside a patient-matched serum or plasma specimen) or with other authorized specimen types.

X. Authorized laboratories will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.[9]

Y. Authorized laboratories will collect information on the performance of the test and report to Vela any suspected occurrence of false positive or false negative results of which they become aware.

Z. All laboratory personnel using the test should be appropriately trained in RT-PCR techniques and use appropriate laboratory and personal protective equipment when handling this kit, and use the test in accordance with the authorized labeling.

Vela Diagnostics USA, Inc., Its Authorized Distributor(s) and Authorized Laboratories

AA. Vela, its authorized distributor(s), and authorized laboratories, will ensure that any records associated with this EUA are maintained until notified by FDA. Such records will be made available to FDA for inspection upon request.

Conditions Related to Advertising and Promotion

BB. All advertising and promotional descriptive printed matter relating to the use of the authorized *Sentosa*® SA ZIKV RT-PCR Test shall be consistent with the Fact Sheets and authorized labeling, as well as the terms set forth in this EUA and the applicable requirements set forth in the Act and FDA regulations.

CC. All advertising and promotional descriptive printed matter relating to the use of the authorized *Sentosa*® SA ZIKV RT-PCR Test shall clearly and conspicuously state that:

- This test has not been FDA cleared or approved;
- This test has been authorized by FDA under an EUA for use by authorized laboratories;
- This test has been authorized only for the detection of RNA from Zika virus and diagnosis of Zika virus infection, not for any other viruses or pathogens; and

[9] For questions related to reporting Zika test results to relevant public health authorities, it is recommended that Vela, other authorized distributor(s), and authorized laboratories consult with the applicable country, state or territory health department(s). According to CDC, Zika virus disease is a nationally notifiable condition. http://www.cdc.gov/zika/.

- This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of *in vitro* diagnostic tests for detection of Zika virus and/or diagnosis of Zika virus infection under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

No advertising or promotional descriptive printed matter relating to the use of the authorized *Sentosa®* SA ZIKV RT-PCR Test may represent or suggest that this test is safe or effective for the diagnosis of Zika virus infection.

The emergency use of the authorized *Sentosa®* SA ZIKV RT-PCR Test as described in this letter of authorization must comply with the conditions and all other terms of this authorization.

V. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of *in vitro* diagnostic tests for detection of Zika virus and/or diagnosis of Zika virus infection is terminated under section 564(b)(2) of the Act or the EUA is revoked under section 564(g) of the Act.

Sincerely,

Robert M. Califf, M.D.
Commissioner of Food and Drugs

Enclosures

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

September 28, 2016

Dr. Jerry Hussong
Chief Medical Officer, Director of Labs
ARUP Laboratories
Mail Code 209-D02
500 Chipeta Way
Salt Lake City, UT 84108

Dear Dr. Hussong:

This letter is in response to your request that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for emergency use of the ARUP Laboratories' Zika Virus Detection by RT-PCR test for the qualitative detection of RNA from Zika virus in human serum, EDTA plasma and urine (collected alongside a patient-matched serum or EDTA plasma specimen) from individuals meeting Centers for Disease Control and Prevention (CDC) Zika virus clinical criteria (e.g., clinical signs and symptoms associated with Zika virus infection) and/or CDC Zika virus epidemiological criteria (e.g., history of residence in or travel to a geographic region with active Zika transmission at the time of travel, or other epidemiological criteria for which Zika virus testing may be indicated). Testing is limited to laboratories designated by ARUP Laboratories[1] that are certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity tests, pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 360bbb-3).[2] Test results are for the identification of Zika virus RNA. Zika virus RNA is generally detectable in these specimens during the acute phase of infection and, according to the updated CDC Guidance for U.S. Laboratories Testing for Zika Virus Infection,[3] up to 14 days in serum and urine (possibly longer in urine), following onset of symptoms, if present. Positive results are indicative of current infection.

On February 26, 2016, pursuant to section 564(b)(1)(C) of the Act (21 U.S.C. § 360bbb-3(b)(1)(C)), the Secretary of Health and Human Services (HHS) determined that there is a significant potential for a public health emergency that has a significant potential to affect national security or the health and security of U.S. citizens living abroad and that involves Zika virus.[4] Pursuant to section 564(b)(1) of the Act (21 U.S.C. § 360bbb-3(b)(1)), and on the basis

[1] At the time of authorization, ARUP Laboratories in Salt Lake City, Utah is the only designated laboratory.
[2] For ease of reference, this letter will refer to "laboratories designated by ARUP Laboratories that are certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity tests," as "authorized laboratories."
[3] Available at http://www.cdc.gov/zika/laboratories/lab-guidance.html (last updated on September 1, 2016).
[4] As amended by the Pandemic and All Hazards Preparedness Reauthorization Act, Pub. L. No. 113-5, under section 564(b)(1)(C) of the Act, the Secretary may make a determination of a public health emergency, or of a significant potential for a public health emergency.

of such determination, the Secretary of HHS then declared that circumstances exist justifying the authorization of the emergency use of *in vitro* diagnostic tests for detection of Zika virus and/or diagnosis of Zika virus infection, subject to the terms of any authorization issued under 21 U.S.C. § 360bbb-3(a).[5]

Having concluded that the criteria for issuance of this authorization under section 564(c) of the Act (21 U.S.C. § 360bbb-3(c)) are met, I am authorizing the emergency use of the Zika Virus Detection by RT-PCR test (as described in the Scope of Authorization section of this letter (Section II)) in individuals meeting CDC Zika virus clinical criteria (e.g., clinical signs and symptoms associated with Zika virus infection) and/or CDC Zika virus epidemiological criteria (e.g., history of residence in or travel to a geographic region with active Zika transmission at the time of travel, or other epidemiological criteria for which Zika virus testing may be indicated) (as described in the Scope of Authorization section of this letter (Section II)) for the detection of Zika virus infection by authorized laboratories, subject to the terms of this authorization.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of the Zika Virus Detection by RT-PCR test for the detection of Zika virus and diagnosis of Zika virus infection in the specified population meets the criteria for issuance of an authorization under section 564(c) of the Act, because I have concluded that:

1. The Zika virus can cause Zika virus infection, a serious or life-threatening disease or condition to humans infected with the virus;

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that the Zika Virus Detection by RT-PCR test, when used with the specified instrument(s) and in accordance with the Scope of Authorization, may be effective in detecting Zika virus and diagnosing Zika virus infection, and that the known and potential benefits of the Zika Virus Detection by RT-PCR test for detecting Zika virus and diagnosing Zika virus infection outweigh the known and potential risks of such product; and

3. There is no adequate, approved, and available alternative to the emergency use of the Zika Virus Detection by RT-PCR test for detecting Zika virus and diagnosing Zika virus infection.[6]

II. Scope of Authorization

I have concluded, pursuant to section 564(d)(1) of the Act, that the scope of this authorization is limited to the use of the authorized Zika Virus Detection by RT-PCR test by authorized laboratories for the detection of RNA from Zika virus and diagnosis of Zika virus infection in individuals meeting CDC Zika virus clinical criteria (e.g., clinical signs and symptoms associated with Zika virus infection) and/or CDC Zika virus epidemiological criteria (e.g.,

[5] HHS. *Determination and Declaration Regarding Emergency Use of in Vitro Diagnostic Tests for Detection of Zika Virus and/or Diagnosis of Zika Virus Infection.* 81 Fed. Reg. 10878 (March 2, 2016).

[6] No other criteria of issuance have been prescribed by regulation under section 564(c)(4) of the Act.

history of residence in or travel to a geographic region with active Zika transmission at the time of travel, or other epidemiological criteria for which Zika virus testing may be indicated).

The Authorized Zika Virus Detection by RT-PCR test

The ARUP Laboratories' Zika Virus Detection by RT-PCR test is a real-time reverse transcription polymerase chain reaction (rRT-PCR) assay for the qualitative detection of RNA from Zika virus in human serum, EDTA plasma, urine (collected alongside a patient-matched serum or EDTA plasma specimen) and other authorized specimen types.

To perform the Zika Virus Detection by RT-PCR test, specimens are first extracted to isolate the Zika virus RNA. Nucleic acids are isolated and purified from the sample using the chemagic MSM I extraction platform (Perkin Elmer) with the protocol for total nucleic acid extraction, or other authorized extraction methods.

The purified nucleic acid is reverse transcribed into cDNA and amplified using a 2X custom Multiplex 1-step RT-qPCR master mix (Quanta Bioscience), which contains reagents and enzymes for reverse transcription and specific amplification of the Zika virus region. In the amplification process, the probe anneals to the specific target sequence located between the forward and reverse primers generating a fluorescent signal. With each cycle, additional amplicon is produced, increasing the amount of annealed probe and subsequent fluorescence signal. The RT-PCR is performed on the QuantStudio 12K Flex real-time PCR instrument (Thermo Fisher), or other authorized instruments.

The Zika Virus Detection by RT-PCR test uses the following materials, or other authorized materials or ancillary products:

- Zika Virus Enzyme Mix
- Zika Virus Primer/Probe Mix
- Zika Virus Internal Control
- Zika Virus Negative Extraction Control
- Zika Virus Positive Extraction Control
- No Template Control (nuclease free water)

The Zika Virus Detection by RT-PCR test requires the following control materials, or other authorized control materials, to be included in each run; all controls listed below must generate expected results in order for a test to be considered valid, as outlined in the Zika Virus Detection by RT-PCR, ARUP Laboratories, Instructions for Use:

- Zika Virus Internal Control
  - The internal control consists of a bacteriophage MS2 that is added to each specimen prior to extraction, is co-purified with each specimen, and is amplified by a specific primers and probe set.
  - The internal control MS2 controls for sample extraction, reverse transcription, amplification and detection and also ensures the absence of non-specific PCR inhibition of a sample.

- No Template Control

- RNase, DNase-free water.
- A no template control is included in each RT-PCR run of specimen extractions to monitor for Zika virus contamination.

- Zika Virus Negative Extraction Control
  - Known negative sample.
  - A negative extraction control is included in each run of specimen extractions to monitor for Zika virus contamination.

- Zika Virus Positive Extraction Control
  - Live Zika whole virus.
  - A positive control is included in each run of specimen extractions to monitor nucleic acid isolation and detection of Zika virus RNA.

The above described Zika Virus Detection by RT-PCR test, when labeled consistently with the labeling authorized by FDA entitled "Zika Virus Detection by RT-PCR, ARUP Laboratories, Instructions for Use" (available at http://www.fda.gov/MedicalDevices/Safety/EmergencySituations/ucm161496.htm), which may be revised by ARUP Laboratories in consultation with the Division of Microbiology Devices (DMD)/Office of In Vitro Diagnostics and Radiological Health (OIR)/Center for Devices and Radiological Health (CDRH), is authorized to be distributed to and used by authorized laboratories under this EUA, despite the fact that it does not meet certain requirements otherwise required by federal law.

The above described Zika Virus Detection by RT-PCR test is authorized to be accompanied by the following information pertaining to the emergency use, which is authorized to be made available to healthcare providers and patients, including pregnant women:

- Fact Sheet for Healthcare Providers: Interpreting Zika Virus Detection by RT-PCR Test Results
- Fact Sheet for Patients: Understanding Results from the Zika Virus Detection by RT-PCR Test

As described in Section IV below, ARUP Laboratories, and other authorized distributer(s), are also authorized to make available additional information relating to the emergency use of the authorized Zika Virus Detection by RT-PCR test that is consistent with, and does not exceed, the terms of this letter of authorization.

I have concluded, pursuant to section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of the authorized Zika Virus Detection by RT-PCR test in the specified population, when used for detection of Zika virus and to diagnose Zika virus infection and used consistently with the Scope of Authorization of this letter (Section II), outweigh the known and potential risks of such a product.

I have concluded, pursuant to section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that the authorized Zika Virus Detection by RT-PCR test may be effective in the detection of Zika virus and diagnosis of Zika virus infection, when used consistently with the Scope of Authorization of this letter (Section II), pursuant to section 564(c)(2)(A) of the Act.

FDA has reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I above, and concludes that the authorized Zika Virus Detection by RT-PCR test, when used for detection of Zika virus and to diagnose Zika virus infection in the specified population (as described in the Scope of Authorization of this letter (Section II)), meets the criteria set forth in section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of the authorized Zika Virus Detection by RT-PCR test under this EUA must be consistent with, and may not exceed, the terms of this letter, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section IV). Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination described above and the Secretary of HHS's corresponding declaration under section 564(b)(1), the Zika Virus Detection by RT-PCR test described above is authorized to detect Zika virus and diagnose Zika virus infection in individuals meeting CDC Zika virus clinical criteria (e.g., clinical signs and symptoms associated with Zika virus infection) and/or CDC Zika virus epidemiological criteria (e.g., history of residence in or travel to a geographic region with active Zika virus transmission at the time of travel, or other epidemiological criteria for which Zika virus testing may be indicated).

This EUA will cease to be effective when the HHS declaration that circumstances exist to justify the EUA is terminated under section 564(b)(2) of the Act or when the EUA is revoked under section 564(g) of the Act.

III. Waiver of Certain Requirements

I am waiving the following requirements for the Zika Virus Detection by RT-PCR test during the duration of this EUA:

- Current good manufacturing practice requirements, including the quality system requirements under 21 CFR Part 820 with respect to the design, manufacture, packaging, labeling, storage, and distribution of the Zika Virus Detection by RT-PCR test.

- Labeling requirements for cleared, approved, or investigational devices, including labeling requirements under 21 CFR 809.10 and 21 CFR 809.30, except for the intended use statement (21 CFR 809.10(a)(2), (b)(2)), adequate directions for use (21 U.S.C. 352(f)), (21 CFR 809.10(b)(5), (7), and (8)), any appropriate limitations on the use of the device including information required under 21 CFR 809.10(a)(4), and any available information regarding performance of the device, including requirements under 21 CFR 809.10(b)(12).

IV. Conditions of Authorization

Pursuant to section 564 of the Act, I am establishing the following conditions on this authorization:

ARUP Laboratories and/or Other Authorized Distributor(s)

A. ARUP Laboratories and other authorized distributor(s) will distribute the authorized Zika Virus Detection by RT-PCR test with the authorized labeling only to authorized laboratories. Changes to the authorized labeling may be made by ARUP Laboratories in consultation with, and require concurrence of, DMD/OIR/CDRH.

B. ARUP Laboratories and other authorized distributor(s) will provide to authorized laboratories the authorized Zika Virus Detection by RT-PCR test Fact Sheet for Healthcare Providers and the authorized Zika Virus Detection by RT-PCR test Fact Sheet for Patients.

C. ARUP Laboratories and other authorized distributor(s) will make available on their websites the authorized Zika Virus Detection by RT-PCR test Fact Sheet for Healthcare Providers and the authorized Zika Virus Detection by RT-PCR test Fact Sheet for Patients.

D. ARUP Laboratories and other authorized distributor(s) will inform authorized laboratories and relevant public health authority(ies) of this EUA, including the terms and conditions herein.

E. ARUP Laboratories and other authorized distributor(s) will ensure that the authorized laboratories using the authorized Zika Virus Detection by RT-PCR test have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.[7]

F. Through a process of inventory control, ARUP Laboratories and other authorized distributor(s) will maintain records of device usage.

G. ARUP Laboratories and other authorized distributor(s) will collect information on the performance of the test. ARUP Laboratories will report to FDA any suspected occurrence of false positive and false negative results and significant deviations from the established performance characteristics of the test of which ARUP Laboratories becomes aware.

H. ARUP Laboratories and other authorized distributor(s) are authorized to make available additional information relating to the emergency use of the authorized Zika Virus Detection by RT-PCR test that is consistent with, and does not exceed, the terms of this letter of authorization.

ARUP Laboratories

I. ARUP Laboratories will notify FDA of any authorized distributor(s) of the Zika Virus Detection by RT-PCR test, including the name, address, and phone number of any authorized distributor(s).

J. ARUP Laboratories will provide other authorized distributor(s) with a copy of this

[7] For questions related to reporting Zika test results to relevant public health authorities, it is recommended that ARUP Laboratories, authorized distributors, and authorized laboratories consult with the applicable country, state or territory health department(s). According to CDC, Zika virus disease is a nationally notifiable condition. http://www.cdc.gov/zika/.

EUA, and communicate to other authorized distributor(s) any subsequent amendments that might be made to this EUA and other authorized accompanying materials (e.g., Fact Sheets, Instructions for Use).

K. ARUP Laboratories may request changes to the authorized Zika Virus Detection by RT-PCR test Fact Sheet for Healthcare Providers and the authorized Zika Virus Detection by RT-PCR test Fact Sheet for Patients. Such requests will be made by ARUP Laboratories in consultation with, and require concurrence of, DMD/OIR/CDRH.

L. ARUP Laboratories may request the addition of other instruments for use with the authorized Zika Virus Detection by RT-PCR test. Such requests will be made by ARUP Laboratories in consultation with, and require concurrence of, DMD/OIR/CDRH.

M. ARUP Laboratories may request the addition of other extraction methods for use with the authorized Zika Virus Detection by RT-PCR test. Such requests will be made by ARUP Laboratories in consultation with, and require concurrence of, DMD/OIR/CDRH.

N. ARUP Laboratories may request the addition of other specimen types for use with the authorized Zika Virus Detection by RT-PCR test. Such requests will be made by ARUP Laboratories in consultation with, and require concurrence of, DMD/OIR/CDRH.

O. ARUP Laboratories may request the addition of other control materials for use with the authorized Zika Virus Detection by RT-PCR test. Such requests will be made by ARUP Laboratories in consultation with, and require concurrence of, DMD/OIR/CDRH.

P. ARUP Laboratories may request the addition and/or substitution of other ancillary reagents and materials for use with the authorized Zika Virus Detection by RT-PCR test. Such requests will be made by ARUP Laboratories in consultation with, and require concurrence of, DMD/OIR/CDRH.

Q. ARUP Laboratories will assess traceability[$] of the Zika Virus Detection by RT-PCR test with FDA recommended reference material(s). After submission to FDA and DMD/OIR/CDRH's review of and concurrence with the data, ARUP Laboratories will update its labeling to reflect the additional testing.

R. ARUP Laboratories will track adverse events and report to FDA under 21 CFR Part 803.

Authorized Laboratories

S. Authorized laboratories will include with reports of the results of the Zika Virus Detection by RT-PCR test the authorized Fact Sheet for Healthcare Providers and the authorized Fact Sheet for Patients. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.

[$] Traceability refers to tracing analytical sensitivity/reactivity back to a FDA recommended reference material.

T. Authorized laboratories will perform the Zika Virus Detection by RT-PCR test on the QuantStudio 12K Flex real-time PCR instrument (Thermo Fisher), or other authorized instruments.

U. Authorized laboratories will perform the Zika Virus Detection by RT-PCR test using the chemagic MSM I extraction platform (Perkin Elmer) with the protocol for total nucleic acid extraction, or with other authorized extraction methods.

V. Authorized laboratories will perform the Zika Virus Detection by RT-PCR test on human serum, EDTA plasma, or urine (collected with a patient-matched serum or EDTA plasma specimen) or with other authorized specimen types.

W. Authorized laboratories will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.[9]

X. Authorized laboratories will collect information on the performance of the test and report to ARUP Laboratories, any suspected occurrence of false positive or false negative results of which they become aware.

Y. All laboratory personnel using the test should be appropriately trained in RT-PCR techniques and use appropriate laboratory and personal protective equipment when handling this kit, and use the test in accordance with the authorized labeling.

ARUP Laboratories, Other Authorized Distributor(s) and Authorized Laboratories

Z. ARUP Laboratories, other authorized distributor(s) and authorized laboratories, will ensure that any records associated with this EUA are maintained until notified by FDA. Such records will be made available to FDA for inspection upon request.

Conditions Related to Advertising and Promotion

AA. All advertising and promotional descriptive printed matter relating to the use of the authorized Zika Virus Detection by RT-PCR test shall be consistent with the Fact Sheets and authorized labeling, as well as the terms set forth in this EUA and the applicable requirements set forth in the Act and FDA regulations.

BB. All advertising and promotional descriptive printed matter relating to the use of the authorized Zika Virus Detection by RT-PCR test shall clearly and conspicuously state that:

- This test has not been FDA cleared or approved;
- This test has been authorized by FDA under an EUA for use by authorized laboratories;

[9] For questions related to reporting Zika test results to relevant public health authorities, it is recommended that ARUP Laboratories, authorized distributors, and authorized laboratories consult with the applicable country, state or territory health department(s). According to CDC, Zika virus disease is a nationally notifiable condition. http://www.cdc.gov/zika/.

Page 9 – Dr. Hussong, ARUP Laboratories

- This test has been authorized only for the detection of RNA from Zika virus and diagnosis of Zika virus infection, not for any other viruses or pathogens; and
- This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of *in vitro* diagnostic tests for detection of Zika virus and/or diagnosis of Zika virus infection under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

No advertising or promotional descriptive printed matter relating to the use of the authorized Zika Virus Detection by RT-PCR test may represent or suggest that this test is safe or effective for the diagnosis of Zika virus infection.

The emergency use of the authorized Zika Virus Detection by RT-PCR test as described in this letter of authorization must comply with the conditions and all other terms of this authorization.

V. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of *in vitro* diagnostic tests for detection of Zika virus and/or diagnosis of Zika virus infection is terminated under section 564(b)(2) of the Act or the EUA is revoked under section 564(g) of the Act.

Sincerely,

Robert M. Califf, M.D.
Commissioner of Food and Drugs

Enclosures

Dated: October 28, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–26532 Filed 11–2–16; 8:45 am]

BILLING CODE 4164–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0719]

Agency Information Collection Activities: Proposed Collection; Comment Request; Guidance for Industry on Planning for the Effects of High Absenteeism To Ensure Availability of Medically Necessary Drug Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. 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 of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection in the guidance on planning for the effects of high absenteeism to ensure availability of medically necessary drug products.

DATES: Submit either electronic or written comments on the collection of information by January 3, 2017.

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–2013–N–0719 for ''Agency Information Collection Activities: Proposed Collection; Comment Request; Guidance for Industry on Planning for the Effects of High Absenteeism to Ensure Availability of Medically Necessary Drug Products.'' 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: FDA PRA Staff, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: 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. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Guidance for Industry on Planning for the Effects of High Absenteeism To Ensure Availability of Medically Necessary Drug Products (OMB Control Number 0910–0675)—Extension

The guidance recommends that manufacturers of drug and therapeutic biological products and manufacturers of raw materials and components used in those products develop a written Emergency Plan (Plan) for maintaining an adequate supply of medically necessary drug products (MNPs) during an emergency that results in high employee absenteeism. The guidance discusses the issues that should be covered by the Plan, such as: (1) Identifying a person or position title (as well as two designated alternates) with the authority to activate and deactivate the Plan and make decisions during the emergency, (2) prioritizing the manufacturer's drug products based on medical necessity, (3) identifying actions that should be taken prior to an anticipated period of high absenteeism, (4) identifying criteria for activating the Plan, (5) performing quality risk assessments to determine which manufacturing activities may be reduced to enable the company to meet a demand for MNPs, (6) returning to normal operations and conducting a post-execution assessment of the execution outcomes, and (7) testing the Plan. The guidance recommends developing a Plan for each individual manufacturing facility as well as a broader Plan that addresses multiple sites within the organization. For purposes of this information collection analysis, we consider the Plan for an individual manufacturing facility as well as the broader Plan to comprise one Plan for each manufacturer. Based on FDA's data on the number of manufacturers that would be covered by the guidance, we estimate that approximately 70 manufacturers will develop a Plan as recommended by the guidance (*i.e.,* one Plan per manufacturer to include all manufacturing facilities, sites, and drug products), and that each Plan will take approximately 500 hours per year to develop, maintain, and update.

The guidance also encourages manufacturers to include a procedure in their Plan for notifying the FDA Center for Drug Evaluation and Research (CDER) when the Plan is activated and when returning to normal operations. The guidance recommends that these notifications occur within 1 day of a Plan's activation and within 1 day of a Plan's deactivation. The guidance specifies the information that should be included in these notifications, such as which drug products will be manufactured under altered procedures, which products will have manufacturing temporarily delayed, and any anticipated or potential drug shortages. We expect that approximately two notifications (for purposes of this analysis, we consider an activation and a deactivation notification to equal one notification) will be sent to CDER by approximately two manufacturers each year, and that each notification will take approximately 16 hours to prepare and submit.

The guidance also refers to previously approved collections of information found in FDA regulations. Under the guidance, if a manufacturer obtains information after releasing an MNP under its Plan leading to suspicion that the product might be defective, CDER should be contacted immediately at

drugshortages@fda.hhs.gov in adherence to existing recall reporting regulations (21 CFR 7.40) (OMB control number 0910–0249), or defect reporting requirements for drug application products (21 CFR 314.81(b)(1)) and therapeutic biological products regulated by CDER (21 CFR 600.14) (OMB control numbers 0910–0001 and 0910–0458, respectively).

In addition, the following collections of information found in FDA current good manufacturing practice (CGMP) regulations in part 211 (21 CFR part 211) are approved under OMB control number 0190–0139. The guidance encourages manufacturers to maintain records, in accordance with the CGMP requirements (*see, e.g.,* § 211.180) that support decisions to carry out changes to approved procedures for manufacturing and release of products under the Plan. The guidance states that a Plan should be developed, written, reviewed, and approved within the site's change control quality system in accordance with the requirements in §§ 211.100(a) and 211.160(a); execution of the Plan should be documented in accordance with the requirements described in § 211.100(b); and standard operating procedures should be reviewed and revised or supplementary procedures developed and approved to enable execution of the Plan.

FDA estimates the burden of this information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Absenteeism guidance	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Notify FDA of Plan Activation and Deactivation	2	1	2	16	32

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Absenteeism guidance	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Develop Initial Plan	70	1	70	500	35,000

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: October 28, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–26527 Filed 11–2–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Request for Data and Information on Zebrafish Embryo Chemical Screening

SUMMARY: The National Toxicology Program (NTP) Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM) requests data and information on zebrafish embryo screening tests and protocol design, including pharmacokinetics measurements. Submitted information will be used to assess the state of the science and determine technical needs for non-animal test methods used to evaluate the potential of chemicals to induce developmental effects in offspring.

DATES: Receipt of information: Deadline is December 30, 2016.

ADDRESSES: Data and information should be submitted electronically to *niceatm@niehs.nih.gov.*

FOR FURTHER INFORMATION CONTACT: Dr. Warren Casey, Director, NICEATM; email: *warren.casey@nih.gov;* telephone: (919) 316–4729.

SUPPLEMENTARY INFORMATION:

Background: NICEATM, which fosters the evaluation and promotion of alternative test methods for regulatory use, supports efforts to develop, validate, and implement alternative approaches for identifying potential developmental toxicants that replace, reduce, or refine animal use. Multiple regulatory agencies require testing a substance's potential to cause developmental toxicity, which may necessitate the use of large numbers of animals.

Request for Information: NICEATM requests data and information related to chemical screening in the zebrafish embryo. Respondents should provide information on any activities relevant to the development or validation of zebrafish embryo screening assays. NICEATM is particularly interested in how the study design may influence measures of toxicity/bioactivity and the kinetics associated with chemical uptake. For comparative purposes, NICEATM also requests any available data from *in vivo* developmental studies using the same chemicals.

NICEATM specifically requests information on efforts to optimize zebrafish embryo screening tests and protocol design including comparison of (1) zebrafish strains, (2) embryos with and without an intact chorion, and (3) static and static renewal exposures. NICEATM also requests available data on chemical uptake for developing a better understanding of pharmacokinetics in the zebrafish embryo model.

Respondents to this request for information should include their name, affiliation (if applicable), mailing address, telephone, email, and sponsoring organization (if any) with their communications. The deadline for receipt of the requested information is December 30, 2016. Please contact NICEATM at *niceatm@niehs.nih.gov* if you have questions or concerns about your submission. Responses to this notice will be posted at: *http://ntp.niehs.nih.gov/go/dev-nonanimal.* Persons submitting responses will be identified on the Web page by name and affiliation or sponsoring organization, if applicable.

Responses to this request are voluntary. No proprietary, classified, confidential, or sensitive information should be included in responses. This request for information is for planning purposes only and is not a solicitation for applications or an obligation on the part of the U.S. Government to provide support for any ideas identified in response to the request. Please note that the U.S. Government will not pay for the preparation of any information

submitted or for its use of that information.

Background Information on NICEATM: NICEATM conducts data analyses, workshops, independent validation studies, and other activities to assess new, revised, and alternative test methods and strategies. NICEATM also provides support for the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM). The ICCVAM Authorization Act of 2000 (42 U.S.C. 285*l*–3) provides authority for ICCVAM and NICEATM in the development of alternative test methods. Information about NICEATM and ICCVAM is found at *http://ntp.niehs.nih.gov/go/niceatm* and *http://ntp.niehs.nih.gov/go/iccvam.*

Dated: October 27, 2016.

Linda S. Birnbaum,

Director, National Institute of Environmental, Health Sciences and National Toxicology Program.

[FR Doc. 2016–26605 Filed 11–2–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Announcement of Availability of the Fourteenth Report on Carcinogens

SUMMARY: The Department of Health and Human Services released the 14th Report on Carcinogens (RoC) to the public on November 3, 2016. The report is available on the RoC Web site at: *http://ntp.niehs.nih.gov/go/roc* or from the Office of the RoC (see **ADDRESSES**).

DATES: The 14th RoC is available to the public on November 3, 2016.

ADDRESSES: Dr. Ruth Lunn, Director, Office of the RoC, National Toxicology Program (NTP), National Institute of Environmental Health Sciences (NIEHS), P.O. Box 12233, MD K2–14, Research Triangle Park, NC 27709; telephone: (919) 316–4637; FAX: (301) 480–2970; *lunn@niehs.nih.gov.*

FOR FURTHER INFORMATION CONTACT: Questions or comments concerning the 14th RoC should be directed to Dr. Lunn (see **ADDRESSES**).

SUPPLEMENTARY INFORMATION:

Background Information on the RoC

The RoC is a congressionally mandated document that identifies and discusses agents, substances, mixtures, or exposure circumstances (collectively referred to as ''substances'') that may pose a hazard to human health because of their carcinogenicity. Substances are listed in the report as either *known* or *reasonably anticipated to be human carcinogens.* The listing of a substance in the RoC indicates a potential hazard, but does not establish the exposure conditions that pose a cancer hazard to individuals in their daily lives. For each listed substance, the RoC provides information from cancer studies that support the listing, as well as information about potential sources of exposure and current federal regulations to limit exposures. Each edition of the RoC is cumulative, that is, it lists newly reviewed substances in addition to substances listed in the previous edition. Information about the RoC is available on the RoC Web site (*http://ntp.niehs.nih.gov/go/roc*) or by contacting Dr. Lunn (see **ADDRESSES**).

NTP prepares the RoC on behalf of the Secretary of Health and Human Services. For the 14th RoC, NTP followed an established, multi-step process with multiple opportunities for public input, and used established criteria to evaluate the scientific evidence on each candidate substance under review (*http://ntp.niehs.nih.gov/go/rocprocess*).

New Listings in the 14th RoC: The 14th RoC contains 248 listings, some of which consist of a class of structurally related chemicals or agents. There are six new listings and one revised listing in this edition. The revised listing is for trichloroethylene, which was previously listed as *reasonably anticipated to be a human carcinogen* and is now listed as *known to be a human carcinogen.* Five of the new listings are in the category of *known to be a human carcinogen:* Epstein Bar virus, Kaposi sarcoma-associated herpesvirus, human T-cell lymphotropic virus type 1, human immunodeficiency virus-type 1, and Merkel cell polyomavirus. The new listing in the category of *reasonably anticipated to be a human carcinogen* is for cobalt and cobalt compounds that release cobalt ions in vivo.

Dated: October 25, 2016.

Linda S. Birnbaum,

Director, National Institute of Environmental Health Science and National Toxicology Program.

[FR Doc. 2016–26604 Filed 11–2–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Toxicology Program Board of Scientific Counselors; Announcement of Meeting; Request for Comments

SUMMARY: This notice announces the next meeting of the National Toxicology Program (NTP) Board of Scientific Counselors (BSC). The BSC, a federally chartered, external advisory group composed of scientists from the public and private sectors, will review and provide advice on programmatic activities. The meeting is open to the public except for parts that are closed, as indicated on the agenda. Registration is requested for both attendance and oral comment and required to access the webcast. Information about the meeting and registration are available at *http://ntp.niehs.nih.gov/go/165.*

DATES: *Meeting:* December 14–15, 2016, 8:30 a.m. Eastern Standard Time (EST) on both days and continues to adjournment.

Written Public Comment Submissions: Deadline is November 30, 2016.

Registration for Oral Comments: Deadline is December 7, 2016.

Registration to Attend and/or View Webcast: Deadline is December 15, 2016. Registration to view the meeting via the webcast is required.

ADDRESSES: *Meeting Location:* Rodbell Auditorium, Rall Building, National Institute of Environmental Health Sciences (NIEHS), 111 T.W. Alexander Drive, Research Triangle Park, NC 27709.

Meeting Web page: The preliminary agenda, registration, and other meeting materials are at *http://ntp.niehs.nih.gov/go/165.*

Webcast: The meeting will be webcast on December 15; the URL will be provided to those who register for viewing.

FOR FURTHER INFORMATION CONTACT: Dr. Lori White, Designated Federal Officer for the BSC, Office of Liaison, Policy, and Review, Division of NTP, NIEHS, P.O. Box 12233, K2–03, Research Triangle Park, NC 27709. Phone: 919–541–9834, Fax: 301–480–3272, Email: *whiteld@niehs.nih.gov.* Hand Deliver/Courier address: 530 Davis Drive, Room K2124, Morrisville, NC 27560.

SUPPLEMENTARY INFORMATION:

Meeting and Registration: Parts of the meeting are open to the public as indicated on the agenda; in-person attendance at NIEHS is limited only by the space available. Parts of the meeting

are closed to the public as indicated on the agenda in accordance with the provisions set forth in section 552(c)(6), Title 5 U.S.C., as amended, for the review, discussion, and evaluation of individual intramural programs and projects conducted by the NIEHS, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

The BSC will provide input to the NTP on programmatic activities and issues. Preliminary agenda topics include: Reports from the NIEHS/NTP Director and the NTP Associate Director, updates on projects and recent meetings, a report on release of the 14th Report on Carcinogens, and draft concepts for substances nominated for the Report on Carcinogens.

A preliminary agenda, roster of BSC members, background materials, public comments, and any additional information, when available, will be posted on the BSC meeting Web site (*http://ntp.niehs.nih.gov/go/165*) or may be requested in hardcopy from the Designated Federal Officer for the BSC. Following the meeting, summary minutes will be prepared and made available on the BSC meeting Web site.

The public may attend the open portions of the meeting in person on both days or view the webcast on December 15. Registration is required to view the Web cast; the URL for the webcast will be provided in the email confirming registration. Individuals who plan to provide oral comments (see below) are encouraged to register online at the BSC meeting Web site (*http://ntp.niehs.nih.gov/go/165*) by December 7, 2016, to facilitate planning for the meeting. Individuals interested in this meeting are encouraged to access the Web site to stay abreast of the most current information regarding the meeting. Visitor and security information for those attending in-person is available at *niehs.nih.gov/about/visiting/index.cfm.* Individuals with disabilities who need accommodation to participate in this event should contact Ms. Robbin Guy at phone: (919) 541–4363 or email: *guyr2@niehs.nih.gov.* TTY users should contact the Federal TTY Relay Service at 800–877–8339. Requests should be made at least five business days in advance of the event.

Request for Comments: Written comments submitted in response to this notice should be received by November 30, 2016. Comments will be posted on the BSC meeting Web site and persons submitting them will be identified by their name, affiliation, and sponsoring organization, if applicable. Persons submitting written comments should include their name, affiliation (if applicable), phone, email, and sponsoring organization (if any) with the document. Guidelines for public comments are at *http://ntp.niehs.nih.gov/ntp/about_ntp/guidelines_public_comments_508.pdf.*

Time is allotted during the meeting, as indicated on the agenda, for the public to present oral comments to the BSC on the agenda topics. Public comments can be presented in-person at the meeting or by teleconference line. There are 50 lines for this call; availability is on a first-come, first-served basis. The lines will be open on December 15 from 8:30 a.m. until adjournment; however, the BSC will receive public comments only during the formal public comment periods, which are indicated on the preliminary agenda. Each organization is allowed one time slot per agenda topic. Each speaker is allotted at least 7 minutes, which if time permits, may be extended to 10 minutes at the discretion of the BSC chair. Please note that the time limit may be modified depending on the number of individuals who register for oral comments. Persons wishing to present oral comments should register on the BSC meeting Web site by December 7, 2016, indicate whether they will present comments in-person or via the teleconference line, and indicate the topic(s) on which they plan to comment. The access number for the teleconference line will be provided to registrants by email prior to the meeting. On-site registration for oral comments will also be available on the meeting day, although time allowed for comments by these registrants may be limited and will be determined by the number of persons who register at the meeting.

Persons registering to make oral comments are asked to send a copy of their statement and/or PowerPoint slides to the Designated Federal Officer by December 7, 2016. Written statements can supplement and may expand upon the oral presentation. If registering on-site and reading from written text, please bring 20 copies of the statement for distribution to the BSC and NTP staff and to supplement the record.

Background Information on the BSC: The BSC is a technical advisory body comprised of scientists from the public and private sectors that provides primary scientific oversight to the NTP. Specifically, the BSC advises the NTP on matters of scientific program content, both present and future, and conducts periodic review of the program for the purpose of determining and advising on the scientific merit of its activities and their overall scientific quality. Its members are selected from recognized authorities knowledgeable in fields such as toxicology, pharmacology, pathology, biochemistry, epidemiology, risk assessment, carcinogenesis, mutagenesis, molecular biology, behavioral toxicology, neurotoxicology, immunotoxicology, reproductive toxicology or teratology, and biostatistics. Members serve overlapping terms of up to four years. The BSC usually meets biannually. The authority for the BSC is provided by 42 U.S.C. 217a, section 222 of the Public Health Service Act (PHS), as amended. The BSC is governed by the provisions of the Federal Advisory Committee Act, as amended (5 U.S.C. app.), which sets forth standards for the formation and use of advisory committees.

Dated: October 27, 2016.

Linda S. Birnbaum,

Director, National Institute of Environmental, Health Sciences and National Toxicology Program.

[FR Doc. 2016–26609 Filed 11–2–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4283–DR; Docket ID FEMA–2016–0001]

Florida; Amendment No. 2 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of Florida (FEMA–4283–DR), dated October 8, 2016, and related determinations.

DATES: *Effective Date:* October 19, 2016.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of Florida is hereby amended to include the following areas among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of October 8, 2016.

Brevard and Indian River Counties for Individual Assistance (already designated for assistance for debris removal and emergency protective measures [Categories A and B], including direct federal assistance, under the Public Assistance program).

Putnam County for assistance for debris removal and emergency protective measures (Categories A and B), including direct federal assistance, under the Public Assistance program (already designated for Individual Assistance).

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050 Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2016–26581 Filed 11–2–16; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4283–DR]; [Docket ID FEMA–2016–0001]

Florida; Amendment No. 1 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of Florida (FEMA–4283–DR), dated October 8, 2016, and related determinations.

DATES: *Effective Date:* October 17, 2016.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of Florida is hereby amended to include the Individual Assistance program for the following areas among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of October 8, 2016.

Flagler, St. Johns, and Volusia Counties for Individual Assistance (already designated for assistance for debris removal and emergency protective measures [Categories A and B], including direct federal assistance, under the Public Assistance program).

Putnam County for Individual Assistance.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050 Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2016–26582 Filed 11–2–16; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4284–DR]; [Docket ID FEMA–2016–0001]

Georgia; Amendment No. 3 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of Georgia (FEMA–4284–DR), dated October 8, 2016, and related determinations.

DATES: *Effective Date:* October 20, 2016.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of Georgia is hereby amended to include the following areas among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of October 8, 2016.

Brantley, Candler, Emanuel, Evans, Jenkins, Long, Pierce, Tattnall, and Toombs Counties for Public Assistance, including direct federal assistance.

Bryan, Bulloch, Chatham, Effingham, Glynn, McIntosh, and Wayne for Public Assistance [Categories C–G] (already designated for Individual Assistance and assistance for debris removal and emergency protective measures [Categories A and B], including direct federal assistance, under the Public Assistance program).

Camden, Liberty, and Screven Counties for Public Assistance [Categories C–G] (already designated for assistance for debris removal and emergency protective measures [Categories A and B], including direct federal assistance, under the Public Assistance program).

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050 Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2016–26579 Filed 11–2–16; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4283–DR]; [Docket ID FEMA–2016–0001]

Florida; Amendment No. 6 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of Florida (FEMA–4283–DR), dated October 8, 2016, and related determinations.

DATES: *Effective Date:* October 27, 2016.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of Florida is hereby amended to include the following areas among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of October 8, 2016.

Bradford and Lake Counties for Public Assistance, including direct federal assistance. Seminole County for Public Assistance, including direct federal assistance (already designated for Individual Assistance).

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050 Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2016–26575 Filed 11–2–16; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4284–DR; Docket ID FEMA–2016–0001]

Georgia; Amendment No. 2 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of Georgia (FEMA–4284–DR), dated October 8, 2016, and related determinations.

DATES: *Effective Date:* October 17, 2016.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of Georgia is hereby amended to include the Individual Assistance program and following areas among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of October 8, 2016.

Bryan, Chatham, Glynn, and McIntosh Counties for Individual Assistance (already designated for assistance for debris removal and emergency protective measures [Categories A and B], including direct federal assistance, under the Public Assistance program).

Bulloch, Effingham, and Wayne Counties for Individual Assistance and assistance for debris removal and emergency protective measures (Categories A and B), including direct federal assistance, under the Public Assistance program.

Screven County for assistance for debris removal and emergency protective measures (Categories A and B), including direct federal assistance, under the Public Assistance program.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050 Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2016–26573 Filed 11–2–16; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4283–DR]; [Docket ID FEMA–2016–0001]

Florida; Amendment No. 3 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of Florida (FEMA–4283–DR), dated October 8, 2016, and related determinations.

DATES: *Effective Date:* October 24, 2016.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of Florida is hereby amended to include the following areas among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of October 8, 2016.

Duval County for Individual Assistance (already designated for assistance for debris removal and emergency protective measures [Categories A and B], including direct federal assistance, under the Public Assistance program).

Clay and Martin Counties for Public Assistance, including direct federal assistance.

Indian River, Putnam, St. Johns, and Volusia Counties for Public Assistance [Categories C–G] (already designated for Individual Assistance and assistance for debris removal and emergency protective measures [Categories A and B], including direct federal assistance, under the Public Assistance program).

Nassau County for Public Assistance [Categories C–G] (already designated for assistance for debris removal and emergency protective measures [Categories A and B], including direct federal assistance, under the Public Assistance program).

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050 Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2016–26580 Filed 11–2–16; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4283–DR: Docket ID FEMA–2016–0001

Florida; Amendment No. 5 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of Florida (FEMA–4283–DR), dated October 8, 2016, and related determinations.

DATES: *Effective Date:* October 25, 2016.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of Florida is hereby amended to include the following areas among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of October 8, 2016.

Nassau County for Individual Assistance (already designated for Public Assistance, including direct federal assistance).

Seminole County for Individual Assistance.

Brevard, Duval, and Flagler Counties for Public Assistance [Categories C–G] (already designated for Individual Assistance and assistance for debris removal and emergency protective measures [Categories A and B], including direct federal assistance, under the Public Assistance program).

Palm Beach County for Public Assistance, including direct federal assistance.

St. Lucie County for Public Assistance [Categories C–G] (already designated for assistance for debris removal and emergency protective measures [Categories A and B], including direct federal assistance, under the Public Assistance program).

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050 Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2016–26576 Filed 11–2–16; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4284–DR; Docket ID FEMA–2016–0001]

Georgia; Amendment No. 1 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of Georgia (FEMA–4284–DR), dated October 8, 2016, and related determinations.

DATES: *Effective Date:* October 15, 2016.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: Notice is hereby given that the incident period for this disaster is closed effective October 15, 2016.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2016–26574 Filed 11–2–16; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4283–DR]; [Docket ID FEMA–2016–0001]

Florida; Amendment No. 4 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of Florida (FEMA–4283–DR), dated October 8, 2016, and related determinations.

DATES: *Effective Date:* October 19, 2016.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: Notice is hereby given that the incident period for this disaster is closed effective October 19, 2016.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2016–26578 Filed 11–2–16; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4284–DR]; [Docket ID FEMA–2016–0001]

Georgia; Amendment No. 4 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of Georgia (FEMA–4284–DR), dated October 8, 2016, and related determinations.

DATES: *Effective Date:* October 24, 2016.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of Georgia is hereby amended to include the following areas among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of October 8, 2016.

Evans, Liberty, and Long Counties for Individual Assistance (already designated for Public Assistance).

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050 Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2016–26577 Filed 11–2–16; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLCON06000–L16100000–DR0000–17X]

Notice of Resource Advisory Council Meeting for the Dominguez-Escalante National Conservation Area Advisory Council

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of Public Meetings.

SUMMARY: In accordance with the Federal Land Policy and Management Act of 1976 and the Federal Advisory Committee Act of 1972, the U.S. Department of the Interior, Bureau of Land Management (BLM) Dominguez-Escalante National Conservation Area (NCA) Advisory Council (Council) will meet as indicated below.

DATES: The meeting will be held January 25, 2017. Any adjustments to this meeting will be advertised on the Dominguez-Escalante NCA Resource Management Plan (RMP) Web site: *http://www.blm.gov/co/st/en/nca/denca/denca_rmp.html.*

ADDRESSES: The meeting will be held at the Bill Heddles Recreation Center, 530 Gunnison River Drive, Delta, CO 81416.

FOR FURTHER INFORMATION CONTACT: Collin Ewing, Advisory Council Designated Federal Official, 2815 H Road, Grand Junction, CO 81506. Phone: (970) 244–3049. Email: *cewing@blm.gov.* Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FIRS is available 24 hours a day, seven days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: The 10-member Council advises the Secretary of the Interior, through the BLM, on a variety of planning and management issues associated with the RMP process for the Dominguez-Escalante NCA and Dominguez Canyon Wilderness.

Topics of discussion during the meeting may include presentations from BLM staff on management actions contained in the Proposed RMP and travel management plan. These meetings are open to the public. The public may present written comments to the Council. Time will be allocated at the middle and end of each meeting to hear public comments. Depending on the number of persons wishing to comment and time available, the time for individual, oral comments may be limited at the discretion of the chair.

Ruth Welch,

BLM Colorado State Director.

[FR Doc. 2016–26505 Filed 11–2–16; 8:45 am]

BILLING CODE 4310–JB–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–968]

Certain Radiotherapy Systems and Treatment Planning Software, and Components Thereof; Notice of Request for Statements on the Public Interest

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the presiding administrative law judge (''ALJ'') has issued a recommended determination on remedy and bonding in the above-captioned investigation. The Commission is soliciting submissions from the public on any public interest issues raised by the recommended relief. The ALJ recommended that a limited exclusion order issue against certain radiotherapy systems and treatment planning software, and components thereof, imported by respondents Elekta AB of Stockholm, Sweden; Elekta Ltd. of Crawley, United Kingdom; Elekta GmbH of Hamburg, Germany; Elekta Inc. of Atlanta, Georgia; IMPAC Medical Systems, Inc. of Sunnyvale, California; Elekta Instrument (Shanghai) Limited of Shanghai, China; and Elekta Beijing Medical Systems Co. Ltd. of Beijing, China (collectively, ''Elekta''). The ALJ also recommended that cease and desist orders be directed to Elekta. Parties are to file public interest submissions pursuant to 19 CFR 210.50(a)(4).

FOR FURTHER INFORMATION CONTACT: Ron Traud, Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 205–3427. Copies of non-confidential documents filed in connection with this investigation, including the complaint and the public record, can be accessed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov,* and are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 205–2000. General information concerning the Commission may also be obtained by accessing its Internet server (*https://www.usitc.gov*). Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: Section 337 of the Tariff Act of 1930 provides that if the Commission finds a violation it shall exclude the articles concerned from the United States:

unless, after considering the effect of such exclusion upon the public health and welfare, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, and United States consumers, it finds that such articles should not be excluded from entry.

19 U.S.C. 1337(d)(1). A similar provision applies to cease-and-desist orders. 19 U.S.C. 1337(f)(1).

The Commission is interested in further development of the record on the public interest in these investigations. Accordingly, members of the public are invited to file, pursuant to 19 CFR 210.50(a)(4), submissions of no more than five (5) pages, inclusive of attachments, concerning the public interest in light of the administrative law judge's recommended determination on remedy and bonding

issued in this investigation on October 27, 2016. Comments should address whether issuance of the limited exclusion order and the cease and desist orders (''the recommended remedial orders'') in this investigation would affect the public health and welfare in the United States, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, or United States consumers.

In particular, the Commission is interested in comments that:

(i) Explain how the articles potentially subject to the recommended remedial orders are used in the United States;

(ii) identify any public health, safety, or welfare concerns in the United States relating to the recommended remedial orders;

(iii) identify like or directly competitive articles that complainant, its licensees, or third parties make in the United States which could replace the subject articles if they were to be excluded;

(iv) indicate whether complainant, complainant's licensees, and/or third party suppliers have the capacity to replace the volume of articles potentially subject to the recommended remedial orders within a commercially reasonable time; and

(v) explain how the recommended remedial orders would impact consumers in the United States.

Written submissions must be filed no later than by close of business on December 12, 2016.

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 section 210.4(f) of the Commission's Rules of Practice and Procedure (19 CFR 210.4(f)). Submissions should refer to the investigation number (''Inv. No. 968'') in a prominent place on the cover page and/or the first page. (*See* Handbook for Electronic Filing Procedures, *https://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. All information, including confidential business information and documents for which confidential treatment is properly sought, submitted to the Commission for purposes of this Investigation may be disclosed to and used: (i) By the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. appendix 3; or (ii) by U.S. government employees and contract personnel, solely for cybersecurity purposes (all contract personnel will sign appropriate nondisclosure agreements). All nonconfidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: October 31, 2016.

Lisa R. Barton,

Secretary to the Commission.

[FR Doc. 2016–26602 Filed 11–2–16; 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—ODPI, Inc.

Notice is hereby given that, on September 26, 2016, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), ODPi, Inc. (''ODPi'') 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 invoking the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, Xavient Information System, Herndon, VA; DriveScale, Inc., Sunnyvale, CA; and Redoop, Haidian District, Beijing, PEOPLE'S REPUBLIC OF CHINA, have been added 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 ODPi intends to file additional written notifications disclosing all changes in membership.

On November 23, 2015, ODPi 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 23, 2015 (80 FR 79930).

The last notification was filed with the Department on July 14, 2016. A notice was published in the **Federal Register** pursuant to Section 6(h) of the Act on August 11, 2016 (81 FR 53163).

Patricia A. Brink,

Director of Civil Enforcement, Antitrust Division.

[FR Doc. 2016–26538 Filed 11–2–16; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Cooperative Research Group on Automotive Consortium for Embedded Security™

Notice is hereby given that, on September 27, 2016, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), Southwest Research Institute—Cooperative Research Group on Automotive Consortium for Embedded Security™ (''ACES'') 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, Honda R&D Americas, Inc., Raymond, OH 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 ACES intends to file additional written notifications disclosing all changes in membership.

On March 25, 2015, ACES 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 April 30, 2015 (80 FR 24279).

The last notification was filed with the Department on January 27, 2016. A notice was published in the **Federal Register** pursuant to Section 6(b) of the Act on March 9, 2016 (81 FR 12528).

Patricia A. Brink,

Director of Civil Enforcement, Antitrust Division.

[FR Doc. 2016–26550 Filed 11–2–16; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Open Platform for NFV Project, Inc.

Notice is hereby given that, on October 7, 2016, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), Open Platform for NFV Project, Inc. (''Open Platform for NFV Project'') 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, China Telecommunications Corporation, Beijing, PEOPLE'S REPUBLIC OF CHINA; Dell Technologies, Santa Clara, CA; Fraunhofer Institute for Open Communication Systems FOKUS, Berlin, GERMANY; and Samsung Electronics Co., Ltd., Suwon-City, Gyeonggi-do, REPUBLIC OF KOREA, have been added as parties to this venture.

Also, 6Wind SA, Montigny-le-Bretonneux, FRANCE; ClearPath Networks, El Segundo, CA; Dell USA, LP, Round Rock, TX; Dorado Software, Inc., El Dorado Hills, CA; EMC Corporation, Santa Clara, CA; NTT DOCOMO, Inc., Tokyo, JAPAN; and Vodafone Group PLC, Newbury, UNITED KINGDOM, 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 Open Platform for NFV Project intends to file additional written notifications disclosing all changes in membership.

On October 17, 2014, Open Platform for NFV Project 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 November 14, 2014 (79 FR 68301).

The last notification was filed with the Department on July 20, 2016. A notice was published in the **Federal Register** pursuant to Section 6(b) of the Act on August 11, 2016 (81 FR 53163).

Patricia A. Brink,

Director of Civil Enforcement, Antitrust Division.

[FR Doc. 2016–26536 Filed 11–2–16; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—PXI Systems Alliance, Inc.

Notice is hereby given that, on September 30, 2016, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), PXI Systems Alliance, Inc. 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, PEAK-System Technik GmbH, Darmstadt, GERMANY, has been added as a party to this venture.

Also, Gigatronics, San Ramon, CA, 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 PXI Systems Alliance, Inc. intends to file additional written notifications disclosing all changes in membership.

On November 22, 2000, PXI Systems Alliance, Inc. 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 8, 2001 (66 FR 13971).

The last notification was filed with the Department on February 10, 2016. A notice was published in the **Federal Register** pursuant to Section 6(b) of the Act on March 9, 2016 (81 FR 12527).

Patricia A. Brink,

Director of Civil Enforcement, Antitrust Division.

[FR Doc. 2016–26537 Filed 11–2–16; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—National Shipbuilding Research Program

Notice is hereby given that, on October 12, 2016, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), National Shipbuilding Research Program (''NSRP'') 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, Vigor Shipyards, Inc., Portland, OR, 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 NSRP intends to file additional written notifications disclosing all changes in membership.

On March 13, 1998, NSRP 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 January 29, 1999 (64 FR 4708).

The last notification was filed with the Department on January 23, 2015. A notice was published in the **Federal Register** pursuant to Section 6(b) of the Act on February 27, 2015 (80 FR 10716).

Patricia A. Brink,

Director of Civil Enforcement, Antitrust Division.

[FR Doc. 2016–26548 Filed 11–2–16; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—R Consortium, Inc.

Notice is hereby given that, on October 7, 2016, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), R Consortium, Inc. (''R Consortium'') 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, Environmental Systems Research Institute Inc. (ESRI), Redlands, CA, has been added as a party to this venture. Also, Hewlett-Packard Company, Palo Alto, CA, has been dropped 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 R Consortium intends to file additional written notifications disclosing all changes in membership.

On September 15, 2015, R Consortium 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 October 2, 2015 (80 FR 59815).

The last notification was filed with the Department on July 19, 2016. A notice was published in the **Federal Register** pursuant to Section 6(b) of the Act on August 11, 2016 (81 FR 53162).

Patricia A. Brink,

Director of Civil Enforcement, Antitrust Division.

[FR Doc. 2016–26610 Filed 11–2–16; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Heterogeneous System Architecture Foundation

Notice is hereby given that, on September 27, 2016, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), Heterogeneous System Architecture Foundation (''HSA Foundation'') 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, Technische Universitat Darmstadt, Darmstadt, GERMANY; and North Carolina State University, Raleigh, NC, have been added as parties to this venture.

Also, Symbio, San Jose, CA; Mobica Limited, Wilmslow, Cheshire, UNITED KINGDOM; and Synopsys Inc., Mountain View, 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 HSA Foundation intends to file additional written notifications disclosing all changes in membership.

On August 31, 2012, HSA Foundation 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 October 11, 2012 (77 FR 61786).

The last notification was filed with the Department on July 7, 2016. A notice was published in the **Federal Register** pursuant to Section 6(b) of the Act on August 11, 2016 (81 FR 53162).

Patricia A. Brink,

Director of Civil Enforcement, Antitrust Division.

[FR Doc. 2016–26547 Filed 11–2–16; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Node.js Foundation

Notice is hereby given that, on September 29, 2016, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), Node.js Foundation 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 invoking the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, Snyk Limited, London, United Kingdom, has been added 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 Node.js Foundation intends to file additional written notifications disclosing all changes in membership.

On August 17, 2015, Node.js Foundation 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 September 28, 2015 (80 FR 58297).

The last notification was filed with the Department on July 14, 2016. A notice was published in the **Federal Register** pursuant to Section 6(b) of the Act on August 11, 2016 (81 FR 53161).

Patricia A. Brink,

Director of Civil Enforcement, Antitrust Division.

[FR Doc. 2016–26558 Filed 11–2–16; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Integrated Photonics Institute for Manufacturing Innovation Operating Under the Name of the American Institute for Manufacturing Integrated Photonics

Notice is hereby given that, on September 27, 2016, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), the Integrated Photonics Institute for Manufacturing Innovation operating under the name of the American Institute for Manufacturing Integrated Photonics (''AIM Photonics'') 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, Infinera Corporation, Sunnyvale, CA; Cadence Design Systems, Inc., San Jose, CA; Samtec, Inc., New Albany, IN; Raytheon Company, Waltham, MA; Precision Optical Transceivers, Brockport, NY; PhoeniX B.V. (PhoeniX Software), Enschede, NETHERLANDS;

Harris Corporation, Melbourne, FL; finconTEC (USA) Corporation, San Clemente, CA; DISCO Hi-Tec America, Inc., Santa Clara, CA; The Boeing Company, Chicago, IL; Rochester Institute of Technology, Rochester, NY; University of Rochester, Rochester, NY; Rutgers, The State University of New Jersey, Piscataway, NJ; Quinsigamond Community College, Worcester, MA; Monroe Community College, Rochester, NY; Magic Leap, Inc., Dania Beach, FL; Ebara Technologies Incorporated, Sacramento, CA; IEC Electronics, Newark, NY; ITW Opto Diode, Camarillo, CA; New York Photonics, Rochester, NY; Quatela Lynch Intellectual Property, Rochester, NY; Space System Loral, Palo Alto, CA; Yenista Optics, Inc., Newbury Park, CA; Baker College of Flint, Flint, MI; IEEE Photonics Society, Piscataway, NJ; Luna Innovations Incorporated, Roanoke, VA; Silyb Wafer Services, Gig Harbor, WA; SPIE, Bellingham, WA; Transcat, Inc., Rochester, NY; Viewpoint Systems, Inc., Rochester, NY; and Phoenix Graphics, Inc., Rochester, NY have been added 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 AIM Photonics intends to file additional written notifications disclosing all changes in membership.

On June 16, 2016, AIM Photonics 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 25, 2016 (81 FR 48450).

Patricia A. Brink,

Director of Civil Enforcement, Antitrust Division.

[FR Doc. 2016–26549 Filed 11–2–16; 8:45 am]

BILLING CODE 4410–11–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Consent Decree Under the Comprehensive Environmental Response, Compensation, and Liability Act

On October 28, 2016, the Department of Justice lodged a proposed amended consent decree with the United States District Court for the Western District of New York in the lawsuit entitled *United States* v. *AVX Corporation,* Civil No.: 1:98–CV–54.

In this action the United States sought, pursuant to the Comprehensive Environmental Response, Compensation, and Liability Act (''CERCLA''), 42 U.S.C. 9601, *et seq.,* injunctive relief and recovery of response costs regarding the Olean Well Field Superfund Site in Olean, New York. The matter was originally resolved by a consent decree that was approved by the Court in March 1998. The 1998 consent decree implemented a portion of a remedial action selected by the U.S. Environmental Protection Agency in a September 1996 record of decision (also known as the ''Operable Unit 2 ROD'' or ''OU2 ROD''). The 1998 consent decree required AVX Corporation to perform the portion of the Operable Unit 2 remedial action that was at an area of the site known as the ''AVX Property'' and to reimburse the United States for a portion of its response costs incurred at the site.

On September 30, 2015, EPA issued an amendment to the OU2 ROD, which documented EPA's decision regarding a modification to the remedy to be implemented at the AVX Property. The proposed amended consent decree that was lodged with the Court on October 28 requires AVX Corporation to implement the amended remedy at the AVX Property, and to reimburse the United States for its future response costs regarding the AVX Property. The settlement maintains the resolution of the United States' claims against AVX Corporation regarding the site.

The publication of this notice opens a period for public comment on the proposed amended consent decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to *United States* v. *AVX Corporation,* Civ. No. 1:98–CV–54, D.J. Ref. No. 90–11–3–181B. All comments must be submitted no later than 30 days after the publication date of this notice. Comments may be submitted either by email or by mail:

To submit comments:	Send them to:
By email	*pubcomment-ees.enrd@usdoj.gov.*
By mail	Assistant Attorney General, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

During the public comment period, the proposed amended consent decree may be examined and downloaded at this Justice Department Web site: *https://www.justice.gov/enrd/consent-decrees.* We will provide a paper copy of the proposed amended 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 $61.25 (25 cents per page reproduction cost) payable to the United States Treasury.

Robert E. Maher, Jr.,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2016–26503 Filed 11–2–16; 8:45 am]

BILLING CODE 4410–15–P

THE NATIONAL FOUNDATION FOR THE ARTS AND THE HUMANITIES

Institute of Museum and Library Services

Submission for OMB Review, Comment Request, Proposed Collection: State Library Administrative Agencies Survey FY 2016 & FY 2018

AGENCY: Institute of Museum and Library Services, National Foundation for the Arts and the Humanities.

ACTION: Submission for OMB review, comment request.

SUMMARY: The Institute of Museum and Library Service (''IMLS'') as part of its continuing effort to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act. This pre-clearance consultation program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. The purpose of this Notice is to solicit comments concerning the continuance of the State Library Administrative Agencies Survey for FY 2016 & FY 2018.

A copy of the proposed information collection request can be obtained by contacting the individual listed below in the **ADDRESSES** section of this notice.

DATES: Written comments must be submitted to the office listed in the CONTACT section below on or before December 5, 2016.

ADDRESSES: Matthew Birnbaum, Supervisory Social Science Researcher, Office of Impact Assessment and

Learning, Institute of Museum and Library Services, 955 L'Enfant Plaza North SW., Suite 4000, Washington, DC 20024–2135. Dr. Birnbaum can be reached by Telephone: 202–653–4760, Fax: 202–653–4601, or by email at *mbirnbaum@imls.gov* or by teletype (TTY/TDD) at 202–653–4614.

SUPPLEMENTARY INFORMATION: The Institute of Museum and Library Services (IMLS) is an independent Federal grant-making agency and is the primary source of federal support for the Nation's 123,000 libraries and 35,000 museums. IMLS provides a variety of grant programs to assist the Nation's museums and libraries in improving their operations and enhancing their services to the public. IMLS is responsible for identifying national needs for and trends in museum, library, and information services; measuring and reporting on the impact and effectiveness of museum, library and information services throughout the United States, including programs conducted with funds made available by IMLS; identifying, and disseminating information on, the best practices of such programs; and developing plans to improve museum, library and information services of the United States and strengthen national, State, local, regional, and international communications and cooperative networks (20 U.S.C. Chapter 72, 20 U.S.C. 9108).

OMB is particularly interested in comments that help the agency to:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information including the validity of the 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 the use of appropriate automated electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.* permitting electronic submissions of responses.

Abstract: The State Library Administrative Agencies Survey has been conducted by the Institute of Museum and Library Services under the clearance number 3137–0072, which expires 11/30/2016. State Library Administrative Agencies (''SLAAs'') are the official agencies of each state charged by state law with the extension and development of public library services throughout the state. (20 U.S.C. Chapter 72, 20 U.S.C. 9122.) The purpose of this survey is to provide state and federal policymakers with information about SLAAs, including their governance, allied operations, developmental services to libraries and library systems, support of electronic information networks and resources, number and types of outlets, and direct services to the public. Through the FY 2010 collection, the SLAA Survey was conducted annually; beginning with the FY 2012 collection, the survey is conducted biennially. Because the FY 2016 collection will not begin until early 2017, we are carrying over the documentation and estimated burden associated with the FY 2014 data.

Current Actions: This notice proposes clearance of the State Library Agencies Survey. The 60-day notice for the State Library Administrative Agencies Survey, FY 2016 & FY 2018, was published in the **Federal Register** on May 27, 2016 (81FR 3093933710–33711). No comments were received.

Agency: Institute of Museum and Library Services.

Title: State Library Administrative Agencies Survey, FY 2014.

OMB Number: 3137–0072.

Agency Number: 3137.

Affected Public: Federal, State and local governments, State library administrative agencies, libraries, general public.

Number of Respondents: 51.

Frequency: Biennially.

Burden Hours per Respondent: 25.

Total Burden Hours: 1,275.

Total Annual Costs: $35,623.

Contact: Comments should be sent to Office of Information and Regulatory Affairs, *Attn.:* OMB Desk Officer for Education, Office of Management and Budget, Room 10235, Washington, DC 20503, (202) 395–7316.

Dated: October 31, 2016.

Kim A. Miller,

Grants Management Specialist, Office of the Chief Financial Officer.

[FR Doc. 2016–26566 Filed 11–2–16; 8:45 am]

BILLING CODE 7036–01–P

THE NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

Institute of Museum and Library Services

Submission for OMB Review, Comment Request, Proposed Collection: Public Libraries Survey FY 2016–FY 2018

AGENCY: Institute of Museum and Library Services, National Foundation on the Arts and the Humanities.

ACTION: Submission for OMB review, comment request.

SUMMARY: The Institute of Museum and Library Services (IMLS) announces the submission of the following information collection to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed.

A copy of the proposed information collection request can be obtained by contacting the individual listed below in the **ADDRESSES** section of this notice.

DATES: Written comments must be submitted by December 5, 2016 to be assured of consideration.

OMB is particularly interested in comments that help the agency to

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information including the validity of the methodology and assumptions used;
- Enhance the quality, utility and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.* permitting electronic submissions of responses.

ADDRESSES: You may submit comments to Stephanie Burwell, Chief Information Officer, Office of the Chief Information Officer, Institute of Museum and Library Services, 955 L'Enfant Plaza North SW., Suite 4000, Washington, DC 20024–2135. Ms. Burwell can be reached by

Telephone: 202–653–4684, Fax: 202–653–4625, Email: *sburwell@imls.gov,* or by teletype (TTY/TDD at 202–653–4614). Office hours are from 8:30 a.m. to 5 p.m., ET, Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION: IMLS is the primary source of federal support for the Nation's 123,000 libraries and 35,000 museums. IMLS' mission is to inspire libraries and museums to advance innovation, learning, and civic engagement. IMLS works at the national level and in coordination with state and local organizations to sustain heritage, culture, and knowledge; enhance learning and innovation; and support professional development. IMLS is responsible for identifying national needs for and trends in museum, library, and information services; measuring and reporting on the impact and effectiveness of museum, library and information services throughout the United States, including programs conducted with funds made available by IMLS; identifying, and disseminating information on, the best practices of such programs; and developing plans to improve museum, library, and information services of the United States and strengthen national, State, local, regional, and international communications and cooperative networks (20 U.S.C. Chapter 72, 20 U.S.C. 9108).

Abstract: The Public Libraries Survey (PLS) has been conducted by IMLS under the clearance number 3137–0074, which expires 12/31/2016. The PLS collects annual descriptive data on the universe of public libraries in the United States, the District of Columbia, and outlying areas. Information such as public service hours per year, circulation of library books, number of librarians, population of legal service area, expenditures for library collection, programs for children and young adults, staff salary data, and access to technology, etc., would be collected.

Current Actions: This notice proposes clearance of the PLS. The 60-day notice for the PLS, FY 2016–2018, was published in the **Federal Register** on August 16, 2016, (FR vol. 81, No. 158, pgs. 54608–54609). There were no comments received under this notice.

Agency: Institute of Museum and Library Services.

Title: Public Libraries Survey, FY 2016—FY 2018.

OMB Number: 3137–0074.

Agency Number: 3137.

Affected Public: State and local governments, State library administrative agencies, and public libraries.

Number of Respondents: 56.

Note: 56 is the number of State Library Administrative Agencies (SLAAs) that are responsible for the collection of this information and for reporting it to IMLS. In gathering this information, the SLAAs will request that their sub-entities (*i.e.,* public libraries in their respective states and outlying areas) provide information to the respective SLAA. As the number of sub-entities and questions varies from SLAA to SLAA, it is difficult to assess the exact number of burden hours and costs.

Frequency: Annually.

Burden hours per respondent: 104.98.

Total burden hours: 5,878.88.

Total Annualized capital/startup costs: n/a.

Total Annual Costs: $164,255.91.

Total Annual Federal Costs: $925,193.00.

CONTACT: Comments should be sent to Office of Information and Regulatory Affairs, *Attn.:* OMB Desk Officer for Education, Office of Management and Budget, Room 10235, Washington, DC 20503, (202) 395–7316.

Dated: October 31, 2016.

Kim A. Miller,

Grants Management Specialist, Office of the Chief Financial Officer.

[FR Doc. 2016–26567 Filed 11–2–16; 8:45 am]

BILLING CODE 7036–01–P

NATIONAL SCIENCE FOUNDATION

Notice of Permits Issued Under the Antarctic Conservation Act of 1978

AGENCY: National Science Foundation.

ACTION: Notice of permits issued under the Antarctic Conservation of 1978, Public Law 95–541.

SUMMARY: The National Science Foundation (NSF) is required to publish notice of permits issued under the Antarctic Conservation Act of 1978. This is the required notice.

FOR FURTHER INFORMATION CONTACT: Nature McGinn, ACA Permit Officer, Division of Polar Programs, Rm. 755, National Science Foundation, 4201 Wilson Boulevard, Arlington, VA 22230. Or by email: *ACApermits@nsf.gov.*

SUPPLEMENTARY INFORMATION: On September 9, 2016 the National Science Foundation published a notice in the **Federal Register** of permit applications received. The permits were issued on October 30, 2016 to: Jerry McDonald (Principal in Charge), Leidos Innovations Group, Antarctic Support Contract Permit Nos. 2017–014, 2017–015, 2017–016, 2017–017, 2017–018, 2017–019, 2017–020, 2017–021, 2017–022, 2017–023.

Nadene G. Kennedy,

Polar Coordination Specialist, Division of Polar Programs.

[FR Doc. 2016–26556 Filed 11–2–16; 8:45 am]

BILLING CODE 7555–01–P

NATIONAL SCIENCE FOUNDATION

Sunshine Act Meetings; National Science Board

The National Science Board, pursuant to NSF regulations (45 CFR part 614), the National Science Foundation Act, as amended, (42 U.S.C. 1862n–5), and the Government in the Sunshine Act (5 U.S.C. 552b), hereby gives notice of the scheduling of meetings for the transaction of National Science Board business as follows:

DATE AND TIME: November 8, 2016 from 8:00 a.m. to 5:00 p.m., and November 9, 2016 from 9:00 a.m. to 2:55 p.m. EST.

PLACE: These meetings will be held at the National Science Foundation, 4201 Wilson Blvd., Room 1235, Arlington, VA 22230. All visitors must contact the Board Office (call 703–292–7000 or send an email to *nationalsciencebrd@nsf.gov*) at least 24 hours prior to the meeting and provide your name and organizational affiliation. Visitors must report to the NSF visitor's desk in the lobby of the 9th and N. Stuart Street entrance to receive a visitor's badge.

WEBCAST INFORMATION: Public meetings and public portions of meetings will be webcast. To view the meetings, go to *http://www.tvworldwide.com/events/nsf/161108* and follow the instructions.

UPDATES: Please refer to the National Science Board Web site for additional information. Meeting information and schedule updates (time, place, subject matter, and status of meeting) may be found at *http://www.nsf.gov/nsb/meetings/notices.jsp.*

AGENCY CONTACT: John Veysey, *jveysey@nsf.gov,* 703–292–7000.

PUBLIC AFFAIRS CONTACT: Nadine Lymn, *nlymn@nsf.gov,* 703–292–2490.

STATUS: Portions open; portions closed.

Open Sessions

November 8, 2016

8:00–8:35 a.m. Plenary introduction, NSB Chair and NSF Director Remarks
8:35–9:35 a.m. Committee on Strategy and Budget (CSB)
9:50–10:50 a.m. Committee on Audit and Oversight (A&O)
10:50–11:45 a.m. Committee on Science and Engineering Indicators (SEI)
1:15–3:15 p.m. Committee on Programs and Plans (CPP)

3:35–4:25 p.m. CSB Subcommittee on Facilities (SCF)
4:25–5:00 p.m. Joint session—SCF and CPP

November 9, 2016

12:55–2:55 p.m. (Plenary)

Closed Sessions

November 9, 2016

9:00–10:05 a.m. (CSB)
10:05–10:25 a.m. (CPP)
10:45–11:10 a.m. (Plenary)
11:00–11:25 a.m. (Plenary Executive)

Matters to be Discussed

Tuesday, November 8, 2016

Plenary Board meeting

Open session: 8:00–8:35 a.m.
- NSB Chair's Opening Remarks
  Announcement of New Members and Ceremonial Oath of Office
  Overview of Major Issues for Meeting
  Report on Site Visits
  Highlights from Board Retreat
- NSF Director's Remarks

Committee on Strategy and Budget

Open session: 8:35–9:35 a.m.
- Committee Chairs' Opening Remarks
- Approval of Prior Minutes
- Update on FY 2017 Budget
- Ongoing Development of 2018–2022 Strategic Plan

Committee on Audit and Oversight (A&O)

Open session: 9:50–10:50 a.m.
- A&O Chair's Opening Remarks
  OIG Semiannual Report
- Approval of Prior Minutes
- National Academy of Public Administration (NAPA) Report: Implementation of Recommendation on Management Fee
- Merit Review Pilot Report
- Inspector General's Update
  Update on Financial Statement Audit
  Introduction of New Inspector General for Audit
  OIG FY 2017 Audit Plan
- Chief Financial Officer's Update
- NSF Intergovernmental Personnel Act Program Update

Committee on Science and Engineering Indicators (SEI)

Open session: 10:50–11:45 a.m.
- SEI Chair's Opening Remarks
- Approval of Prior Minutes
- Update on STEM Ph.D.s Career Pathways Companion Brief
- *Discussion:* Indicators 2018 Overview and Transmittal Letter

Committee on Programs and Plans

Open session: 1:15–3:15 p.m.
- CPP Chair's Opening Remarks
- Approval of Prior Minutes
- CY 2017 Schedule of Planned Action and Information Items
- Review of NSB's Delegation of Award Authority
- Advanced Computing Infrastructure and Polar Realignment Updates
- *Overview of BIO Portfolio:* Status and Timelines

CSB Subcommittee on Facilities (SCF)

Open session: 3:35–4:25 p.m.
- SCF Chair's Opening Remarks
- Approval of Prior Minutes
- Discussion of Facilities-related Information Products

Joint Session of SCF and CPP

Open session: 4:25–5:00 p.m.
- Committee Chairs' Opening Remarks
- Discussion of Facilities Roles and Responsibilities
- Discussion of the Annual Facility Plan

Matters to be Discussed

Wednesday, November 9, 2016

Committee on Strategy and Budget

Closed session: 9:00–10:05 a.m.
- CSB Chair's Opening Remarks
- Approval of Prior Minutes
- Update on NSF FY 2018 Budget Request Development

Committee on Programs and Plans

Closed Session: 10:05–10:25 a.m.
- Committee Chair's Opening Remarks
- Approval of Prior Minutes
- NEON Operations and Maintenance Update

Plenary Board

Closed session: 10:45–11:00 a.m.
- NSB Chair's Opening Remarks
- Approval of Prior Minutes
- NSF Director's Remarks
- Closed Committee Reports

Plenary Board (Executive)

Closed session: 11:00 a.m.–11:25 a.m.
- NSB Chair's Opening Remarks
- Approval of Prior Minutes
- Recommendations for 2017 NSB Vannevar Bush and Public Service Awards

Plenary Board

Open session: 12:55–2:55 p.m.
- NSB Chair's Opening Remarks
- Approval of Prior Minutes
- NSF Director's Remarks
- Action Item: Changes to the Waterman Award Terms
- Changes to the Annual Facility Plan
- Discussion of NSB Structure
- Discussion of Materials for the Presidential Transition
- Report from the Congressional Engagement Working Group
- Overview of NSF's Relocation
- Open Committee Reports

Meeting Adjourns—2:55 P.M.

Chris Blair,

Executive Assistant, National Science Board Office.

[FR Doc. 2016–26744 Filed 11–1–16; 4:15 pm]

BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2016–0224]

Restart of a Nuclear Power Plant Shut Down by a Seismic Event

AGENCY: Nuclear Regulatory Commission.

ACTION: Draft regulatory guide; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing for public comment draft regulatory guide (DG) DG–1337, ''Restart of a Nuclear Power Plant Shut Down by a Seismic Event.'' It represents proposed Revision 1 of Regulatory Guide (RG) 1.167. The guide describes methods acceptable to the NRC staff that can be used to demonstrate that a nuclear power plant is safe for restarting after a shutdown caused by a seismic event.

DATES: Submit comments by January 3, 2017. Comments received after this date will be considered if it is practical to do so, but the NRC is able to ensure consideration only for comments received on or before this date. Although a time limit is given, comments and suggestions in connection with items for inclusion in guides currently being developed or improvements in all published guides are encouraged at any time.

ADDRESSES: You may submit comments by any of the following methods (unless this document describes a different method for submitting comments on a specified subject):

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2016–0224. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov*. For technical questions, contact the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *Mail comments to:* Cindy Bladey, Office of Administration, Mail Stop: OWFN–12H08, 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: Thomas Weaver, telephone: 301–415–2383, email: *Thomas.Weaver@nrc.gov* and Edward O'Donnell, telephone: 301–415–3317 email: *Edward.ODonnell@nrc.gov.* Both are staff of the Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2016–0224 when contacting the NRC about the availability of information regarding this action. You may obtain publically-available information related to this action, by any of the following methods:

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2016–0224.
- *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 DG is electronically available in ADAMS under Accession No. ML16182A321.
- *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–2016–0224 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 enters 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.

II. Additional Information

The NRC is issuing for public comment a DG in the NRC's ''Regulatory Guide'' series. This series was developed to describe and make available to the public information regarding methods that are acceptable to the NRC staff for implementing specific parts of the NRC's regulations, techniques that the staff uses in evaluating specific issues or postulated events, and data that the staff needs in its review of applications for permits and licenses.

The DG, entitled ''Restart of a Nuclear Power Plant Shut Down by a Seismic Event,'' is a proposed revised guide temporarily identified by its task number, DG–1337. The proposed revision of RG 1.167 describes methods acceptable to the NRC staff that can be used to demonstrate that a nuclear power plant is safe for restarting after a shutdown caused by a seismic event. It incorporates lessons learned following the shutdown of nuclear power plants due to earthquake ground shaking and post-earthquake evaluations since Revision 0 was issued in 1997. They include experience gained through the shutdown and restart process of the North Anna nuclear power plant following the Mineral, Virginia earthquake in 2011. It endorses, with some exceptions, sections of ANS/ANSI–2.23–2016, ''Nuclear Power Plant Response to an Earthquake,'' that relate to post-shutdown inspections and tests, inspection criteria, documentation, and long-term evaluations. The guidance includes an action level matrix to direct actions based on the earthquake level and observed damage levels at a nuclear power plant.

III. Backfitting and Issue Finality

DG–1337 describes methods acceptable to the NRC staff that can be used to demonstrate that a nuclear power plant is safe for restarting after a shutdown caused by a seismic event. Issuance of this DG, if finalized, would not constitute backfitting as defined in 10 CFR 50.109 (the Backfit Rule) and would not otherwise be inconsistent with the issue finality provisions in 10 CFR part 52. As discussed in the ''Implementation'' section of this DG, the NRC has no current intention to impose this guide, if finalized, on holders of current operating licenses or combined licenses.

This DG may be applied to applications for operating licenses, combined licenses, early site permits, and certified design rules docketed by the NRC as of the date of issuance of the final regulatory guide, as well as future applications submitted after the issuance of the regulatory guide. Such action would not constitute backfitting as defined in the Backfit Rule or be otherwise inconsistent with the applicable issue finality provision in 10 CFR part 52, inasmuch as such applicants or potential applicants are not within the scope of entities protected by the Backfit Rule or the relevant issue finality provisions in part 52.

Dated: October 28, 2016.

For the Nuclear Regulatory Commission.

Thomas H. Boyce,

Chief, Regulatory Guidance and Generic Issues Branch, Division of Engineering, Office of Nuclear Regulatory Research.

[FR Doc. 2016–26524 Filed 11–2–16; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2016–0225]

Guidance for Electronic Submissions to the NRC

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of availability; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is updating and requesting comments on its guidance for electronic submittals to reflect changes in technology by posting the latest version of its ''Guidance for Electronic Submissions to the NRC (Revision 8).'' This guidance document will provide direction for the electronic transmission and submittal of documents to the NRC.

DATES: Submit comments by December 5, 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 comment 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–2016–0225. 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: OWFN–12–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: Marianne Narick, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington DC 20555–0001; telephone: 301–415–2175; email: *Marianne.Narick@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2016–0225 when contacting the NRC about the availability of information regarding this document. You may obtain publicly-available information related to this action by the following methods:

• *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2016–0225.

• *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. Revision 8 of the Electronic Guidance is available in ADAMS under Accession No. ML16293A712.

• *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–2016–0225 in the subject line of your comment submission, in order to ensure that the NRC is able to make your comment submission available to the public in this docket.

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.

II. Background

The NRC eSubmittal Guidance offers direction on how to submit documents electronically to the NRC. It is intended for licensees, applicants, external entities (including Federal, State, and local governments), vendors, participants in adjudicatory proceedings, and members of the public who need to submit documents to the Agency.

This document is an update to the NRC eSubmittal Guidance Version 6.1 found on the NRC intranet at *http://www.nrc.gov/site-help/electronic-sub-ref-mat.html.* Significant changes to the document that are of interest to stakeholders are that the flow of information makes it more user-friendly for submitters, and NRC guidance is more closely aligned with the National Archives and Records Administration requirements.

Dated at Rockville, Maryland, this 27th day of October 2016.

For the Nuclear Regulatory Commission.

Cynthia Rheaume,

Director, IT/IM Portfolio Management and Planning Division, Office of the Chief Information Officer.

[FR Doc. 2016–26562 Filed 11–2–16; 8:45 am]

BILLING CODE 7590–01–P

OFFICE OF SCIENCE AND TECHNOLOGY POLICY

Submittal of Mid-Atlantic Regional Ocean Action Plan for National Ocean Council Certification

AGENCY: Office of Science and Technology Policy National Ocean Council, Council on Environmental Quality; Department of Agriculture; Department of Commerce; Department of Defense; Department of Energy; Environmental Protection Agency; Department of Homeland Security; Department of the Interior; Department of Transportation; and Chairman, Joint Chiefs of Staff.

ACTION: Notice.

SUMMARY: The National Ocean Council notifies the public that the Mid-Atlantic Regional Ocean Action Plan was approved for submittal to the National Ocean Council by the Mid-Atlantic Regional Planning Body and submitted to the National Ocean Council for certification, as required by Executive Order 13547. The National Ocean Council will certify, or not certify, the Mid-Atlantic Regional Ocean Action Plan as consistent with the National Ocean Policy, Final Recommendations of the Interagency Ocean Policy Task Force, and the Marine Planning Handbook no sooner than 30 days from the publication of this Notice. The Mid-Atlantic Regional Ocean Action Plan can be found on the National Ocean Council's Web site at: *https://www.whitehouse.gov/sites/default/files/microsites/ostp/MidARegionalOceanActionPlan_November2016.pdf.*

FOR FURTHER INFORMATION CONTACT: Deerin S. Babb-Brott, Director, National Ocean Council, 202–456–4444.

SUPPLEMENTARY INFORMATION:

I. Background

National Ocean Policy

Executive Order 13547, Stewardship of the Ocean, Our Coasts, and the Great Lakes, signed July 19, 2010, established the National Ocean Policy to protect, maintain, and restore the health and biodiversity of the ocean, coastal, and Great Lakes ecosystems and resources; enhance the sustainability of the ocean and coastal economies and provide for adaptive management; increase our scientific understanding and awareness of changing environmental conditions; and support preservation of navigational rights and freedoms, in accordance with customary international law, which are essential for conservation of marine resources, sustaining the global economy and promoting national

security. The National Ocean Policy encourages a comprehensive, ecosystem-based, and transparent ocean planning process for analyzing current and anticipated uses of ocean and coastal areas and resources. This includes the voluntary development of regional marine plans by intergovernmental regional planning bodies such as the Mid-Atlantic Regional Planning Body (MidA RPB). These regional plans build on existing Federal, state, and tribal planning and decision-making processes to enable a more comprehensive and proactive approach to managing marine resources, sustaining coastal uses and improving the conservation of the ocean, our coasts, and the Great Lakes.

Mid-Atlantic Regional Planning Body

The MidA RPB includes six States (Delaware, Maryland, New Jersey, New York, Pennsylvania and Virginia) and two Federally recognized Indian Tribes in the region, the Shinnencock Indian Nation and the Pamunkey Indian Tribe. Eight Federal Agencies serve on the MidA RPB: Department of Agriculture represented by the Natural Resource Conservation Service; Department of Commerce represented by the National Oceanic and Atmospheric Administration; Department of Defense represented by the U.S. Navy; Department of Energy; Department of Homeland Security represented by the U.S. Coast Guard; Department of the Interior represented by the Bureau of Ocean Energy Management, in coordination with, the National Park Service, the U.S. Fish and Wildlife Service, and U.S. Geological Survey; Department of Transportation represented by the Maritime Administration; Environmental Protection Agency; Chairman of the Joint Chiefs of Staff represented by the U.S. Navy; and the U.S. Army Corps in an *ex officio* status. The Mid-Atlantic Fishery Management Council also serves on the MidA RPB. The MidA RPB is not a regulatory body and has no independent legal authority to regulate or direct Federal, state, or tribal entities, nor does the Mid-Atlantic Regional Ocean Action Plan (Plan) augment or subtract from any agency's existing statutory or regulatory authorities.

National Ocean Council

Executive Order 13547 established the National Ocean Council (NOC) to direct implementation of the National Ocean Policy. The NOC is comprised of: The Secretaries of Agriculture, Commerce, Defense, Energy, Health and Human Services, Homeland Security, Interior, Labor, State, and Transportation; the Attorney General; the Administrators of the Environmental Protection Agency, the National Aeronautics and Space Administration, and National Oceanic and Atmospheric Administration; the Directors of the Office of Management and Budget, National Intelligence, the Office of Science and Technology Policy (OSTP), and National Science Foundation; the Chairman of the Joint Chiefs of Staff; the Chairs of the Council on Environmental Quality (CEQ) and the Federal Energy Regulatory Commission; the Assistants to the President for National Security Affairs, Homeland Security and Counterterrorism, Domestic Policy, Energy and Climate Change, and Economic Policy; and an employee of the Federal Government designated by the Vice President. The Chair of CEQ and the Director of OSTP co-chair the NOC.

NOC Certification of Regional Marine Plans

Executive Order 13547 adopts the Final Recommendations of the Interagency Ocean Policy Task Force (Final Recommendations). The Final Recommendations set forth the process for the NOC to review and certify each regional marine plan to ensure it is consistent with the National Ocean Policy and includes the essential elements described in the Final Recommendations as further characterized by the NOC's subsequent Marine Planning Handbook (Handbook; 2013). Consistent with the Final Recommendations and the Handbook, the NOC will determine whether to certify, or not certify, the Mid-Atlantic Regional Ocean Action Plan no sooner than 30 days from the publication of this Notice. Pursuant to Executive Order 13547, if the NOC certifies the Mid-Atlantic Regional Ocean Action Plan, Federal Agencies shall comply with the Plan in the conduct of their missions and programs to the fullest extent consistent with applicable law.

II. The Mid-Atlantic Regional Ocean Action Plan

The Mid-Atlantic Regional Ocean Action Plan is a comprehensive, flexible, and proactive approach to managing uses and resources in the marine environment of the Mid-Atlantic United States. The Plan is intended to strengthen interagency coordination, enhance public participation, and improve planning and policy implementation. The Plan has two main goals: (1) Healthy ocean ecosystems and (2) sustainable ocean uses. The Plan also describes best practices for coordination among Federal Agencies, Tribes, States, stakeholders, and the public. The Mid-Atlantic Regional Ocean Action Plan is informed by extensive stakeholder data and input. Throughout the planning process, stakeholders were involved in developing data products for human activities (such as shipping, fishing, recreation, and energy) and marine life and habitat (through review of the methods, analyses, and draft products for spatial data characterizing species and their habitats). These data products reside on the Mid-Atlantic Ocean Data Portal (Data Portal or Portal). The MidA RPB uses the Portal, developed by the Mid-Atlantic Regional Council on the Ocean (MARCO), in collaboration with an associated working group, to serve as a user-friendly source of maps, data, and tools that can serve as one source of information to inform ocean planning from New York to Virginia. A range of government entities, non-government organizations, and stakeholders in the Mid-Atlantic region are already using the Portal. It is available to the public online at the MidA Regional Ocean Action Plan Web site: *http://midatlanticocean.org/data-portal/.*

As described in a Notice by the Department of the Interior's Bureau of Ocean Energy Management (BOEM), published in the **Federal Register** on July 6, 2016 (81 FR 44040), the MidA RPB previously released a draft Mid-Atlantic Regional Ocean Action Plan for a 60-day public comment period. The MidA RPB prepared a summary and response to the comments received from the public and stakeholders on this draft that can be found at *http://www.boem.gov/Ocean-Action-Plan.*

III. Implementation of the Mid-Atlantic Regional Ocean Action Plan

The Federal members of the MidA RPB administer a wide range of statutes and programs that involve or affect the marine environment in the Mid-Atlantic regional ocean planning area. These Federal departments and agencies carry out actions under Federal laws involving a wide range of regulatory responsibilities and non-regulatory missions and management activities throughout the Nation's waterways and the ocean. Activities of Federal MidA RPB members include managing and developing marine transportation infrastructure, national security and homeland defense activities; regulating ocean discharges; siting energy facilities; permitting sand removal and beach re-nourishment; managing national parks, national wildlife refuges, and national marine sanctuaries; regulating commercial and recreational fishing; and managing activities

affecting threatened and endangered species and migratory birds.

The specific manner and mechanism each Federal agency will use to implement the Mid-Atlantic Regional Ocean Action Plan will depend on that agency's mission, authorities, and activities. If the NOC certifies that the Mid-Atlantic Regional Ocean Action Plan is consistent with the National Ocean Policy, the Final Recommendations, and the Handbook, each Federal MidA RPB member will use the Mid-Atlantic Regional Ocean Action Plan to inform and guide its planning activities and decision-making actions, including permitting, authorizing, and leasing decisions that involve or affect the Mid-Atlantic regional ocean planning area.

Specifically, consistent with applicable statutory authorities, Executive Order 13547 and the Final Recommendations, the Federal Agencies represented on the MidA RPB, and their relevant components, expressly including the U.S. Army Corps of Engineers in its *ex officio* status for responsibilities beyond those in Title 10, U.S. Code, will: (1) Identify, develop, and make publicly available implementing instructions, such as internal agency guidance, directives, or similar organizational or administrative documents, that describe the way the agency will use the Plan to inform and guide its actions and decisions in or affecting the Mid-Atlantic regional ocean planning area; (2) ensure that the agency, through such internal administrative instructions, will consider the data products available from the Data Portal in its decision making and as it carries out its actions in or affecting the Mid-Atlantic regional ocean planning area; and (3) explain its use of the Plan and Data Portal in its decisions, activities, or planning processes that involve or affect the Mid-Atlantic regional ocean planning area.

IV. Conclusion

The National Ocean Policy provides a path for Federal Agencies, states and tribes to work collaboratively and proactively to manage the many existing and future uses of the Nation's oceans, coasts and Great Lakes. If the NOC certifies the Mid-Atlantic Regional Ocean Action plan, MidA RPB members intend to use the Plan to align their priorities and share data and technical information to minimize conflicts among uses, take actions to promote the productivity of marine resources, sustain healthy ecosystems, and promote the prosperity and security of the Nation's ocean and coastal communities and their economies for the benefit of present and future generations. The NOC will review the Mid-Atlantic Regional Ocean Action Plan for consistency with the National Ocean Policy, Final Recommendations of the Interagency Ocean Policy Task Force, and the Marine Planning Handbook and make its determination no sooner than 30 days from the publication of this Notice.

Authority: Executive Order 13547, ''Stewardship of the Ocean, Our Coasts and the Great Lakes'' (July 19, 2010).

Ted Wackler,

Deputy Chief of Staff and Assistant Director.

[FR Doc. 2016–26623 Filed 11–2–16; 8:45 am]

BILLING CODE 3270–F7–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–79185; File No. SR–Phlx–2016–104]

Self-Regulatory Organizations; NASDAQ PHLX LLC; Notice of Filing of Proposed Rule Change To Amend Phlx Rule 748, Supervision

October 28, 2016.

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 14, 2016, NASDAQ PHLX LLC (''Phlx'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III, below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to a proposal [sic] to amend Phlx Rule 748, Supervision, as explained further below.

The text of the proposed rule change is available on the Exchange's Web site at *http://nasdaqphlx.cchwallstreet.com/*, at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange is proposing to amend several provisions of Rule 748. The proposed rule change is intended to modernize, upgrade and strengthen the Exchange's rules pertaining to supervisory obligations of its members and member organizations.

Rule 748(a)

Rule 748(a) currently provides in the first paragraph that each office, location, department, or business activity of a member or member organization (including foreign incorporated branch offices) shall be under the supervision and control of the member or member organization establishing it and of an appropriately qualified supervisor. The Exchange is amending the first paragraph of Rule 748(a) to clarify and state clearly that each trading system and internal surveillance system of a member or member organization (including foreign incorporated branch offices) shall, inasmuch as they are aspects of their business activity, be under the supervision and control of the member or member organization establishing it and of an appropriately qualified supervisor.

Rule 748(b)

Rule 748(b), Designation of Supervisor by Member Organizations, currently provides in relevant part that the general partners or directors of each member organization shall provide for appropriate supervisory control and shall designate a general partner or principal executive officer to assume overall authority and responsibility for internal supervision and control of the organization and compliance with securities' (sic) laws and regulations, including the By-Laws and Rules of the Exchange. It provides that the designated person shall delegate to qualified principals or qualified employees responsibility and authority for supervision and control of each office, location, department, or business activity, (including foreign incorporated branch offices), and provide for

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

appropriate written procedures of supervision and control. The Exchange proposes to amend Rule 748(b) to provide that the delegated person shall likewise delegate to qualified principals or qualified employees responsibility and authority for supervision and control of each trading system and internal surveillance system.[3]

Rule 748(c)

Rule 748(c) currently provides that each person with supervisory control, as described in paragraphs (a) and (b) of Rule 748, must meet the Exchange's qualification requirements for supervisors, including successful completion of the appropriate examination. The Exchange proposes to add to Rule 748(c) a new requirement that each member or member organization must make reasonable efforts to determine that each person with supervisory control, as described in paragraphs (a) and (b) of Rule 748, is qualified by virtue of experience or training to carry out his or her assigned responsibilities.

Rule 748(g)

Rule 748(g), Office Inspections, currently provides that each member or member organization for which the Exchange is the DEA shall inspect each office or location (including foreign incorporated branch offices) of the member or member organization according to a cycle that shall be established in its written supervisory procedures. In establishing such inspection cycle, the member or member organization shall give consideration to the nature and complexity of the securities activities for which the office or location is responsible, the volume of business done, and the number of registered representatives, employees, and associated persons at each office or location. Rule 748(g) is proposed to be amended to provide that an inspection may not be conducted by any person within that office or location who has supervisory responsibilities or by any individual who is directly or indirectly supervised by such person. The Exchange also proposes to add language requiring the examination schedule and an explanation of the factors considered in determining the frequency of the examinations in the cycle to be set forth in the member or member organization's written supervisory procedures. It also proposes to require that the inspection be reasonably designed to assist in preventing and detecting violations of, and achieving compliance with, applicable securities laws and regulations, and with applicable Exchange rules.

Rule 748(h)

Rule 748(h) in the first paragraph currently requires each member or member organization to establish, maintain, and enforce written supervisory procedures, and a system for applying such procedures, to supervise the types of business(es) in which the member or member organization engages and to supervise the activities of all registered representatives, employees, and associated persons. The written supervisory procedures and the system for applying such procedures shall reasonably be expected to prevent and detect, insofar as practicable, violations of the applicable securities laws and regulations, including the By-Laws and Rules of the Exchange. The Exchange proposes to substitute the word ''designed'' for the word ''expected.''

Rule 748(h) in the second paragraph currently requires that the written supervisory procedures set forth the supervisory system established by the member or member organization and include the name, title, registration status, and location of all supervisory personnel required by this rule, the dates for which supervisory designations were or are effective, and the responsibilities of supervisory personnel as these relate to the types of business(es) the member or member organization engages in, and securities laws and regulations, including the By-Laws and Rules of the Exchange. The Exchange proposes to add a requirement that this record be preserved for a period of not less than three years, the first two in an easily accessible place.

Rule 748(h) in the third paragraph currently requires a copy of the written supervisory procedures to be kept and maintained at each location where supervisory activities are conducted on behalf of the member or member organization. It requires each member or member organization to amend its written supervisory procedures as appropriate within a reasonable time after changes occur in supervisory personnel or supervisory procedures, and to communicate such changes throughout its organization within a reasonable time. The Exchange proposes to amend Rule 748(h) to likewise amend and communicate changes to its written supervisory procedures as appropriate within a reasonable time after changes occur in applicable securities laws and regulations and Exchange rules.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[4] in general, and furthers the objectives of Section 6(b)(5) of the Act,[5] in particular, in that it is 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, by enhancing its rules relating to supervision as set forth in Rule 748. Requiring increased comprehensive supervision by members and member organizations of their activities should promote the Exchange's ability to enforce compliance by members and member organizations with the Act and the regulations thereunder.

Amending Rules 748(a) and (b) to require trading systems and internal surveillance systems to be under the supervision and control of the member or member organization establishing them and of an appropriately qualified supervisor, and requiring the general partner or principal executive officer with overall authority and responsibility for internal supervision and control of the organization and compliance with securities laws and regulations to delegate responsibility and authority for supervision and control of each trading system and internal surveillance system to qualified principals or qualified employees, should protect investors and the public interest by specifically requiring supervision and control of these aspects of the member or member organization's business by an appropriately qualified individual.

The proposed amendment to Rule 748(c) should protect investors and the public interest by requiring that each person with supervisory control as described in Rules 748(a) and (b) to be qualified by virtue of experience or training to carry out his or her assigned responsibilities, such that the individual has the actual capacity to fulfill those responsibilities.

The proposed amendments to Rule 748(g) regarding office inspections should protect investors and the public interest by minimizing the potential for conflicts of interest in the conduct of office inspections. The amendments would prohibit the required inspections from being conducted by any person within that office or location who has supervisory responsibilities or by any individual who is directly or indirectly supervised by such a person who may

[3] The Exchange is also deleting the extraneous apostrophe following the word ''securities''.

[4] 15 U.S.C. 78f(b).

[5] 15 U.S.C. 78f(b)(5).

be incentivized to minimize any compliance issues identified in the inspection. The proposed amendments to Rule 748(g) concerning the examination schedule and specifically requiring that the inspection be reasonably designed to assist in preventing and detecting violations of, and achieving compliance with, applicable securities laws and regulations and with applicable Exchange rules should assure that inspections take place with a predictable and adequate frequency and are reasonably designed to identify violations of applicable law and rules.

The proposed amendments to Rule 748(h) are also designed to protect investors and the public interest, by requiring the written supervisory procedures to be preserved for a period of not less than three years, the first two in an easily accessible place, in order to facilitate identification of instances where the procedures were not followed. Stating that the written supervisory procedures and the system for applying such procedures shall reasonably be ''designed'' rather than ''expected'' to prevent and detect violations clarifies the affirmative nature of the member or member organization's obligations under the rule when creating such procedures.

Finally, the Rule 748(h) amendment requiring members or member organizations to update their written supervisory procedures following changes in applicable securities laws and regulations, and Exchange rules should promote the continued usefulness of the procedures in the context of ongoing changes in the regulatory environment in which members and member organizations conduct their business.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The amendments will apply to all members and member organizations subject to Rule 748.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the Exchange consents, the Commission shall: (a) By order approve or disapprove such proposed rule change, or (b) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml);* or
- Send an email to *rule-comments@sec.gov. Please include File Number SR–Phlx–2016–104 on the subject line.*

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number *SR–Phlx–2016–104.* 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–Phlx–2016–104* and should be submitted on or before November 25, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[6]

Brent J. Fields,

Secretary.

[FR Doc. 2016–26511 Filed 11–2–16; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–79182; File No. SR–MIAX–2016–40]

Self-Regulatory Organizations; Miami International Securities Exchange LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Adopt Exchange Rule 322, Disruptive Quoting and Trading Activity Prohibited and Exchange Rule 1018, Expedited Suspension Proceeding

October 28, 2016.

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 20, 2016, Miami International Securities Exchange LLC (''MIAX'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is filing a proposal to adopt Exchange Rule 322, Disruptive Quoting and Trading Activity Prohibited, to clearly prohibit disruptive quoting and trading activity on the Exchange as described below. The Exchange also proposes to adopt new Exchange Rule 1018, Expedited Suspension Proceeding, to permit the Exchange to take prompt action to

[6] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

suspend Members or their clients that violate such rule.

The text of the proposed rule change is available on the Exchange's Web site at *http://www.miaxoptions.com/filter/wotitle/rule_filing,* at MIAX's principal office, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to adopt new Exchange Rule 322, Disruptive Quoting and Trading Activity Prohibited, to clearly prohibit disruptive trading activity on the Exchange and to adopt a new Exchange Rule 1018, Expedited Suspension Proceeding, to permit the Exchange to take prompt action to suspend Members or their clients that violate such rule.

Background

As a national securities exchange registered pursuant to Section 6 of the Act, the Exchange is required to be organized and to have the capacity to enforce compliance by its members and persons associated with its members, with the Act, the rules and regulations, thereunder, and the Exchange's Rules. Further, the Exchange's Rules are required to be ''designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade . . . and, in general, to protect investors and the public interest.'' [3] In fulfilling these requirements, the Exchange has developed a comprehensive regulatory program that includes automated surveillance of trading activity that is both operated directly by Exchange staff and by staff of the Financial Industry Regulatory Authority (''FINRA'') pursuant to a Regulatory Services Agreement (''RSA''). When disruptive and potentially manipulative or improper quoting and trading activity is identified, the Exchange or FINRA (acting as an agent of the Exchange) conducts an investigation into the activity, requesting additional information from the Member or Members involved. To the extent violations of the Act, the rules and regulations thereunder, or Exchange Rules have been identified and confirmed, the Exchange or FINRA, as its agent, will commence the enforcement process, which might result in, among other things, a censure, a requirement to take certain remedial actions, one or more restrictions on future business activities, a monetary fine, or even a temporary or permanent ban from the securities industry.

The process described above, from the identification of disruptive and potentially manipulative or improper quoting and trading activity to a final resolution of the matter, can often take several years. The Exchange believes that this time period is generally necessary and appropriate to afford the subject Member adequate due process, particularly in complex cases. However, as described below, the Exchange believes that there are certain obvious and uncomplicated cases of disruptive and manipulative behavior or cases where the potential harm to investors is so large that the Exchange should have the authority to initiate an expedited suspension proceeding in order to stop the behavior from continuing on the Exchange.

In recent years, several cases have been brought and resolved by exchanges and other SROs that involved allegations of wide-spread market manipulation, much of which was ultimately being conducted by foreign persons and entities using relatively rudimentary technology to access the markets and over which the exchanges and other SROs had no direct jurisdiction. In each case, the conduct involved a pattern of disruptive quoting and trading activity indicative of manipulative layering [4] or spoofing.[5]

The exchanges and other SROs were able to identify the disruptive quoting and trading activity in real-time or near real-time; nonetheless, in accordance with Exchange Rules and the Act, the Members responsible for such conduct or responsible for their customers' conduct were allowed to continue the disruptive quoting and trading activity on the Exchange and other exchanges during the entirety of the subsequent lengthy investigation and enforcement process. The Exchange believes that it should have the authority to initiate an expedited suspension proceeding in order to stop the behavior from continuing on the Exchange if a Member is engaging in or facilitating disruptive quoting and trading activity and the Member has received sufficient notice with an opportunity to respond, but such activity has not ceased.

The following two examples are instructive on the Exchange's rationale for the proposed rule change.

In July 2012, Biremis Corp. (formerly Swift Trade Securities USA, Inc.) (the ''Firm'') and its CEO were barred from the industry for, among other things, supervisory violations related to a failure by the Firm to detect and prevent disruptive and allegedly manipulative trading activities, including layering, short sale violations, and anti-money laundering violations.[6]

The Firm's sole business was to provide trade execution services via a proprietary day trading platform and order management system to day traders located in foreign jurisdictions. Thus, the disruptive and allegedly manipulative trading activity introduced by the Firm to U.S. markets originated directly or indirectly from foreign clients of the Firm. The pattern of disruptive and allegedly manipulative quoting and trading activity was widespread across multiple exchanges, FINRA, and other SROs identified clear patterns of the behavior in 2007 and 2008. Although the Firm and its principals were on notice of the disruptive and allegedly manipulative quoting and trading activity that was occurring, the Firm took little to no action to attempt to supervise or prevent such quoting and trading activity until at least 2009. Even when it put some controls in place, they were deficient and the pattern of disruptive and allegedly manipulative trading activity continued to occur. As noted above, the final resolution of the enforcement action to bar the Firm and its CEO from the industry was not concluded until

[3] 15 U.S.C. 78(f)(b)(1).

[4] ''Layering'' is a form of market manipulation in which multiple, non-bona fide limit orders are entered on one side of the market at various price levels in order to create the appearance of a change in the levels of supply and demand, thereby artificially moving the price of the security. An order is then executed on the opposite side of the market at the artificially created price, and the non-bona fide orders are cancelled.

[5] ''Spoofing'' is a form of market manipulation that involves the market manipulator placing non-bona fide orders that are intended to trigger some type of market movement and/or response from other market participants, from which the market manipulator might benefit by trading bona fide orders.

[6] *See* Biremis Corp. and Peter Beck, FINRA Letter of Acceptance, Waiver and Consent No. 2010021162202, July 30, 2012.

2012, four years after the disruptive and allegedly manipulative trading activity was first identified.

In September of 2012, Hold Brothers On-Line Investment Services, Inc. (the ''Firm'') settled a regulatory action in connection with the Firm's provision of a trading platform, trade software and trade execution, support and clearing services for day traders.[7] Many traders using the Firm's services were located in foreign jurisdictions. The Firm ultimately settled the action with FINRA and several exchanges, for a total monetary fine of $3.4 million. In a separate action, the Firm settled with the Commission for a monetary fine of $2.5 million.[8] Among the alleged violations in the case were disruptive and allegedly manipulative quoting and trading activity, including spoofing, layering, wash trading, and pre-arranged trading. Through its conduct and insufficient procedures and controls, the Firm also allegedly committed anti-money laundering violations by failing to detect and report manipulative and suspicious trading activity. The Firm was alleged to have not only provided foreign traders with access to the U.S. markets to engage in such activities, but that its principals also owned and funded foreign subsidiaries that engaged in the disruptive and allegedly manipulative quoting and trading activity. Although the pattern of disruptive and allegedly manipulative quoting and trading activity was identified in 2009, as noted above, the enforcement action was not concluded until 2012. Thus, although disruptive and allegedly manipulative quoting and trading was promptly detected, it continued for several years.

The Exchange also notes the current criminal proceedings that have commenced against Navinder Singh Sarao. Mr. Sarao's allegedly manipulative trading activity, which included forms of layering and spoofing in the futures markets, has been linked as a contributing factor to the ''Flash Crash'' of 2010, and yet continued through 2015.

The Exchange believes that the activities described in the cases above provide justification for the proposed rule change, which is described below. In addition, while the examples provided are related to the equities market, the Exchange believes that this type of conduct should be prohibited for options as well. The Exchange believes that these patterns of disruptive and allegedly manipulative quoting and trading activity need to be addressed and the product should not limit the action taken by the Exchange.

Rule 1018—Expedited Suspension Proceeding

The Exchange proposes to adopt new Rule 1018, titled ''Expedited Suspension Proceeding,'' to set forth procedures for issuing suspension orders, immediately prohibiting a Member from conducting continued disruptive quoting and trading activity on the Exchange. Importantly, these procedures would also provide the Exchange the authority to order a Member to cease and desist from providing access to the Exchange to a client of the Member that is conducting disruptive quoting and trading activity in violation of proposed Rule 322. The proposed new Rule 322 would be titled, ''Disruptive Quoting and Trading Activity Prohibited.'' Under proposed paragraph (a) of Rule 1018, with the prior written authorization of the Chief Regulatory Officer (''CRO'') or such other senior officers as the CRO may designate, the Office of the General Counsel or Regulatory Department of the Exchange (such departments generally referred to as the ''Exchange'' for purposes of the proposed Rule 1018) may initiate an expedited suspension proceeding with respect to alleged violations of proposed Rule 322, which is proposed as part of this filing and described in detail below. Proposed paragraph (a) would also set forth the requirements for notice and service of such notice pursuant to the Rule, including the required method of service and the content of notice.

Proposed paragraph (b) of Rule 1018 would govern the appointment of a Hearing Panel as well as potential disqualification or recusal of Panel Members. The proposed provision is consistent with existing Exchange Rule 1006(a). The proposed rule provides for a Panel Member to be recused in the event he or she has a conflict of interest or bias or other circumstances exist where his or her fairness might reasonably be questioned in accordance with Rule 1018(b)(2). In addition to recusal initiated by such a Panel Member, a party to the proceeding will be permitted to file a motion to disqualify a Panel Member. However, due to the compressed schedule pursuant to which the process would operate under Rule 1018, the proposed rule would require such motion to be filed no later than 5 days after the announcement of the Hearing Panel and the Exchange's brief in opposition to such motion would be required to be filed no later than 5 days after service thereof. Pursuant to existing Rule 1006(a)(3), any time a person serving on a Panel has a conflict of interest or bias or circumstances otherwise exist where his or her fairness might be reasonably questioned, the person must withdraw from the Panel. The applicable Panel Member shall remove himself or herself and the Panel Chairman may request the Chairman of the Business Conduct Committee to select a replacement such that the Hearing Panel still meets the compositional requirements described in Rule 1006(a).

Under paragraph (c) of the proposed Rule, the hearing would be held not later than 15 days after the service of the notice initiating the suspension proceeding, unless otherwise extended by the Chairman of the Hearing Panel with the consent of the Parties for good cause shown. In the event of a recusal or disqualification of a Panel Member, the hearing shall be held not later than five days after a replacement Panel Member is appointed. Proposed paragraph (c) would also govern how the hearing is conducted, including the authority of Panel Members, witnesses, additional information that may be required by the Hearing Panel, the requirement that a transcript of the proceeding be created and details related to such transcript, and details regarding the creation and maintenance of the record of the proceeding. Proposed paragraph (c) would also state that if a Respondent fails to appear at a hearing for which it has notice, the allegations in the notice and accompanying declaration may be deemed admitted, and the Hearing Panel may issue a suspension order without further proceedings. Finally, as proposed, if the Exchange fails to appear at a hearing for which it has notice, the Hearing Panel may order that the suspension proceeding be dismissed.

Under paragraph (d) of the proposed Rule, the Hearing Panel would be required to issue a written decision stating whether a suspension order would be imposed. The Hearing Panel would be required to issue the decision not later than 10 days after receipt of the hearing transcript, unless otherwise extended by the Chairman of the Hearing Panel with the consent of the Parties for good cause shown. The Rule would state that a suspension order shall be imposed if the Hearing Panel finds by a preponderance of the evidence that the alleged violation specified in the notice has occurred and that the violative conduct or continuation thereof is likely to result in

[7] *See* Hold Brothers On-Line Investment Services, LLC, FINRA Letter of Acceptance, Waiver and Consent No. 20100237710001, September 25, 2012.

[8] In the Matter of Hold Brothers On-Line Investment Services, LLC, Exchange Act Release. No. 67924, September 25, 2012.

significant market disruption or other significant harm to investors.

Proposed paragraph (d) would also describe the content, scope and form of a suspension order. As proposed, a suspension order shall be limited to ordering a Respondent to cease and desist from violating proposed Rule 322 and/or to ordering a Respondent to cease and desist from providing access to the Exchange to a client of Respondent that is causing violations of proposed Rule 322. Under the proposed rule, a suspension order shall also set forth the alleged violation and the significant market disruption or other significant harm to investors that is likely to result without the issuance of an order. The order shall describe in reasonable detail the act or acts the Respondent is to take or refrain from taking, and suspend such Respondent unless and until such action is taken or refrained from. Finally, the order shall include the date and hour of its issuance. As proposed, a suspension order would remain effective and enforceable unless modified, set aside, limited, or revoked pursuant to proposed paragraph (e), as described below. Finally, paragraph (d) would require service of the Hearing Panel's decision and any suspension order consistent with other portions of the proposed rule related to service.

Proposed paragraph (e) of Rule 1018 would state that at any time after the Hearing Panel served the Respondent with a suspension order, a Party could apply to the Hearing Panel to have the order modified, set aside, limited, or revoked. If any part of a suspension order is modified, set aside, limited, or revoked, proposed paragraph (e) of Rule 1018 provides the Hearing Panel discretion to leave the cease and desist part of the order in place. For example, if a suspension order suspends Respondent unless and until Respondent ceases and desists providing access to the Exchange to a client of Respondent, and after the order is entered the Respondent complies, the Hearing Panel is permitted to modify the order to lift the suspension portion of the order while keeping in place the cease and desist portion of the order. With its broad modification powers, the Hearing Panel also maintains the discretion to impose conditions upon the removal of a suspension—for example, the Hearing Panel could modify an order to lift the suspension portion of the order in the event a Respondent complies with the cease and desist portion of the order but additionally order that the suspension will be re-imposed if Respondent violates the cease and desist provisions modified order in the future. The Hearing Panel generally would be required to respond to the request in writing within 10 days after receipt of the request. An application to modify, set aside, limit or revoke a suspension order would not stay the effectiveness of the suspension order.

Finally, proposed paragraph (f) would provide that sanctions issued under the proposed Rule 1018 would constitute final and immediately effective disciplinary sanctions imposed by the Exchange, and that the right to have any action under the Rule reviewed by the Commission would be governed by Section 19 of the Act. The filing of an application for review would not stay the effectiveness of a suspension order unless the Commission otherwise ordered.

Rule 322—Disruptive Quoting and Trading Activity Prohibited

The Exchange currently has authority to prohibit and take action against manipulative trading activity, including disruptive quoting and trading activity, pursuant to its general market manipulation rules, including Rules 301, Just and Equitable Principles of Trade, and 318, Manipulation. The Exchange proposes to adopt new Rule 322, which would more specifically define and prohibit disruptive quoting and trading activity on the Exchange. As noted above, the Exchange proposes to apply the proposed suspension rules to proposed Rule 322.

Proposed Rule 322 would prohibit Members from engaging in or facilitating disruptive quoting and trading activity on the Exchange, as described in proposed Rule 322(a)(1) and (2), including acting in concert with other persons to effect such activity. The Exchange believes that it is necessary to extend the prohibition to situations when persons are acting in concert to avoid a potential loophole where disruptive quoting and trading activity is simply split between several brokers or customers. The Exchange believes, that with respect to persons acting in concert perpetrating an abusive scheme, it is important that the Exchange have authority to act against the parties perpetrating the abusive scheme, whether it is one person or multiple persons.

To provide proper context for the situations in which the Exchange proposes to utilize its proposed authority, the Exchange believes it is necessary to describe the types of disruptive quoting and trading activity that would cause the Exchange to use its authority. Accordingly, the Exchange proposes to adopt Rule 322(a)(1) and (2) providing additional details regarding disruptive quoting and trading activity. Proposed Rule 322(a)(1)(i) describes disruptive quoting and trading activity containing many of the elements indicative of layering. It would describe disruptive quoting and trading activity as a frequent pattern in which the following facts are present: (i) A party enters multiple limit orders on one side of the market at various price levels (the ''Displayed Orders''); and (ii) following the entry of the Displayed Orders, the level of supply and demand for the security changes; and (iii) the party enters one or more orders on the opposite side of the market of the Displayed Orders (the ''Contra-Side Orders'') that are subsequently executed; and (iv) following the execution of the Contra-Side Orders, the party cancels the Displayed Orders.

Proposed Rule 322(a)(1)(ii) describes disruptive quoting and trading activity containing many of the elements indicative of spoofing and would describe disruptive quoting and trading activity as a frequent pattern in which the following facts are present: (i) A party narrows the spread for a security by placing an order inside the national best bid or offer; and (ii) the party then submits an order on the opposite side of the market that executes against another market participant that joined the new inside market established by the order described in proposed Rule 322(a)(1)(ii)(A) that narrowed the spread. The Exchange believes that the proposed descriptions of disruptive quoting and trading activity articulated in the rule are consistent with the activities that have been identified and described in the client access cases described above. The Exchange further believes that the proposed descriptions will provide Members with clear descriptions of disruptive quoting and trading activity that will help them to avoid in engaging in such activities or allowing their clients to engage in such activities.

The Exchange proposes to make clear in proposed Rule 322(a)(2), unless otherwise indicated, the descriptions of disruptive quoting and trading activity do not require the facts to occur in a specific order in order for the rule to apply. For instance, with respect to the pattern defined in proposed Rule 322(a)(1)(i) it is of no consequence whether a party first enters Displayed Orders and then Contra-side Orders or vice-versa. However, as proposed, it is required for supply and demand to change following the entry of the Displayed Orders. The Exchange also proposes to make clear that disruptive quoting and trading activity includes a

pattern or practice in which some portion of the disruptive quoting and trading activity is conducted on the Exchange and the other portions of the disruptive quoting and trading activity are conducted on one or more other exchanges. The Exchange believes that this authority is necessary to address market participants who would otherwise seek to avoid the prohibitions of the proposed Rule by spreading their activity amongst various execution venues. In sum, proposed Rule 322 coupled with proposed Rule 1018 would provide the Exchange with the authority to promptly act to prevent disruptive quoting and trading activity from continuing on the Exchange.

Below is an example of how the proposed rule would operate.

Assume that through its surveillance program, Exchange staff identifies a pattern of potentially disruptive quoting and trading activity. After an initial investigation the Exchange would then contact the Member responsible for the orders that caused the activity to request an explanation of the activity as well as any additional relevant information, including the source of the activity. If the Exchange were to continue to see the same pattern from the same Member and the source of the activity is the same or has been previously identified as a frequent source of disruptive quoting and trading activity then the Exchange could initiate an expedited suspension proceeding by serving notice on the Member that would include details regarding the alleged violations as well as the proposed sanction. In such a case the proposed sanction would likely be to order the Member to cease and desist providing access to the Exchange to the client that is responsible for the disruptive quoting and trading activity and to suspend such Member unless and until such action is taken.

The Member would have the opportunity to be heard in front of a Hearing Panel at a hearing to be conducted within 15 days of the notice. If the Hearing Panel determined that the violation alleged in the notice did not occur or that the conduct or its continuation would not have the potential to result in significant market disruption or other significant harm to investors, then the Hearing Panel would dismiss the suspension order proceeding.

If the Hearing Panel determined that the violation alleged in the notice did occur and that the conduct or its continuation is likely to result in significant market disruption or other significant harm to investors, then the Hearing Panel would issue the order including the proposed sanction, ordering the Member to cease providing access to the client at issue and suspending such Member unless and until such action is taken. If such Member wished for the suspension to be lifted because the client ultimately responsible for the activity no longer would be provided access to the Exchange, then such Member could apply to the Hearing Panel to have the order modified, set aside, limited or revoked. The Exchange notes that the issuance of a suspension order would not alter the Exchange's ability to further investigate the matter and/or later sanction the Member pursuant to the Exchange's standard disciplinary process for supervisory violations or other violations of Exchange rules or the Act.

The Exchange reiterates that it already has broad authority to take action against a Member in the event that such Member is engaging in or facilitating disruptive or manipulative trading activity on the Exchange. For the reasons described above, and in light of recent cases like the client access cases described above, as well as other cases currently under investigation, the Exchange believes that it is equally important for the Exchange to have the authority to promptly initiate expedited suspension proceedings against any Member who has demonstrated a clear pattern or practice of disruptive quoting and trading activity, as described above, and to take action including ordering such Member to terminate access to the Exchange to one or more of such Member's clients if such clients are responsible for the activity.

The Exchange recognizes that its proposed authority to issue a suspension order is a powerful measure that should be used very cautiously. Consequently, the proposed rules have been designed to ensure that the proceedings are used to address only the most clear and serious types of disruptive quoting and trading activity and that the interests of Respondents are protected. For example, to ensure that proceedings are used appropriately and that the decision to initiate a proceeding is made only at the highest staff levels, the proposed rules require the CRO or another senior officer of the Exchange to issue written authorization before the Exchange can institute an expedited suspension proceeding. In addition, the rule by its terms is limited to violations of Rule 322, when necessary to protect investors, other Members and the Exchange. The Exchange will initiate disciplinary action for violations of proposed Rule 322, pursuant to proposed Rule 1018. Further, the Exchange believes that the proposed expedited suspension provisions described above that provide the opportunity to respond as well as a Hearing Panel determination prior to taking action will ensure that the Exchange would not utilize its authority in the absence of a clear pattern or practice of disruptive quoting and trading activity.

2. Statutory Basis

MIAX believes that its proposed rule change is consistent with Section 6(b) of the Act [9] in general, and furthers the objectives of Section 6(b)(5) of the Act [10] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanisms of a free and open market and a national market system and, in general, to protect investors and the public interest. Pursuant to the proposal, the Exchange will have a mechanism to promptly initiate expedited suspension proceedings in the event the Exchange believes that it has sufficient proof that a violation of proposed Rule 322 has occurred and is ongoing.

Further, the Exchange believes that the proposal is consistent with Sections 6(b)(1) and 6(b)(6) of the Act,[11] which require that the rules of an exchange enforce compliance with, and provide appropriate discipline for, violations of the Commission and Exchange rules. The Exchange also believes that the proposal is consistent with the public interest, the protection of investors, or otherwise in furtherance of the purposes of the Act because the proposal helps to strengthen the Exchange's ability to carry out its oversight and enforcement responsibilities as a self-regulatory organization in cases where awaiting the conclusion of a full disciplinary proceeding is unsuitable in view of the potential harm to other Members and their customers. Also, the Exchange notes that if this type of conduct is allowed to continue on the Exchange, the Exchange's reputation could be harmed because it may appear to the public that the Exchange is not acting to address the behavior. The expedited process would enable the Exchange to address the behavior with greater speed.

As explained above, the Exchange notes that it has defined the prohibited

[9] 15 U.S.C. 78f(b).

[10] 15 U.S.C. 78f(b)(5).

[11] 15 U.S.C. 78f(b)(1) and 78f(b)(6).

disruptive quoting and trading activity by modifying the traditional definitions of layering and spoofing [12] to eliminate an express intent element that would not be proven on an expedited basis and would instead require a thorough investigation into the activity. As noted throughout this filing, the Exchange believes it is necessary for the protection of investors to make such modifications in order to adopt an expedited process rather than allowing disruptive quoting and trading activity to occur for several years.

Through this proposal, the Exchange does not intend to modify the definitions of spoofing and layering that have generally been used by exchanges and other regulators in connection with actions like those cited above. The Exchange believes that the pattern of disruptive and allegedly manipulative quoting and trading activity was widespread across multiple exchanges, FINRA, and other SROs identified clear patterns of behavior in 2007 and 2008 in the equities markets.[13] The Exchange believes that this proposal will provide the Exchange with the necessary means to enforce against such behavior in an expedited manner while providing Members with the necessary due process. The Exchange believes that its proposal is consistent with the Act because it provides the Exchange with the ability 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 from such ongoing behavior.

Further, the Exchange believes that adopting a rule applicable to market participants is consistent with the Act because it provides the Exchange with the ability 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 from such ongoing behavior.

Further, the Exchange believes that adopting a rule applicable to market participants is consistent with the Act because the Exchange believes that this type of behavior should be prohibited for all Members. The type of product should not be the determining factor, rather the behavior which challenges the market structure is the primary concern for the Exchange. While this behavior may not be as prevalent on the options market today, the Exchange does not believe that the possibility of such behavior in the future would not have the same market impact and thereby warrant an expedited process.

The Exchange further believes that the proposal is consistent with Section 6(b)(7) of the Act,[14] which requires that the rules of an exchange ''provide a fair procedure for the disciplining of members and persons associated with members . . . and the prohibition or limitation by the exchange of any person with respect to access to services offered by the exchange or a member thereof.'' Finally, the Exchange also believes the proposal is consistent with Sections 6(d)(1) and 6(d)(2) of the Act,[15] which require that the rules of an exchange with respect to a disciplinary proceeding or proceeding that would limit or prohibit access to or membership in the exchange require the exchange to: Provide adequate and specific notice of the charges brought against a member or person associated with a member, provide an opportunity to defend against such charges, keep a record, and provide details regarding the findings and applicable sanctions in the event a determination to impose a disciplinary sanction is made. The Exchange believes that each of these requirements is addressed by the notice and due process provisions included within Rule 1018. Importantly, as noted above, the Exchange will use the authority only in clear and egregious cases when necessary to protect investors, other Members and the Exchange, and in such cases, the Respondent will be afforded due process in connection with the suspension proceedings.

Further, the Exchange believes that adopting a rule applicable to options is consistent with the Act because the Exchange believes that this type of behavior should be prohibited for all Members. The type of product should not be the determining factor, rather the behavior which challenges the market structure is the primary concern for the Exchange. While this behavior may not be as prevalent on the options market today, the Exchange does not believe that the possibility of such behavior in the future would not have the same market impact and thereby warrant an expedited process.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. To the contrary, the Exchange believes that each self-regulatory organization should be empowered to regulate trading occurring on its market consistent with the Act and without regard to competitive issues. The Exchange is requesting authority to take appropriate action if necessary for the protection of investors, other Members and the Exchange. The Exchange also believes that it is important for all exchanges to be able to take similar action to enforce their rules against manipulative conduct thereby leaving no exchange prey to such conduct.

The Exchange does not believe that the proposed rule change imposes an undue burden on competition, rather this process will provide the Exchange with the necessary means to enforce against violations of manipulative quoting and trading activity in an expedited manner, while providing Members with the necessary due process. The Exchange's proposal would treat all Members in a uniform manner with respect to the type of disciplinary action that would be taken for violations of manipulative quoting and trading activity.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days after the date of the filing, or such shorter time as the Commission may designate, it has become effective pursuant to 19(b)(3)(A) of the Act [16] and Rule 19b–4(f)(6) [17] 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

[12] *See supra* note 4 and 5.

[13] *See* Section 3 herein, the Purpose section, for examples of conduct referred to herein.

[14] 15 U.S.C. 78f(b)(7).

[15] 15 U.S.C. 78f(d)(1) and 78f(d)(2).

[16] 15 U.S.C. 78s(b)(3)(A).

[17] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

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–2016–40 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–2016–40. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly.

All submissions should refer to File Number SR–MIAX–2016–40 and should be submitted on or before November 25, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[18]

Brent J. Fields,

Secretary.

[FR Doc. 2016–26514 Filed 11–2–16; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–79184; File No. SR–BatsEDGX–2016–58]

Self-Regulatory Organizations; Bats EDGX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend EDGX Rule 21.12, Clearing Member Give Up

October 28, 2016.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on October 19, 2016, Bats EDGX Exchange, Inc. (the ''Exchange'' or ''EDGX'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of the Substance of the Proposed Rule Change

The Exchange filed a proposal to amend Rule 21.12 in order to codify the requirement that for each transaction in which the User[3] participates, the User must give up the name of the Clearing Member[4] through which the transaction will be cleared (''give up'').

The text of the proposed rule change is available at the Exchange's Web site at *www.batstrading.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange is proposing to amend Rule 21.12 (Clearing Member Give Up) to expand upon the procedure related to the ''give up'' of a Clearing Member by Exchange Users. The Exchange believes that this proposal would result in the fair and reasonable use of resources by both the Exchange and the User. In addition, the proposed change would align the Exchange with competing options exchanges that have adopted rules consistent with this proposal.[5]

Background

Under current Exchange rules, Users entering transactions on the Exchange must either be a Clearing Member or must establish a clearing arrangement with a Clearing Member, and must have a Letter of Guarantee issued by a Clearing Member. In addition, under current Rule 21.12, a User must give up the name of the Clearing Member through which each transaction will be cleared. Every Clearing Member accepts financial responsibility for all EGDX Options transactions made by the guaranteed User pursuant to Rule 22.8(b) (Terms of Letter of Guarantee). The Exchange believes the proposed amendment will result in a more structured and coherent streamlined give up process.

[18] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] A User is defined as ''any Options member or Sponsored Participant who is authorized to obtain access to the System pursuant to Rule 11.3 (Access).'' *See* Exchange Rule 16.1(a)(63).

[4] A Clearing Member is defined as ''an Options Member that is self-clearing or an Options Member that clears EDGX Options Transactions for other Members of EDGX Options.'' *See* Exchange Rule 16.1(a)(15). An Option Member is defined as ''a firm, or organization that is registered with the Exchange pursuant to Chapter XVII of these Rules for purposes of participating in options trading on EDGX Options as an 'Options Order Entry Firm' or 'Options Market Maker.'" *See* Exchange Rule 16.1(a)(38).

[5] *See* Securities Exchange Act Release Nos. 75642 (August 7, 2015), 80 FR 48594 (August 13, 2015) (SR–NYSEMKT–2015–55) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change Amending Rule 961 To Establish Exchange Rules Governing the Give Up of a Clearing Member by Users and Conforming Changes to Rules 960 and 954NY); 72668 (July 24, 2014), 79 FR 44229 (July 30, 2014) (SR–CBOE–2014–048) (Order Approving Proposed Rule Change Relating to the ''Give Up'' Process, the Process by which a Trading Permit Holder ''Gives Up'' or Selects and Indicates the Clearing Trading Permit Holder Responsible for the clearance of an Exchange transaction).

Designated Give Ups and Guarantors

The Exchange proposes to amend Rule 21.12 by replacing the current rule text with details regarding the give up procedure for a User executing transactions on the Exchange. As amended, Rule 21.12 would provide that a User may only give up a Designated Give Up or its Guarantor, as those roles would be defined in the Rule.

Specifically, amended Rule 21.12(b)(1) would define the term Designated Give Up as any Clearing Member that a User (other than a Market Maker[6]) identifies to the Exchange, in writing, as a Clearing Member the User requests the ability to give up. To designate a Designated Give Up, a User must submit written notification to the Exchange, in a form and manner prescribed by the Exchange (''Notification Form''). A copy of the proposed Notification Form is included with this filing in Exhibit 3. Similarly, should a User no longer want the ability to give up a particular Designated Give Up, the User would have to submit written notification to the Exchange, in a form and manner prescribed by the Exchange.

The Exchange notes that, as proposed, a User may designate any Clearing Member as a Designated Give Up, and there would be no maximum number of Designated Give Ups that a User can identify. The Exchange would notify a Clearing Member, in writing and as soon as practicable, of each User that has identified it as a Designated Give Up. The Exchange, however, would not accept any instructions, and would not give effect to any previous instructions, from a Clearing Member not to permit a User to designate the Clearing Member as a Designated Give Up. Further, the Exchange notes that there is no subjective evaluation of a User's list of proposed Designated Give Ups by the Exchange. Rather, the Exchange proposes to process each list as submitted and ensure that the Clearing Members identified as Designated Give Ups are in fact current Clearing Members, as well as confirm that the Notification Forms are complete and accurate, with emphasis on the accuracy of the Options Clearing Corporation (''OCC'') numbers listed for each Clearing Member.

As amended, Rule 21.12(b)(2) would define the term Guarantor as a Clearing Member that has issued a Letter of Guarantee for the executing User, pursuant to the Rules of the Exchange[7] that are in effect at the time of the execution of the applicable trade. An executing User may give up its Guarantor without such Guarantor being a Designated Give Up. The Exchange's Rule 22.8 provides that a Letter of Guarantee is required to be issued and filed by each Clearing Member through which a User clears transactions. Accordingly, a Market Maker would only be enabled to give up a Guarantor that had executed a Letter of Guarantee on its behalf pursuant to Rule 22.8. Thus, Market Makers would not identify any Designated Give Ups. As noted above, amended Rule 21.12 would provide that a User may give up only (i) the name of a Clearing Member that has previously been identified and processed by the Exchange as a Designated Give Up for that User, if not a Market Maker; or (ii) its Guarantor.[8] This proposed requirement would be enforced by the Exchange's trading systems. Specifically, the Exchange has configured its trading systems to only accept orders from a User that identifies a Designated Give Up or Guarantor for that User, and would reject any order entered by a User that designates a give up that is not at the time a Designated Give Up or a Guarantor of the User.[9] The Exchange notes that it would notify a User in writing when an identified Designated Give Up becomes effective (*i.e.,* when a Clearing Member that has been identified by the User as a Designated Give Up, has been enabled by the Exchange's trading systems to be given up). A Guarantor for a User, by virtue of having an effective Letter of Guarantee on file with the Exchange, would be enabled to be given up for that User without any further action by the User. The Exchange notes that this configuration (*i.e.,* the trading systems accepting only orders that identify a Designated Give Up or a Guarantor) is intended to help reduce keypunch errors (errors involving erroneous data entry), and prevent the User from mistakenly giving up the name of a Clearing Member that it does not have the ability to give up a trade.

Acceptance of a Trade

The Exchange proposes in amended Rule 21.12(e) (Acceptance of a Trade) that a Designated Give Up and a Guarantor may, in certain circumstances, determine not to accept a trade on which its name was given up. If a Designated Give Up or a Guarantor determines not to accept a trade, the proposed Rule would provide that it may reject the trade in accordance with the procedures described more fully below under amended Rule 21.12(f) (Procedures to Reject a Trade). As proposed, a Designated Give Up may determine to not accept a trade on which its name was given up so long as it believes in good faith that it has a valid reason not to accept the trade and follows the procedures to reject a trade in proposed Rule 21.12(f).[10] The Exchange also proposes to provide that a Guarantor may opt to not accept and thereby reject, a non-Market Maker trade on which its name was given up, provided that the following steps are completed: (i) Another Clearing Member agrees to be the give up on the trade (''New Clearing Member''); (ii) the New Clearing Member has notified both the Exchange and executing User in writing of its intent to accept the trade; and (iii) the procedures in proposed Rule 21.12(f) are followed. In addition, the give up must be changed to the New Clearing Member that has agreed to accept the trade in accordance with the procedures in Rule 21.12(f). A Guarantor may not reject a trade given up by a Market Maker. The Exchange notes that only a Designated Give Up or Guarantor whose name was initially given up on a trade is permitted to reject the trade, subject to the conditions noted above. The New Clearing Member or Guarantor that becomes the give up on a rejected trade may not also reject the trade.[11]

Procedures To Reject a Trade

The Exchange proposes to include in amended Rule 21.12 procedures that must be followed and completed in order for a Designated Give Up or Guarantor to reject a trade. Specifically, a Designated Give Up can only change the give up to (1) another Clearing Member that has agreed to be the give up on the subject trade, provided the New Clearing Member has notified the Exchange and the executing User in writing of its intent to accept the trade in the form and manner prescribed by

[6] For purposes of this rule, Market Maker refers to Options Members acting in the capacity of Market Maker and includes all Exchange Market Maker capacities *e.g.,* Primary Market Makers. As explained below, Market Makers give up Guarantors that have executed a Letter of Guarantee on behalf of the Marker Maker, pursuant to Rule 22.8.

[7] *See* Exchange Rule 22.8 (Letters of Guarantee).

[8] As described below, amended Rule 21.12 (f) provides that a Designated Give Up or Guarantor may, under certain circumstances, reject a trade on which it is given up and another Clearing Member may agree to accept the subject trade.

[9] *See id.*

[10] An example of a valid reason to reject a trade may be that the Designated Give Up does not have a customer for that particular trade.

[11] A New Clearing Member cannot later reject the trade. Requiring the New Clearing Member to provide notice to the Exchange of its intent to accept the trade and prohibiting the New Clearing Member from later rejecting the trade would provide finality to the trade and ensure that the trade is not repeatedly reassigned from one Clearing Member to another.

the Exchange; or (2) a Guarantor for the executing User, provided the Designated Give Up has notified the Guarantor in writing that it is changing the give up on the trade to the Guarantor.[12] Further, as proposed, a Guarantor can only reject a non-Market Maker trade [13] for which its name was the initial give up by a User and change the give up to another Clearing Member that has agreed to be the give up on the subject trade, provided the New Clearing Member has notified the Exchange and the executing User in writing of its intent to accept the trade (by filling out a Give-Up Change Form for Accepting Clearing Member, as described below). A Guarantor that becomes the give up on a trade as a result of the Designated Give Up rejecting the trade is prohibited from not accepting or rejecting the trade. This prohibition would provide finality to the trade and ensure that the trade is not repeatedly reassigned from one Clearing Member to another.

As proposed, a Guarantor may only reject a non-Market Maker trade for which its name was the initial give up by a User if another Clearing Member has agreed to be the give up on the trade and has notified the Exchange and executing User in writing of its intent to accept the trade. If a Guarantor of a User decides to reject a trade on the trade date, it must follow the same procedures to change the give up as would be followed by a Designated Give Up. The ability to make any changes, either by the Designated Give Up or Guarantor, to the give up pursuant to this procedure would end at the Trade Date Cutoff Time, as defined below. Finally, once the give up on a trade has been changed, the Designated Give Up or Guarantor making the change must immediately thereafter notify in writing the Exchange, the parties to the trade and the Clearing Member given up of the change.

Rejection on Trade Date

As proposed, a trade may only be rejected on (i) the trade date or (ii) the business day following the trade date (''T+1'') (an exception would be transactions in expiring options series on the last trading day prior to expiration, which may not be rejected on T+1). If, on the trade date, a Designated Give Up decides to reject a trade, or another Clearing Member agrees to be the give up on a trade for which a Guarantor's name was given up, the Exchange proposes that the rejecting Designated Give Up or Guarantor must notify, as soon as possible in writing, the executing User or its designated agent, and attempt to resolve the disputed give up. This requirement puts the executing User on notice that the give up on the trade may be changed and provides the executing User and Designated Give Up or Guarantor an opportunity to resolve the dispute. The Exchange notes that a Designated Give Up or Guarantor may request from the Exchange the contact information of the executing User or its designated agent for any trade it intends to reject. Following notification to the executing User on the trade date, a Designated Give Up or Guarantor may request the ability from the Exchange to change the give up on the trade, in a form and manner prescribed by the Exchange (''Give-Up Change Form''). A copy of the proposed Give-Up Change Form is included with this filing in Exhibit 3. Provided that the Exchange is able to process the request prior to the trade input cutoff time established by the OCC (or the applicable later time if the Exchange receives and is able to process a request to extend its time of final trade submission to the OCC) (''Trade Date Cutoff Time''), the Exchange would provide the Designated Give Up or Guarantor the ability to make the change to the give up on the trade to either (1) another Clearing Member or, as applicable, (2) the executing User's Guarantor.

Rejection on T+1

The Exchange acknowledges that some clearing firms may not reconcile their trades until after the Trade Date Cutoff Time. A clearing firm, therefore, may not realize that a valid reason exists to not accept a particular trade until after the close of the trading day or until the following morning. Accordingly, the Exchange proposes to establish a procedure for a Designated Give Up or Guarantor of a User that is not a Market Maker to reject a trade on the following trade day (''T+1'').[14] The Exchange notes that a separate procedure must be established for T+1 changes because to effectively change the give up on a trade on T+1 an offsetting reversal must occur—as opposed to merely identifying a different Clearing Member on the trade. Consistent with amended Rule 21.12(f), a Designated Give Up or Guarantor [15] that wishes to reject a trade on T+1 would have to notify the executing User in writing, and attempt to resolve the dispute. In addition, a Designated Give Up or Guarantor may contact the Exchange and request the ability to reject the trade on T+1. Provided that the Exchange receives the request prior to 12:00 p.m. Eastern Standard Time on T+1 (''T+1 Cutoff Time''), the Exchange would provide the Designated Give Up or Guarantor the ability to enter trade records into the Exchange's systems that would effect a transfer of the trade to another Clearing Member. As noted above, if a New Clearing Member agrees to the give up on a trade, it would be required to inform the Exchange of its acceptance via the Give-Up Change Form for Accepting Clearing Members. A Guarantor that becomes the new give up on T+1 would not need to notify the Exchange of its intent to accept the trade, nor would it need to submit any notification or form.

The Designated Give Up however, would be required to provide written notice to the Guarantor that it will be making this change on T+1. The Exchange notes that the ability for either a Designated Give Up or Guarantor to make these changes would end at the T+1 Cutoff Time, and would provide finality and certainty as to which Clearing Member will be the give up on the subject trade. In addition, once any change to the give up has been made, the Designated Give Up or Guarantor making the change would be required to immediately thereafter notify, in writing, the Exchange, the parties to the trade and the Clearing Member given up, of the change. As discussed above, the Exchange proposes to allow Users that are not Market Makers to identify any Clearing Member as a Designated Give Up. The Exchange's proposal does not permit a Clearing Member to provide the Exchange instructions to prohibit a particular User from giving up the Clearing Member's name. This limitation prevents the Exchange from being placed in the position of arbiter among the Clearing Member, the User and the customer. The Exchange recognizes, however, that Users should not be given the ability to give up any Clearing Member without also providing a method of recourse to those Clearing Members which, for the prescribed

[12] The Guarantor would not need to notify the Exchange of its intent to accept the trade.

[13] A Guarantor of a User that is a Market Maker may not reject a trade for which its name was given up in relation to such Market Maker.

[14] The Exchange proposes that no changes to the give up on trades in expiring options series that take place on the last trading day prior to their expiration may take place on T+1. Rather, a Designated Give Up or Guarantor may only reject these transactions on the trade date until the Trade Date Cutoff Time in accordance with the trade date procedures described above.

[15] The Exchange again notes that, as proposed, only a Guarantor whose name was initially given up is permitted to reject a trade (*i.e.,* a Guarantor cannot reject a trade on T+1 for which it has become the give up as a result of a Designated Give Up not accepting the trade).

reasons discussed above,[16] should not be obligated to clear certain trades for which they are given up. Accordingly, the Exchange is proposing to provide Designated Give Ups and Guarantors the ability to reject a trade, provided each has a good faith basis for doing so. Ultimately, however, the trade must clear with a clearing firm and there must be finality to the trade. The Exchange believes that the executing User's Guarantor, absent a Clearing Member that agrees to accept the trade, should become the give up on any trade which a Designated Give Up determines to reject in accordance with these proposed rule provisions, because the Guarantor, by virtue of having issued a Letter of Guarantee, has already accepted financial responsibility for all Exchange transactions made by the executing User. The Exchange, however, does not want to prevent a Clearing Member that agrees to accept the trade from being able to do so, and accordingly, the Exchange also provides that a New Clearing Member may become the give up on a trade in accordance with the procedure discussed above.

Other Give Up Changes

The Exchange also proposes in Rule 21.12(g) three scenarios in which a give up on a transaction may be changed without Exchange involvement. First, if an executing User has the ability through an Exchange system to do so, it could change the give up on a trade to another Designated Give Up or its Guarantor. The Exchange notes that Users often make these changes when, for example, there is a keypunch error. The ability of the executing User to make any such change would end at the Trade Date Cutoff Time.[17] Next, the modified rule would provide that, if a Designated Give Up has the ability to do so, it may change the give up on a transaction for which it was given up to (i) another Clearing Member affiliated with the Designated Give Up or (ii) a Clearing Member for which the Designated Give Up is a back office agent. The ability to make such a change would end at the Trade Date Cutoff Time. The procedures to reject a trade, as set forth in proposed Rule 21.12(f) and described above, would not apply in these instances. The Exchange notes that often Clearing Members themselves have the ability to change a give up on a trade for which it was given up to another Clearing Member affiliate or Clearing Member for which the Designated Give Up is a back office agent. Therefore, Exchange involvement in these instances is not necessary. In addition, the proposed rule provides that if both a Designated Give Up or Guarantor and a Clearing Member have the ability through an Exchange system to do so, the Designated Give Up or Guarantor and Clearing Member may each enter trade records into the Exchange's systems on T+1 that would effect a transfer of the trade in a non-expired option series from that Designated Give Up to that Clearing Member. Likewise, if a Guarantor of a User trade (that is not a Market Maker trade) and a Clearing Member have the ability through an Exchange system to do so, the Guarantor and Clearing Member may each enter trade records into the Exchange's systems on T+1 that would effect a transfer of the trade in a non-expired option series from that Guarantor to that Clearing Member. The Designated Give Up or Guarantor could not make any such change after the T+1 Cutoff Time. The Exchange notes that a Designated Give Up or Guarantor must notify, in writing, the Exchange and all the parties to the trade, of any such change made pursuant to this provision. This notification alerts the parties and the Exchange that a change to the give up has been made. Finally, the Designated Give Up or Guarantor would be responsible for monitoring the trade and ensuring that the other Clearing Member has entered its side of the transaction timely and correctly. If either a Designated Give Up (or Guarantor) or Clearing Member cannot themselves enter trade records into the Exchange's systems to effect a transfer of the trade from one to the other, the Designated Give Up (or Guarantor) may request the ability from the Exchange to enter both sides of the transaction in accordance with amended Rule 21.12(g)(3).

Responsibility

The Exchange proposes Rule 21.12(h) to state that a Clearing Member would be financially responsible for all trades for which it is the give up at the Applicable Cutoff Time (for purposes of the proposed rule, the ''Applicable Cutoff Time'' shall refer to the T+1 Cutoff Time for non-expiring option series and to the Trade Date Cutoff Time for expiring option series). The Exchange notes, however, that nothing in the proposed rule shall preclude a different party from being responsible for the trade outside of the Rules of the Exchange pursuant to OCC Rules, any agreement between the applicable parties, other applicable rules and regulations, arbitration, court proceedings or otherwise.[18] Moreover, in processing a request to provide a Designated Give Up the ability to change a give up on a trade, the Exchange would not consider or validate whether the Designated Give Up has satisfied the requirements of this Rule in relation to having a good faith belief that it has a valid reason not to accept a trade or having notified the executing User and attempted to resolve the disputed give up prior to changing the give up. Rather, upon request, the Exchange would always provide a Designated Give Up or Guarantor the ability to change the give up or to reject a trade pursuant to the proposed Rule so long as the Designated Give Up or Guarantor, and New Clearing Member, if applicable, have provided a completed set of give up Change Forms within the prescribed time period. The Exchange notes that given the inherent time constraints in making a change to a give up on a transaction, the Exchange would not be able to adequately consider the above-mentioned requirements and make a determination within the prescribed period of time. Rather, the Exchange would examine trades for which a give up was changed pursuant to subparagraphs (e) and (f) after the fact to ensure compliance with the requirements set forth in amended Rule 21.12. Particularly, the Exchange notes that the give up Change Forms that Designated Give Ups, Guarantors and New Clearing Members must submit would help to ensure that the Exchange obtains, in a uniform format, the information that it needs to monitor and regulate this Rule and these give up changes in particular. This information, for example, would better allow the Exchange to determine whether the Designated Give Up had a valid reason to reject the trade, as well as assist the Exchange in cross checking and confirming the accuracy of the statements made by the Designated Give Up or Guarantor with its conduct (*e.g.,* check that the New Clearing Member identified in the give up Change Form was the Clearing Member that actually was identified on the trade as the give up). Additionally, the proposed Rule does not preclude these factors from being considered in a different forum (*e.g.,* court or arbitration), nor does it preclude any Clearing Member that

[16] *See supra* note 12.

[17] After that time, the User would no longer have the ability to make this type of change, as the trade will have been submitted to OCC.

[18] *See* proposed Interpretation and Policy .01 to Rule 21.12 (''Nothing herein will be deemed to preclude the clearance of Exchange transactions by a non-User pursuant to the By-Laws of the Options Clearing Corporation so long as a Clearing Member who is a User is also designated as having responsibility under these Rules for the clearance of such transactions.'').

violates any provision of amended Rule 21.12 from being subject to disciplinary actions in accordance with Exchange rules.

Implementation

The Exchange proposes to announce the implementation of the proposed rule change effective November 1, 2016.

2. Statutory Basis

The Exchange believes that the proposed change is consistent with Section 6(b) of the Act,[19] in general, and furthers the objectives of Section 6(b)(5),[20] in particular, in that it is designed to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to, and perfect the mechanism of a free and open market and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[21] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

First, detailing in the rules how Users would give up Clearing Members and how Clearing Members may reject a trade provides transparency and operational certainty. The Exchange believes additional transparency removes a potential impediment to, and would contribute to perfecting, the mechanism of a free and open market and a national market system, and, in general, would protect investors and the public interest. Moreover, the Exchange notes that amended Rule 21.12 requires Users to adhere to a standardized process to ensure a seamless administration of the Rule. For example, all notifications relating to a change in give up must be made in writing. The Exchange believes that these requirements will aid the Exchange's efforts to monitor and regulate Users and Clearing Members as they relate to amended Rule 21.12 and changes in give ups, thereby protecting investors and the public interest.

Additionally, the Exchange believes that its proposed give up rule strikes the right balance between the various views and interests of market participants. For example, although the rule allows Users that are not Market Makers to identify any Clearing Member as a Designated Give Up, it also provides that Clearing Members would receive notice of any User that has designated it as a Designated Give Up and provides for a procedure for a Clearing Member to reject a trade in accordance with the Rules, both on the trade date and T+1.

The Exchange recognizes that Users should not be given the ability to give up any Clearing Members without also providing a method of recourse to those Clearing Members which, for the prescribed reasons discussed above, should not be obligated to clear certain trades for which they are given up. The Exchange believes that providing Designated Give Ups the ability to reject a trade within a reasonable amount of time is consistent with the Act as, pursuant to the proposed rule, the Designated Give Ups may only do so if they have a valid reason and because ultimately, the trade can always be assigned to the Guarantor of the executing User if a New Clearing Member is not willing to step in and accept the trade. A trade must clear with a Clearing Member and there must be finality to the trade. Absent a New Clearing Member that agrees to accept the trade, the Exchange believes that the executing User's Guarantor, should become the give up on any trade that a Designated Give Up determines to reject, in accordance with the proposed rule provisions, because the Guarantor, by virtue of having issued a Letter of Guarantee, has already accepted financial responsibility for all Exchange transactions made by the executing User. Therefore, amended Rule 21.12 is reasonable and provides certainty that a Clearing Member will always be responsible for a trade, which protects investors and the public interest. The Exchange notes that amended Rule 21.12 does not preclude a different party than the party given up from being responsible for the trade outside of the Rules of the Exchange, pursuant to OCC Rules, any agreement between the applicable parties, other applicable rules and regulations, arbitration, court proceedings or otherwise. The Exchange acknowledges that it would not consider whether the Designated Give Up has satisfied the requirements of this Rule in relation to having a good faith belief that it has a valid reason not to accept a trade or having notified the executing User and attempting to resolve the disputed give up prior to changing the give up, due to inherent time restrictions. However, the Exchange believes investor and public interest are still protected as the Exchange will still examine trades for which a give up was changed pursuant to subparagraphs (e) and (f) of amended Rule 21.12 after the fact to ensure compliance with the requirements set forth in the Rule. As noted above, the implementation of a standardized process and the requirement that certain notices be in writing would assist monitoring any give up changes and enforcing amended Rule 21.12.

Further, the Exchange notes that the Rule does not preclude these factors from being considered in a different forum (*e.g.,* court or arbitration) nor does it preclude any User or Clearing Member that violates any provision of amended Rule 21.12 from being subject to disciplinary actions by the Exchange.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that this proposed rule change would impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The Exchange does not believe that the proposed rule change would impose an unnecessary burden on competition because it would apply equally to all similarly situated Users. The Exchange also notes that, should the proposed changes make the Exchange more attractive for trading, market participants trading on other exchanges can always elect to become Users on the Exchange to take advantage of the trading opportunities. Thus, the proposed rule change will promote competition because it will allow the Exchange to offer its Users similar features as are available at other exchanges and thus further compete with other exchanges for order flow.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange has not solicited, and does not intend to solicit, comments on this proposed rule change. The Exchange has not received any written comments from members or other interested parties.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section

[19] 15 U.S.C. 78f(b).

[20] 15 U.S.C. 78f(b)(5).

[21] *Id.*

19(b)(3)(A)(iii) of the Act[22] and subparagraph (f)(6) of Rule 19b–4 thereunder.[23] A proposed rule change filed under Rule 19b–4(f)(6) normally does not become operative prior to 30 days after the date of filing.[24] Rule 19b–4(f)(6)(iii), however, permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest.[25]

The Exchange has requested that the Commission waive the 30-day operative delay. The Commission believes that the proposed rule change is designed to ensure that there will always be a Clearing Member that will be financially responsible for a trade, which should promote greater operational certainty and facilitate cooperation and coordination with persons engaged in clearing transactions. In addition, the Commission believes that the proposal addresses the role of different parties involved in the give up process in a balanced manner and is designed to provide a fair and reasonable methodology for the give up process. The Commission notes that it has considered a substantially similar proposed rule change filed by the Chicago Board Options Exchange, Incorporated (''CBOE'') and NYSE MKT LLC (''NYSE MKT''), which it approved after a notice and comment period.[26] This proposed rule change does not raise any new or novel issues from those considered in the CBOE and NYSE MKT proposals. Based on the foregoing, the Commission believes that it is consistent with the protection of investors and the public interest to waive the 30-day operative date so that the proposal may take effect upon filing.[27]

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) of the Act[28] 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–BatsEDGX–2016–58 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–BatsEDGX–2016–58. 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–BatsEDGX–2016–58, and should be submitted on or before November 25, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[29]

Brent J. Fields,

Secretary.

[FR Doc. 2016–26512 Filed 11–2–16; 8:45 am]

BILLING CODE 8011–01–P

[22] 15 U.S.C. 78s(b)(3)(a)(iii).

[23] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[24] 17 CFR 240.19b–4(f)(6)(iii).

[25] *Id.*

[26] *See supra* note 5.

[27] For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[28] 15 U.S.C. 78s(b)(2)(B).

[29] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–79183; File No. SR–BatsBZX–2016–30]

Self-Regulatory Organizations; Bats BZX Exchange, Inc.; Notice of Filing of Amendment No. 1 to a Proposed Rule Change to BZX Rule 14.11(e)(4), Commodity-Based Trust Shares, To List and Trade Winklevoss Bitcoin Shares Issued by the Winklevoss Bitcoin Trust

October 28, 2016.

On June 30, 2016, Bats BZX Exchange, Inc. (''BZX'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] a proposed rule change to list and trade Winklevoss Bitcoin Shares issued by the Winklevoss Bitcoin Trust under BZX Rule 14.11(e)(4). The proposed rule change was published for comment in the **Federal Register** on July 14, 2016.[3]

On August 23, 2016, pursuant to Section 19(b)(2) of the Act,[4] the Commission designated a longer period within which to approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to disapprove the proposed rule change.[5] On October 12, 2016, the Commission instituted proceedings under Section 19(b)(2)(B) of the Act[6] to determine whether to approve or disapprove the proposed rule change.[7] The Commission has

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 78262 (Jul. 8, 2016), 81 FR 45554.

[4] 15 U.S.C. 78s(b)(2).

[5] *See* Securities Exchange Act Release No. 78653, 81 FR 59256 (Aug. 29, 2016). The Commission designated October 12, 2016, as the date by which it should approve, disapprove, or institute proceedings to determine whether to disapprove the proposed rule change.

[6] 15 U.S.C. 78s(b)(2)(B).

[7] *See* Securities Exchange Act Release No. 79084, 81 FR 71778 (Oct. 18, 2016) (''Order Instituting Proceedings''). Specifically, the Commission instituted proceedings to allow for additional analysis of the proposed rule change's consistency

received 17 comment letters on the proposed rule change.[8]

On October 20, 2016, the Exchange filed Amendment No. 1 to the proposed rule change, as described in Items I and II below, which Items have been prepared by the Exchange.[9] The Commission is publishing this notice to solicit comments on Amendment No. 1 to the proposed rule change from interested persons.[10]

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange filed a proposal to list and trade Winklevoss Bitcoin Shares (the ''Shares'') issued by the Winklevoss Bitcoin Trust (the ''Trust'') under BZX Rule 14.11(e)(4), Commodity-Based Trust Shares.

The text of the proposed rule change is available at the Exchange's Web site at *www.batstrading.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV [sic] 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

This Amendment No. 1 to SR–BatsBZX–2016–30 amends and replaces in its entirety the proposal as originally submitted on June 30, 2016. The Exchange submits this Amendment No. 1 in order to clarify certain points and add additional details about the Trust.

The Exchange proposes to list and trade the Shares under BZX Rule 14.11(e)(4),[11] which governs the listing and trading of Commodity-Based Trust Shares on the Exchange.[12] The Shares will be offered by the Trust, which was established as a Delaware statutory trust on December 30, 2014. The Trust will not be registered as an investment company under the Investment Company Act of 1940[13] and is not required to register under such act. The Trust will not be a commodity pool for purposes of the Commodity Exchange Act (''CEA'').[14] The Shares of the Trust will be registered with the Commission by means of the Trust's registration statement on Form S–1 (the ''Registration Statement'') under the Securities Act of 1933 (the ''Securities Act''). The most recent amendment to the Registration Statement was filed on October 18, 2016 and the Registration Statement will be effective as of the date of any offer and sale pursuant to the Registration Statement.[15]

Service Providers of the Trust

Digital Asset Services, LLC, formerly Math-Based Asset Services, LLC, will be the sponsor of the Trust (the ''Sponsor'').[16] The Trust's administrator (the ''Administrator'')[17] and transfer agent (the ''Transfer Agent'') will be State Street Bank and Trust Company (''State Street'').[18] State Street is a trust company organized under the laws of the Commonwealth of Massachusetts. Gemini Trust Company, LLC will be the custodian of the Trust (the ''Custodian'').[19] The Custodian is a New

with Section 6(b)(5) of the Act, which requires, among other things, that the rules of a national securities exchange be ''designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade,'' and ''to protect investors and the public interest.'' *See id.,* 81 FR at 71781.

[8] *See* Letters from Robert D. Miller, VP Technical Services, RKL eSolutions (July 11, 2016); Jorge Stolfi, Full Professor, Institute of Computing UNICAMP (July 13, 2016); Guillaume Lethuillier (July 26, 2016); Michael B. Casey (July 31, 2016); Erik A. Aronesty, Sr. Software Engineer, Bloomberg LP (Aug. 2, 2016); Dan Anderson (Aug. 27, 2016); Robert Miller (Oct. 12, 2016); Lysle Shaw-McMinn, O.D. (Oct. 13, 2016); Nils Neidhardt (Oct. 13, 2016); Dana K. Barish (2 letters; Oct. 13, 2016); Xin Lu (Oct. 13, 2016); Rodger Delehanty CFA (Oct. 14, 2016); Dylan (Oct. 14, 2016); Dana K. Barish (Oct. 14, 2016); and Dana K. Barish (2 letters; Oct. 15, 2016). All comments on the proposed rule change are available on the Commission's Web site at: *https://www.sec.gov/comments/sr-batsbzx-2016-30/batsbzx201630.shtml.*

[9] Among other things, Amendment No. 1 (1) identifies State Street Bank and Trust Company as the Trust's Administrator and Transfer Agent (*see* Section II.A.1, *infra* (discussion in subheading ''Service Providers of the Trust'')); (2) clarifies that the price of bitcoin is measured by the clearing price of a two-sided auction which occurs every day at 4:00 p.m. Eastern Time on the Gemini exchange (*see* Section II.A.1, *infra* (discussion in subheading ''Service Providers of the Trust'')) and notes various conflicts of interest that may arise among the Sponsor and its affiliates, including the Custodian and the Gemini Exchange, on one hand, and the Trust and its Shareholders, on the other hand (*see* Section II.A.1, *infra* (discussion in subheading ''Overview of the Bitcoin Industry and Market'' under ''The Gemini Exchange'')); (3) provides additional information on the Bitcoin exchange ''lit'' market (*see* Section II.A.1, *infra* (discussion in subheading ''Bitcoin Market'' under ''Bitcoin Exchange Lit Market'')); (4) provides additional information on security, the Custodian's Cold Storage System, the Custodian's insurance arrangements and proof of control auditing (*see* Section II.A.1, *infra* (discussion in subheading ''Description of the Trust and Shares'' under ''Proprietary Cold Storage System'')); and (5) changes the value of creation/redemption Baskets from 50,000 Shares to 10,000 Shares (*see* Section II.A.1, *infra* (discussion in subheading ''Creation and Redemption of Shares'')).

[10] In formulating comments, commenters should consider whether this Amendment No. 1 addresses any of the questions posed in the Order to Institute Proceeding mentioned in footnote 5, *supra.*

[11] The Commission approved BZX Rule 14.11(e)(4) in Securities Exchange Act Release No. 65225 (August 30, 2011), 76 FR 55148 (September 6, 2011) (SR–BATS–2011–018).

[12] All statements and representations made in this filing regarding (a) the description of the portfolio, (b) limitations on portfolio holdings or reference assets, or (c) the applicability of Exchange rules and surveillance procedures shall constitute continued listing requirements for listing the Shares on the Exchange.

[13] 15 U.S.C. 80a–1.

[14] 17 U.S.C. 1.

[15] *See* Registration Statement on Form S–1, dated October 18, 2016 (File No. 333–189752). The descriptions of the Trust and the Shares contained herein are based, in part, on information in the Registration Statement.

[16] The Sponsor is a Delaware limited liability company formed on May 9, 2013, and is wholly owned by Winklevoss Capital Fund LLC. Under the Delaware Limited Liability Company Act and the governing documents of the Sponsor, Winklevoss Capital Fund LLC, the sole member of the Sponsor, is not responsible for the debts, obligations and liabilities of the Sponsor solely by reason of being the sole member of the Sponsor. The Sponsor will be the exclusive licensee, within the field of use of operation of an exchange-traded product (''ETP''), of certain patent-pending intellectual property regarding the operation of the Trust. Winklevoss IP LLC, an affiliate of the Sponsor, is the owner of and is licensing to the Sponsor such intellectual property for use by the Trust and the Custodian and other service providers in the operation of the Trust. The Sponsor arranged for the creation of the Trust and will arrange for the registration of the Shares for their public offering in the United States and their listing on the Exchange.

[17] Pursuant to the Administration Agreement between the Administrator and the Trust, the Administrator provides fund administration and fund accounting services with regard to the Trust, including calculating the Trust's net asset value and NAV, maintaining the Trust's records, and providing such other administrative services as are specified in the Administration Agreement.

[18] The Transfer Agent serves as the transfer agent in accordance with the provisions of the Transfer Agency and Services Agreement. The Transfer Agent, among other things, provides transfer agent services with respect to the creation and redemption of Baskets by Authorized Participants.

[19] The Custodian is an affiliate of the Sponsor and a New York State-chartered limited liability trust company that operates under the direct supervision and regulatory authority of the New York State Department of Financial Services (''NYSDFS''). Although the Trust's bitcoin is not stored in a physical sense, all transactions involving the Trust's bitcoin are recorded on the Bitcoin Network's Blockchain and associated with a public Bitcoin address. The Trust's public Bitcoin addresses are established by the Custodian using its proprietary hardware and software security technology (''Cold Storage System''), which holds the Trust's bitcoin and permits the Trust to move its bitcoin. Access and control of those Bitcoin addresses, and the bitcoin associated with them, is restricted through the public-private key pair relating to each Bitcoin address. The Custodian is

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York State-chartered limited liability trust company that operates under the direct supervision and regulatory authority of the NYSDFS. The Custodian is a fiduciary and must meet the capitalization, compliance, anti-money laundering, consumer protection and cyber security requirements as set forth by the NYSDFS. The Custodian will hold the bitcoin deposited with the Custodian on behalf of the Trust in a segregated custody account (the ''Trust Custody Account'') in accordance with the Trust Custody Agreement. The Custodian will use its proprietary and patent-pending offline (*i.e.,* air-gapped) Cold Storage System to store the Trust's bitcoin, as further described herein. Delaware Trust Company acts as the trustee of the Trust (the ''Trustee'').[20]

The Trust will only hold bitcoin, which is a digital commodity [21] that is not issued by any government, bank or central organization. Bitcoin is a digital asset (''Digital Asset'') based on the decentralized, open source protocol of the peer-to-peer Bitcoin computer network (the ''Bitcoin Network'' or ''Bitcoin'') [22] that hosts the decentralized public transaction ledger, known as the ''Blockchain,'' on which all bitcoin is recorded. The Bitcoin Network software source code includes the protocols that govern the creation of bitcoin and the cryptographic system that secures and verifies Bitcoin transactions.

The Trust is expected to issue and redeem Shares from time to time only in one or more whole Baskets. Certain Authorized Participants are the only persons that may place orders to create or redeem Baskets. Authorized Participants or their affiliated market makers are expected to have the facility to participate directly on one or more Bitcoin Exchanges (as defined below).

The investment objective of the Trust is for the Shares to track the price of bitcoin, as measured by the clearing price of a two-sided auction which occurs every day at 4:00 p.m. Eastern Time on the Gemini exchange (''Gemini Exchange'') (the ''Gemini Exchange Auction Price''), each day the Exchange is open for trading (each a ''Business Day''), less the Trust's liabilities (which include accrued but unpaid fees and expenses). The Gemini Exchange is a Digital Asset exchange owned and operated by the Custodian and is an affiliate of the Sponsor. The Gemini Exchange does not receive any compensation from the Trust or the Sponsor for providing the Gemini Exchange Auction Price. The Sponsor believes that, for many investors, the Shares will represent a cost-effective and convenient means of gaining investment exposure to bitcoin similar to a direct investment in bitcoin. The Shares represent units of fractional undivided beneficial interest in and ownership of the Trust and are expected to be traded under the ticker symbol ''COIN.''

Overview of the Bitcoin Industry and Market

Bitcoin is a Digital Asset that is issued by, and transmitted through, the decentralized, open source protocol of the peer-to-peer Bitcoin Network. The Bitcoin Network hosts the decentralized public transaction ledger, known as the Blockchain, on which all bitcoin is recorded. No single entity owns or operates the Bitcoin Network, the infrastructure of which is collectively maintained by a decentralized user base. Bitcoin can be used to pay for goods and services or can be converted to fiat currencies, such as the U.S. Dollar, at rates determined on bitcoin exchanges (each a ''Bitcoin Exchange'') [23] or in individual end-user-to-end-user transactions under a barter system. See ''Uses of Bitcoin—Bitcoin Exchange Market,'' below.

Bitcoin is ''stored'' or reflected on the Blockchain, which is a digital file stored in a decentralized manner on the computers of each Bitcoin Network user. The Bitcoin Network software source code includes the protocols that govern the creation of bitcoin and the cryptographic system that secures and verifies Bitcoin transactions. The Blockchain is a canonical record of every bitcoin, every Bitcoin transaction (including the creation or ''mining'' of new bitcoin) and every Bitcoin address associated with a quantity of bitcoin. The Bitcoin Network and Bitcoin Network software programs can interpret the Blockchain to determine the exact bitcoin balance, if any, of any public Bitcoin address listed in the Blockchain as having taken part in a transaction on the Bitcoin Network. The Bitcoin Network utilizes the Blockchain to evidence the existence of bitcoin in any public Bitcoin address. A Bitcoin private key controls the transfer or ''spending'' of bitcoin from its associated public Bitcoin address. A Bitcoin ''wallet'' is a collection of private keys and their associated public Bitcoin addresses.

The Blockchain is comprised of a digital file, downloaded and stored, in whole or in part, on all Bitcoin Network users' software programs. The file includes all blocks that have been solved by miners and is updated to include new blocks as they are solved. See ''Bitcoin Mining & Creation of New Bitcoin.'' As each newly solved block refers back to and ''connects'' with the immediately prior solved block, the addition of a new block adds to the Blockchain in a manner similar to a new link being added to a chain. Each new block records outstanding Bitcoin transactions, and outstanding transactions are settled and validated through such recording. The Blockchain represents a complete, transparent and unbroken history of all transactions of the Bitcoin Network. Each Bitcoin transaction is broadcast to the Bitcoin Network and recorded in the Blockchain.

The Bitcoin Network is decentralized and does not rely on either governmental authorities or financial institutions to create, transmit or

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responsible for the safekeeping of the private keys used to access and transfer the Trust's bitcoin. The Custodian also facilitates the transfer of bitcoin in accordance with the Administrator's instructions pursuant to the terms of the Administration Agreement. Pursuant to the terms of the Trust Agreement and the trust custody agreement (''Trust Custody Agreement''), the Custodian will store all of the Trust's bitcoin on a segregated basis in its unique Bitcoin addresses with balances that can be directly verified on the Blockchain. It will provide the Trust's public Bitcoin addresses to the Administrator. Pursuant to the provisions of the Trust Custody Agreement, the Custodian will use the Cold Storage System to manage and safeguard a system utilizing numerous Bitcoin addresses that are kept offline either (i) in computers that are not directly connected to or accessible from the internet or (ii) through the storage of the public and private keys relating to such Bitcoin addresses only in ''cold storage.''

[20] The Trustee, a Delaware trust company, acts as the trustee of the Trust for the purpose of creating a Delaware statutory trust in accordance with the Delaware Statutory Trust Act (''DSTA''). The duties of the Trustee will be limited to (i) accepting legal process served on the Trust in the State of Delaware and (ii) the execution of any certificates required to be filed with the Delaware Secretary of State which the Delaware Trustee is required to execute under the DSTA. To the extent that, at law or in equity, the Trustee has duties (including fiduciary duties) and liabilities relating thereto to the Trust or the Sponsor, such duties and liabilities will be replaced by the duties and liabilities of the Trustee expressly set forth in the Trust Agreement.

[21] Bitcoin is a commodity as defined in Section 1a(9) of the Commodity Exchange Act. 7 U.S.C. 1a(9). *See In re* Coinflip, Inc., No. 15–29 (CFTC Sept. 17, 2015), *available at: http://www.cftc.gov/ucm/groups/public/@lrenforcementactions/documents/legalpleading/enfcoinfliprorder09172015.pdf* (''Coinflip'').

[22] By common convention, Bitcoin with a capital ''B'' typically refers to the Bitcoin Network as a whole, whereas bitcoin with a lowercase ''b'' refers to the Digital Asset of the Bitcoin Network, including the Trust's bitcoin. This naming convention is used throughout this document.

[23] The Gemini Exchange is a United States-based Bitcoin Exchange that began trading on October 8, 2015. It is currently operational in 35 states, Washington, DC, Canada, Hong Kong, Singapore, and the U.K., and allows trading between bitcoin, U.S. Dollars, and other Digital Assets.

determine the value of bitcoin. Rather, bitcoin is created and allocated by the Bitcoin Network protocol through a ''mining'' process subject to a strict, well-known issuance schedule. The value of bitcoin is determined by the supply of and demand for bitcoin in the ''Bitcoin Exchange Market'' [24] (and in private end-user-to-end-user transactions), as well as the number of merchants that accept them. As Bitcoin transactions can be broadcast to the Bitcoin Network by any user's Bitcoin Network software and bitcoin can be transferred without the involvement of intermediaries or third parties, there are currently little or no transaction fees in direct peer-to-peer transactions on the Bitcoin Network. Third party service providers such as Bitcoin Exchanges and third-party Bitcoin payment processing services may charge fees for processing transactions and for converting, or facilitating the conversion of, bitcoin to or from fiat currency.

The Bitcoin Network was initially contemplated in a white paper that also described bitcoin and the operating software to govern the Bitcoin Network. The white paper was purportedly authored by Satoshi Nakamoto; however, no individual with that name has been reliably identified as Bitcoin's creator, and the general consensus is that the name is a pseudonym for the actual inventor or inventors. The first bitcoin was created in 2009 after Nakamoto released the Bitcoin Network source code (the software and protocol that created and launched the Bitcoin Network). Since its introduction, the Bitcoin Network has been under active development by a group of contributors currently headed by Wladimir J. van der Laan who was appointed project maintainer in April 2014 by Gavin Andresen (who was previously appointed maintainer by Satoshi Nakamoto in 2010). As an open source project, Bitcoin is not represented by an official organization or authority.

Overview of the Bitcoin Network's Operations

In order to own, transfer or use bitcoin, a person generally must have internet access to connect to the Bitcoin Network. Bitcoin transactions may be made directly between end-users without the need for a third-party intermediary, although there are entities that provide third-party intermediary services. To prevent the possibility of double-spending bitcoin, a user must notify the Bitcoin Network of the transaction by broadcasting the transaction data to its network peers. The Bitcoin Network provides confirmation against double-spending by memorializing every transaction in the Blockchain, which is publicly accessible and transparent. This memorialization and verification against double-spending is accomplished through the Bitcoin Network mining process, which adds ''blocks'' of data, including recent transaction information, to the Blockchain. See ''Cryptographic Security Used in the Bitcoin Network—Double-Spending and the Bitcoin Network Confirmation System,'' below.

Brief Description of Bitcoin Transfers

Prior to engaging in Bitcoin transactions, a user generally must first install on its computer or mobile device a Bitcoin Network software program that will allow the user to generate a private and public key pair associated with a Bitcoin address (analogous to a Bitcoin account). The Bitcoin Network software program and the Bitcoin address also enable the user to connect to the Bitcoin Network and engage in the transfer of bitcoin with other users. The computer of a user that downloads a version of the Bitcoin Network software program will become a ''node'' on the Bitcoin Network that assists in validating and relaying transactions from other users. See ''Cryptographic Security Used in the Bitcoin Network—Double-Spending and the Bitcoin Network Confirmation System,'' below. Alternatively, a user may retain a third party to create a Bitcoin address, or collection of Bitcoin addresses known as a digital wallet to be used for the same purpose. There is no limit on the number of Bitcoin addresses a user can have, and each such Bitcoin address consists of a ''public key'' and a ''private key,'' which are mathematically related. See ''Cryptographic Security Used in the Bitcoin Network—Public and Private Keys,'' below.

In a Bitcoin transaction, the bitcoin recipient must provide its public Bitcoin address, which serves as a routing number for the recipient on the Blockchain, to the party initiating the transfer. This activity is analogous to a recipient providing a routing address in wire instructions to the payor so that cash may be wired to the recipient's account. The recipient, however, does not make public or provide to the sender its related private key. The payor, or ''spending'' party, does reveal its public key in signing and verifying its spending transaction to the Blockchain.

Neither the recipient nor the sender reveal their public Bitcoin addresses' private key in a transaction, because the private key authorizes access to, and transfer of, the funds in that Bitcoin address to other users. Therefore, if a user loses his private key, the user permanently loses access to the bitcoin contained in the associated Bitcoin address. Likewise, bitcoin is irretrievably lost if the private key associated with them is deleted and no backup has been made. When sending bitcoin, a user's Bitcoin Network software program must ''sign'' the transaction with the associated private key. The resulting digitally signed transaction is sent by the user's Bitcoin Network software program to the Bitcoin Network to allow transaction confirmation. The digital signature serves as validation that the transaction has been authorized by the holder of the Bitcoin addresses' private key. This signature process is typically automated by software that has access to the public and private keys.

Summary of a Bitcoin Transaction

In a Bitcoin transaction between two parties, the following circumstances must be in place: (i) The party seeking to send bitcoin must have a public Bitcoin address and the Bitcoin Network must recognize that public Bitcoin address as having sufficient bitcoin for the spending transaction; (ii) the receiving party must have a public Bitcoin address; and (iii) the spending party must have internet access with which to send its spending transaction.

Next, the receiving party must provide the spending party with its public Bitcoin address, an identifying series of twenty-seven (27) to thirty-four (34) alphanumeric characters that represents the routing number on the Bitcoin Network and allow the Blockchain to record the sending of bitcoin to that public Bitcoin address. The receiving party can provide this address to the spending party in alphanumeric format or an encoded format such as a Quick Response Code (commonly known as a ''QR Code''), which may be scanned by a smartphone or other device to quickly transmit the information.

After the provision of a recipient's public Bitcoin address, the spending party must enter the address into its Bitcoin Network software program along with the number of bitcoin to be sent. The number of bitcoin to be sent will typically be agreed upon between the two parties based on a set number of bitcoin or an agreed upon conversion of the value of fiat currency to bitcoin. Most Bitcoin Network software

[24] For purposes of this filing, the term Bitcoin Exchange Market means the global Bitcoin Exchange Market for the trading of bitcoin, which consists of transactions on various electronic Bitcoin Exchanges.

programs also allow, and often suggest, the payment of a transaction fee (also known as a miner's fee). Transaction fees are not required to be included by many Bitcoin Network software programs, but, when they are included, they are paid by the spending party on top of the specified quantity of bitcoin being sent in the transaction. Transaction fees, if any, are typically a fractional number of bitcoin (*e.g.,* 0.005 or 0.0005 bitcoin) and are automatically transferred by the Bitcoin Network to the Bitcoin Network miner that solves and adds the block recording the spending transaction on the Blockchain.

After the entry of the Bitcoin address, the number of bitcoin to be sent and the transaction fees, if any, to be paid, the spending party will transmit the spending transaction. The transmission of the spending transaction results in the creation of a data packet by the spending party's Bitcoin Network software program, which data packet includes data showing (i) the destination public Bitcoin address, (ii) the number of bitcoin being sent, (iii) the transaction fees, if any, and (iv) the spending party's digital signature, verifying the authenticity of the transaction. The data packet also includes references called ''inputs'' and ''outputs,'' which are used by the Blockchain to identify the source of the bitcoin being spent and record the flow of bitcoin from one transaction to the next transaction in which the bitcoin is spent. The digital signature exposes the spending party's public Bitcoin address and public key to the Bitcoin Network, though, for the receiving party, only its public Bitcoin address is revealed. The spending party's Bitcoin Network software will transmit the data packet onto the decentralized Bitcoin Network, resulting in the propagation of the information among the software programs of Bitcoin users across the Bitcoin Network for eventual inclusion in the Blockchain. Typically, the data will spread to a vast majority of Bitcoin Network miners within the course of less than a minute.

As discussed in greater detail below in ''Bitcoin Mining & Creation of New Bitcoin,'' Bitcoin Network miners record transactions when they solve for and add blocks of information to the Blockchain. When a miner solves for a block, it creates that block, which includes data relating to (i) the solution to the block, (ii) a reference to the prior block in the Blockchain to which the new block is being added, and (iii) transactions that have occurred but have not yet been added to the Blockchain. The miner becomes aware of outstanding, unrecorded transactions through the data packet transmission and propagation discussed above. Typically, Bitcoin transactions will be recorded in the next chronological block if the spending party has an internet connection and at least one (1) minute has passed between the transaction's data packet transmission and the solution of the next block. If a transaction is not recorded in the next chronological block, it is usually recorded in the next block thereafter.

Upon the addition of a block included in the Blockchain, the Bitcoin Network software program of both the spending party and the receiving party will show confirmation of the transaction on the Blockchain and reflect an adjustment to the bitcoin balance in each party's public Bitcoin address, completing the bitcoin transaction. Typically, Bitcoin Network software programs will automatically check for and display additional confirmations of six or more blocks in the Blockchain. See ''Cryptographic Security Used in the Bitcoin Network—Double-Spending and the Bitcoin Network Confirmation System.''

Cryptographic Security Used in the Bitcoin Network

Public and Private Keys

The Bitcoin Network uses sophisticated cryptography to maintain the integrity of the Blockchain ledger. Transactions are digitally signed by their senders. Before adding a transaction to a block, miners will verify both that the sender has not already spent the bitcoin being sent and that the digital signature information in the transaction is valid. Besides the requirement of containing only valid transactions (as described in the preceding sentence), blocks are validated by means of properties of their cryptographic hashes. By extension, blocks in the Blockchain can be validated by verifying that each block contains the cryptographic hash of the prior block. The cryptographic algorithms and cryptographic parameters, including key sizes, used by the Bitcoin Network provide adequate security for the foreseeable future.

Double-Spending and the Bitcoin Network Confirmation System

To ensure the integrity of Bitcoin transactions from the recipient's side (*i.e.,* to prevent double-spending by a spending party), every Bitcoin transaction is broadcast to the Bitcoin Network and recorded in the Blockchain through the ''mining'' process, which timestamps the transaction and memorializes the change in the ownership of bitcoin transferred. See ''Bitcoin Mining & Creation of New Bitcoin,'' below. Adding a block to the Blockchain requires Bitcoin Network miners to exert significant computational effort. Requiring this ''proof of work'' prevents a malicious actor from either adding fraudulent blocks to generate bitcoin (*i.e.,* counterfeit bitcoin) or overwriting existing valid blocks to reverse prior transactions.

A Bitcoin transaction between two parties is recorded in the Blockchain in a block only if that block is accepted as valid by a majority of the nodes on the Bitcoin Network. Validation of a block is achieved by confirming the cryptographic hash value included in the block's solution and by the block's addition to the longest confirmed Blockchain on the Bitcoin Network. For a transaction, inclusion in a block on the Blockchain constitutes a ''confirmation'' of a Bitcoin transaction. As each block contains a reference to the immediately preceding block, additional blocks appended to and incorporated into the Blockchain constitute additional confirmations of the transactions in such prior blocks, and a transaction included in a block for the first time is confirmed once against double-spending. The layered confirmation process makes changing historical blocks (and reversing transactions) exponentially more difficult the further back one goes in the Blockchain. Bitcoin Exchanges and users can set their own threshold as to how many confirmations they require until funds from the transferor are considered valid.

To undo past transactions in a block recorded on the Blockchain, a malicious actor would have to exert tremendous hashrate in resolving each block in the Blockchain starting with and after the target block and broadcasting all such blocks to the Bitcoin Network. The Bitcoin Network is generally programmed to consider the longest Blockchain containing solved blocks to be the most accurate Blockchain. In order to undo multiple layers of confirmation and alter the Blockchain, a malicious actor must resolve all of the old blocks sought to be regenerated and be able to continuously add new blocks to the Blockchain at a speed that would have to outpace that of all of the other miners on the Bitcoin Network, who would be continuously solving for and adding new blocks to the Blockchain. Given the size and speed of the Bitcoin Network, it is generally agreed that the cost of amassing such computational power exceeds the profit to be obtained

by double-spending or attempting to fabricate prior blocks.

If a malicious actor is able to amass ten (10) percent of the Bitcoin Network's aggregate hashrate, there is estimated to be a 0.1 percent chance that it would be able to overcome six (6) confirmations. Therefore, given the difficulty in amassing such hashrate, six (6) confirmations is an often-cited standard for the validity of transactions. The Trust has adopted a policy whereby a transaction will be deemed confirmed upon this industry standard of six (6) confirmations (the ''Confirmation Protocol''). As one (1) block is added to the Blockchain approximately every six (6) to twelve (12) minutes, a Bitcoin transaction will be, on average, confirmed using the Confirmation Protocol beyond a reasonable doubt in approximately one (1) hour. Merchants selling high-value goods and services, as well as Bitcoin Exchanges and many experienced users, are believed to generally use the six (6) confirmations standard. This confirmation system, however, does not mean that merchants must always wait for multiple confirmations for transactions involving low-value goods and services. As discussed below, the value of a successful double-spending attack involving a low-value transaction may, and perhaps likely will, be significantly less than the cost involved in arranging and executing such double-spending attacks. Furthermore, merchants engaging in low-value transactions may then view the reward of quicker transaction settlements with limited or no Blockchain confirmation as greater than the related risk of not waiting for six (6) confirmations with respect to low-value transactions at points of sale. Conversely, for high-value transactions that are not time sensitive, additional settlement security can be provided by waiting for more than six (6) confirmations.

Bitcoin Mining & Creation of New Bitcoin

Mining Process

The process by which bitcoin is ''mined'' results in new blocks being added to the Blockchain and new bitcoin being issued to the miners. Bitcoin Network miners engage in a set of prescribed complex mathematical calculations in order to add a block to the Blockchain and thereby confirm Bitcoin transactions included in that block's data. Miners that are successful in adding a block to the Blockchain are automatically awarded a fixed number of bitcoin for their effort. This reward system is the method by which new bitcoin enter into circulation to the public and is accomplished in the added block through the notation of the new bitcoin creation and their allocation to the successful miner's public Bitcoin address. To begin mining, a user can download and run Bitcoin Network mining software, which, like regular Bitcoin Network software programs, turns the user's computer into a ''node'' on the Bitcoin Network that validates blocks. See ''Overview of the Bitcoin Network's Operations,'' above.

All Bitcoin transactions are recorded in blocks added to the Blockchain. Each block contains (i) the details of some or all of the most recent transactions that are not memorialized in prior blocks, (ii) a reference to the most recent prior block, and (iii) a record of the award of bitcoin to the miner who added the new block. In order to add blocks to the Blockchain, a miner must map an input data set (*i.e.,* a reference to the immediately preceding block in the Blockchain, plus a block of the most recent Bitcoin Network transactions and an arbitrary number called a ''nonce'') to a desired output data set of predetermined length (''hash value'') using a cryptographic hash algorithm. To ''solve'' or ''calculate'' a block, a miner must repeat this computation with a different nonce until the miner generates a hash of a block's header that has a value less than or equal to the current target set by the Bitcoin Network. Each unique block can only be solved and added to the Blockchain by one (1) miner; therefore, all individual miners and mining pools on the Bitcoin Network are engaged in a competitive process and are incentivized to increase their computing power to improve their likelihood of solving for new blocks.

The cryptographic hash function that a miner uses is one-way only and is, in effect, irreversible: hash values are easy to generate from input data (*i.e.,* valid recent network transactions, Blockchain and nonce), but neither a miner nor participant is able to determine the original input data solely from the hash value. As a result, generating a new valid block with a header value less than or equal to the target prescribed by the Bitcoin Network is initially difficult for a miner, yet other nodes can easily confirm a proposed block by running the hash function just once with the proposed nonce and other input data. A miner's proposed block is added to the Blockchain once a majority of the nodes on the Bitcoin Network confirms the miner's work, and the miner that solved such block receives the reward of a fixed number of bitcoin (plus any transaction fees paid by spenders of transactions that are recorded in the block). Therefore, ''hashing'' is akin to a mathematical lottery, and miners that have devices with greater processing power (*i.e.,* the ability to make more hash calculations per second) are more likely to be successful miners because they can generate more hashes or ''entries'' into that lottery.

As more miners join the Bitcoin Network and its aggregate hashrate increases, the Bitcoin Network automatically adjusts the complexity of the block-solving equation in an effort to set distribution such that newly-created blocks will be added to the Blockchain, on average, approximately every ten (10) minutes. Hashrate is added to the Bitcoin Network at irregular rates that have grown with increasing speed since early 2013, though the rate of additional mining power slowed steadily through 2014, until the computational speed of the network temporarily and marginally declined during December 2014.

The rapid growth of the computational power of the Bitcoin Network means that blocks are typically solved faster than the Bitcoin protocol's target of, on average, approximately every ten (10) minutes. Although the difficulty of the mining process is adjusted on a periodic basis, after 2,016 blocks have been added to the Blockchain since the last adjustment, the average solution time for a block has been approximately 8 minutes for the one hundred and eighty (180) days prior to and including October 1, 2016.

Incentives for Mining

Miners dedicate substantial resources to mining. Given the increasing difficulty of the target established by the Bitcoin Network, current miners must invest in expensive mining devices with adequate processing power to hash at a competitive rate. The first mining devices were standard home computers; however, mining computers are currently designed solely for mining purposes. Such devices include application specific integrated circuit (''ASIC'') machines built by specialized companies such as BitFury. Miners also incur substantial electricity costs in order to continuously power and cool their devices while solving for a new block. Although variables such as the rate and cost of electricity are estimated, as of September 1, 2013, Blockchain Luxembourg S.A. estimated that the average 24-hour electricity cost of all mining on the Bitcoin Network to be more than $1.5 million. In late 2013, Blockchain Luxembourg S.A. ceased publishing estimated electric consumption on the Bitcoin Network, in part due to uncertainty in estimating

electrical usage as newer, more energy efficient mining hardware became prevalent. As of October 2016, over the past year, two (2) years, and three (3) years, the aggregate hashrate of the Bitcoin Network has increased approximately 4-fold, 8-fold and 1,500-fold, respectively, due in part to the development of more energy efficient ASIC mining chips and, during the second half of 2013, the substantial increase in the price of bitcoin. Additionally, it can be estimated that the scale of total computing resources devoted to mining on the Bitcoin Network is commensurate with the total rewards, which was approximately $1.2 million U.S. dollars per day as of October 1, 2016.

The Bitcoin Network is designed in such a way that the reward for adding new blocks to the Blockchain decreases over time and the production (and reward) of bitcoin will eventually cease. Once such reward ceases, it is expected that miners will demand compensation in the form of transaction fees to ensure that there is adequate incentive for them to continue mining. The amount of transaction fees will be based upon the need to provide sufficient revenue to incentivize miners, counterbalanced by the need to retain sufficient Bitcoin Network users (and transactions) to make mining profitable.

Though not free from doubt, Bitcoin industry participants have expressed a belief that transaction fees would be enforced through (i) mining operators collectively refusing to record transactions that do not include a payment of a transaction fee or (ii) the updating of Bitcoin Network software to require a minimum transaction fee payment. Indeed, most miners already have a policy regarding transactions fees, albeit the minimum fees are currently low under such policies. Under a regime whereby large miners require fees to record transactions, a transaction where the spending party did not include a payment of transaction fees would not be recorded on the Blockchain until a miner who does not require transaction fees solves for a new block (thereby recording all outstanding transaction records for which it has received data). If popular Bitcoin Network software were to require a minimum transaction fee, users of such programs would be required to include such fees; however, because of the open-source nature of the Bitcoin Network, there may be no way to require that all software instances include minimum transaction fees for spending transactions. Alternatively, a future Bitcoin Network software update could simply build a small transaction fee payment into all spending transactions (*e.g.,* by deducting a fractional number of bitcoin from all transactions on the Bitcoin Network as transaction fees).

The Bitcoin Network protocol already includes transaction fee rules and the mechanics for awarding transaction fees to the miners that solve for blocks in which the fees are recorded; however, users currently may opt not to pay transaction fees (depending on the Bitcoin Network software they use) and miners may choose not to enforce the transaction fee rules since, at present, the bitcoin rewards are far more substantial than transaction fees. As of October 2016, transaction fees accounted for an average of 3.55 percent of miners' total revenue based upon publicly available information, though the percentage of revenue represented by transaction fees is not static and fluctuates based on the number of transactions for which sending users include transaction fees, the levels of those transaction fees and the number of transactions a miner includes in its solved blocks. Typically, transactions do not have difficulty being recorded if transaction fees are not included.

Mining Pools

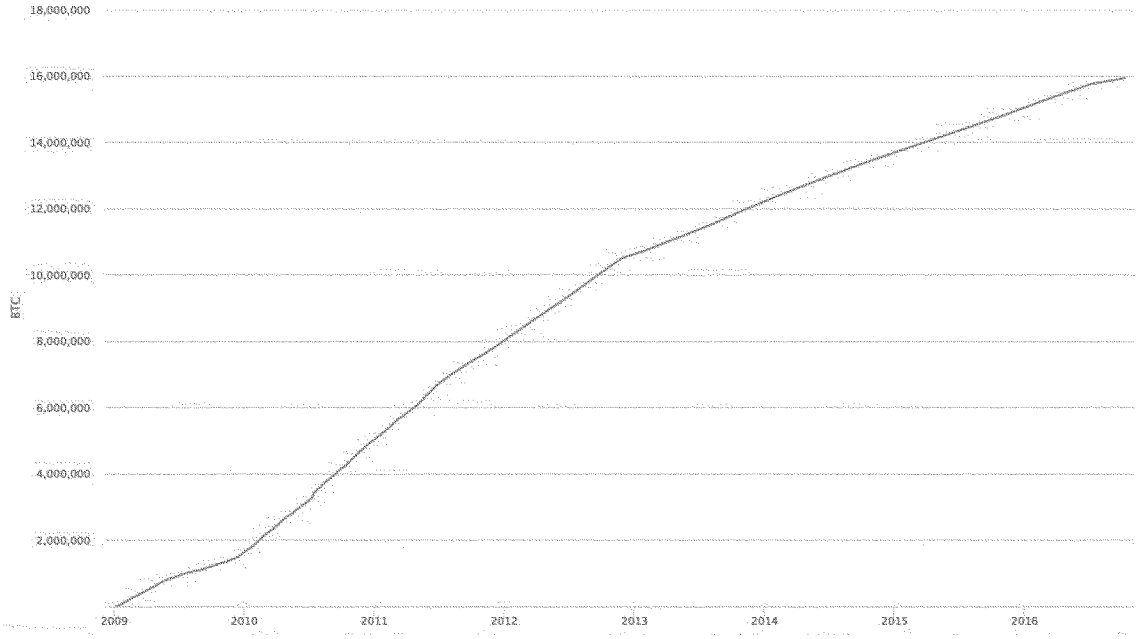
A miner's daily expected reward is proportional to their contribution to the Bitcoin Network's aggregate hashrate. Given the limited number of blocks produced per day and the statistically uncertain nature of finding blocks, a small miner acting alone would experience very high variance in block rewards. Because of this fact most miners join mining pools wherein multiple miners act cohesively and share any rewards.

According to Blockchain Luxembourg S.A., as of October 1, 2016, the largest three (3) known mining pools were AntPool, F2Pool and BTCC Pool, which, when aggregated, represented approximately forty-five (45) percent of the aggregate hashrate of the Bitcoin Network (as calculated by determining the percentage of blocks mined by each such pool over the prior four (4) days). Also according to Blockchain Luxembourg S.A., on such date, the nine (9) largest pools (AntPool, F2Pool, ViaBTC, BitFury, BW.COM, SlushPool, BitFury, BTC.com, and HaoBTC) accounted for approximately eighty-eight (88) percent of the aggregate hashrate of the Bitcoin Network. In late May and early June 2014, reports indicated that a single mining pool approached and, during a twenty-four (24)- to forty-eight (48)-hour period in early June, may have exceeded one-half of the aggregate hashrate of the Bitcoin Network, as measured by the self-reported hashrate of the pool and by measuring the percentage of blocks mined by the pool. As of October 1, 2016, that single mining pool has ceased to exist. As of October 1, 2016, Antpool was determined to be the largest mining pool, having solved for sixteen (16) percent of the blocks discovered during the prior four (4) days.

Mathematically Controlled Supply

The method for creating new bitcoin is mathematically controlled in a manner so that the supply of bitcoin grows at a limited rate pursuant to a pre-set schedule. The number of bitcoin awarded for solving a new block is automatically halved every two hundred and ten thousand (210,000) blocks. Thus, the current fixed reward for solving a new block is twelve and a half (12.5) bitcoin per block; the reward decreased from twenty-five (25) bitcoin per block in July 2016. It is estimated to halve again in about four years. This deliberately controlled rate of bitcoin creation means that the number of bitcoin in existence will never exceed twenty-one (21) million and that bitcoin cannot be devalued through excessive production unless the Bitcoin Network's source code (and the underlying protocol for bitcoin issuance) is altered. See ''Modifications to the Bitcoin Protocol,'' below. As of October 1, 2016, approximately fifteen million, nine hundred and seven thousand (15,907,000) bitcoin have been mined. It is estimated that more than ninety (90) percent of the twenty-one (21) million bitcoin will have been produced by 2022.

The following chart from Blockchain Luxembourg S.A. indicates the number of bitcoin that have been mined since the Bitcoin Network began operation in January 2009 through October 2016.



Modifications to the Bitcoin Protocol

Bitcoin is an open source project (*i.e.,* a product whose source code is freely available to the public and that utilizes crowdsourcing to identify possible issues, problems and defects) and there is no official developer or group of developers that controls the Bitcoin Network. The Bitcoin Network's development is furthered by a collection of active contributors who can access and propose alterations to the Bitcoin Network source code hosted on GitHub, an online service and forum used to share and develop open source code. Other programmers have access to and can propose changes to the Bitcoin Network source code on GitHub, but some contributors have an elevated level of influence over the process. As a result, these contributors are responsible for quasi-official releases of updates and other changes to the Bitcoin Network's source code. Users and miners can accept any changes made to the Bitcoin Network (including those proposed by contributors) by downloading the proposed modification of the source code.

A modification of the source code is only effective with respect to the Bitcoin users and miners that download it. Consequently, as a practical matter, a modification to the source code (*e.g.,* a proposal to increase the twenty-one (21) million total limit on bitcoin or to reduce the average confirmation time target from ten (10) minutes per block) only becomes part of the Bitcoin Network if accepted by participants collectively having an effective majority of the aggregate hashrate of the Bitcoin Network. Additionally, an issue may arise in which a modification is overwhelmingly supported by users but miners do not support it, or vice versa. If a modification is accepted only by a percentage of users and miners, a division in the Bitcoin Network will occur such that one (1) network will run the pre-modification source code and the other network will run the modified source code; such a division is known as a ''fork'' in the Bitcoin Network. It should be noted that, although their power to amend the source code is effectively subject to the approval of users and miners, some contributors have substantial influence over the development of the Bitcoin Network and the direction of the Bitcoin community.

Bitcoin Value

Bitcoin Exchange Valuation

The value of bitcoin is determined by the value that various market participants place on bitcoin through their transactions. The most common means of determining the value of a bitcoin is by surveying one or more Bitcoin Exchanges where bitcoin is traded publicly and transparently (*i.e.,* the Bitcoin Exchange Market) or an index tracking prices on the Bitcoin Exchange Market (*e.g.,* the CoinDesk Bitcoin Price Index).

Bitcoin Exchange Public Market Data

On each online Bitcoin Exchange, bitcoin is traded with publicly disclosed valuations for each executed trade, measured by one or more fiat currencies such as the U.S. Dollar, the Euro or the Chinese Yuan. Bitcoin Exchanges typically publish trade data including last price, bid and ask information, and trade volume, among other data. Although each Bitcoin Exchange has its own market price, it is expected that most Bitcoin Exchanges' market prices should be relatively consistent with the Bitcoin Exchange Market average since market participants can choose the Bitcoin Exchange on which to buy or sell bitcoin (*i.e.,* exchange shopping). Arbitrage between the prices on various Bitcoin Exchanges is possible, but varying fees and fiat currency deposit/withdrawal policies and other concerns appear to have, at times, prevented an active arbitrage mechanism among users on some Bitcoin Exchanges. For example, delayed fiat currency withdrawals imposed by Bitcoin Exchanges and the perceived risks associated with such delayed withdrawals have, at times, resulted in trading on such Bitcoin Exchange to be at a premium for certain periods.

Bitcoin Exchange Price Convergence

Price differentials across Bitcoin Exchanges remain; however, such differentials have been decreasing. For example, the daily opening price data for the one hundred and eighty (180) days prior to October 1, 2016 shows that the top three U.S.-based Bitcoin Exchanges (viz. GDAX, Gemini, and itBit) had an absolute price difference less than 1% percent according to publicly available data. Since 2015, prices on U.S.-based Bitcoin Exchanges have generally been converging. In January of 2015, the average range in

prices across all Bitcoin Exchanges was approximately 3.8%; as of October 2016, that figure has dropped to less than 1.0%. This convergence serves to illustrate the fungibility of bitcoin across Bitcoin Exchanges and the ease with which market participants transfer their assets amongst them.

Bitcoin Exchange Market Manipulation

As the Bitcoin Exchange Market has evolved and matured, licensed entrants have emerged, including two (2) New York limited purpose trust companies, markedly changing the once concentrated and non-regulated landscape of the Bitcoin Exchange Market. For example, in the first half of 2013, Mt.Gox accounted for nearly three-quarters of all Bitcoin Exchange Market trading.[25] Any disruption to Mt.Gox trading, such as a distributed denial of service (''DDOS'') attack had a dramatic impact on the bitcoin price and subsequently the Bitcoin Exchange Market as a whole.[26] Since then, the number of constituents in the Bitcoin Exchange Market has considerably increased and no single Bitcoin Exchange represents a systemically critical part or single point of failure of the Bitcoin ecosystem. In addition, the advent of market participants who are chiefly arbitrageurs results in Bitcoin Exchange prices generally converging after dislodgement. Arbitrageurs must have funds distributed across multiple Bitcoin Exchanges in order to take advantage of temporary price dislocations, thereby discouraging the strong concentration of funds on any particular Bitcoin Exchange. As a result, the potential for manipulation on a particular Bitcoin Exchange would require overcoming the liquidity supply of such arbitrageurs who are actively eliminating any cross-market pricing differences.

The Gemini Exchange

The Gemini Exchange, an affiliate of the Sponsor, is a Digital Asset exchange that has a U.S. dollar-denominated bitcoin order book. As a facility of a New York State-chartered limited liability trust company, the Gemini Exchange is one of only two (2) Bitcoin Exchanges in the world that have such a high level of regulatory oversight. The Bitcoin Exchange Market has experienced several significant incidents at unregulated Bitcoin Exchanges and it is widely-believed that much of the self-reported trade volume numbers of unregulated Bitcoin Exchanges are inaccurate (either intentionally or unintentionally). The Gemini Exchange was established in an effort to improve the Bitcoin ecosystem by having a regulated entity where participants could engage in trading bitcoin.

In establishing the Gemini Exchange, Gemini Trust Company, LLC worked closely with the NYSDFS to obtain a limited purpose trust company license. The term ''limited purpose trust company'' refers to entities that are chartered under the bank and trust company provisions of the New York Banking Law. Under New York Banking Law, a ''trust company'' has general powers available to banks and trust companies, as well as powers generally associated with trustees and other fiduciaries.

Apart from general fiduciary powers, the following activities are among those specifically identified in the statute as activities that New York Trust Companies may conduct with respect to their fiduciary accounts, including (i) the power to accept deposits exclusively in a fiduciary capacity, to receive and disburse money, to transfer, register and countersign evidences of indebtedness or other securities, and to act as attorney in fact or agent;[27] and (ii) the power to accept appointment as receiver, trustee, or committee of the property of an estate of any person in insolvency or bankruptcy proceedings.

A ''limited purpose'' trust company must conduct its business and operations subject to the limitations or restrictions as the NYSDFS may prescribe in its sole discretion. In practice, most limited purpose trust companies typically engage in activities such as employee benefit trust, personal trust, corporate trust, transfer agency, securities clearance, investment management, and custodial services. A trust company, including a limited purpose trust company like Gemini Trust Company, LLC, can serve as the custodian of customer funds itself.

Under New York Banking Law, the same general procedures, requirements and criteria for the formation of a full-service bank apply also to the formation of a limited purpose trust company with two (2) exceptions: (i) No requirement to carry FDIC insurance and (ii) a level of capitalization deemed satisfactory to the Superintendent of Financial Services. Once submitted in acceptable form, a limited purpose trust company application receives the same level of scrutiny as other bank and trust company proposals and ultimately requires the approval of the Superintendent of Financial Services. In addition, trust companies are subject to many of the same requirements that apply to a bank operating under a New York State banking charter, including: (i) Capital requirements, (ii) implementation of an anti-money laundering program,[28] (iii) implementation of a cyber security program, and (iv) consumer protection disclosures.[29] Furthermore, as a limited purpose trust company with fiduciary powers under the Banking Law, all activities of a trust company, including all exchange functions, are subject to examination and supervision by the NYSDFS. Gemini Trust Company, LLC complies with the capital requirements under New York State banking law, has implemented the required anti-money laundering program and cybersecurity program and makes the required consumer protection disclosures. As a facility of a regulated entity, the Gemini Exchange is obliged to put the interests of its customers before its own, to provide accurate public market data and

[25] For most of 2013, Mt. Gox (a Japanese exchange operated by Tibanne Co. Ltd.) was the largest online Bitcoin Exchange in the world. Supporting trading of bitcoin using sixteen (16) different fiat currencies, Mt. Gox accounted for nearly three-quarters of all Bitcoin Exchange Market trading during the first half of 2013. On February 25, 2014, Mt. Gox suspended trading on its platform and, three (3) days later, filed for bankruptcy protection in Japanese courts, stating that it had lost approximately eight hundred and fifty thousand (850,000) bitcoin, including approximately seven hundred fifty thousand (750,000) bitcoin belonging to its customers. Mt. Gox subsequently recovered access to approximately two hundred thousand (200,000) of the lost bitcoin. As no full, reliable accounting has been publicly provided, it is difficult to assess whether Mt. Gox's collapse was due to cyber-attacks (including denial of service and hacking incidents reported in 2011 and 2013), mismanagement or fraud, although many market participants believe Mt. Gox's collapse was due to the latter. Following the cessation of trading activity on its platform, Mt. Gox has been in bankruptcy proceedings in Japan and the United States and is in the process of liquidation.

[26] Bitcoin Exchanges may also be vulnerable to security breaches. For example, in August 2016, a security breach at Bitfinex, a large, Hong Kong-based Bitcoin Exchange, resulted in the loss of one hundred twenty thousand (120,000) bitcoin.

[27] N.Y. Banking Law § 100 (McKinney).

[28] In particular, a prospective trust company must establish policies and procedures designed to ensure and monitor compliance with the Bank Secrecy Act (''BSA'') as amended by the USA PATRIOT Act and the anti-money laundering programs of Part 115 of the General Regulations of the Banking Board. A compliance program must include, at a minimum, a system of internal controls to assure ongoing compliance, independent testing for compliance to be conducted by bank personnel or by an outside party, the designation of an individual or individuals responsible for coordinating and monitoring day-to-day compliance, and training for appropriate personnel.

[29] Limited purpose trust companies operating virtual currency exchanges are required to provide disclosures to current and prospective customers (in a form approved by NYSDFS) regarding the risks of its services and products and are also required to disclose to current and prospective customers the terms and conditions for using the trust company's products and services prior to any customer using the product or service.

pricing information and to monitor for and prevent market manipulation.

As part of its supervision under the NYSDFS and New York Banking Law, Gemini Trust Company, LLC must (i) undergo semiannual bank exams, (ii) submit quarterly financial updates to NYSDFS, (iii) submit independent third-party year-end audited financial statements to NYSDFS,[30] (iv) submit semiannual Federal Financial Institutions Examination Council (''FFIEC'') Call Reports [31] to the NYSDFS, and (v) undergo an annual third-party review of its overall security program as implemented by its Chief Security Officer (''CSO'') that may take the form of a Service Organization Controls (''SOC'') Level 2 audit.

The Gemini Exchange is not the only venue on which Authorized Participants can purchase bitcoin for delivery to the Trust, but it may provide a convenient and stable venue given its regulatory oversight and superior liquidity characteristics. While Authorized Participants are not obliged to use the Gemini Exchange to trade their bitcoin, it may prove to be an efficient way to do so.

Conflicts of interest may arise among the Sponsor and its affiliates, including the Custodian and the Gemini Exchange, on the one hand, and the Trust and its Shareholders, on the other hand. As a result of these conflicts, the Sponsor may favor its own interests and the interests of its affiliates over the Trust and its Shareholders. These potential conflicts include, among others, the following:

- The Sponsor has no fiduciary duties to, and is allowed to take into account the interests of parties other than, the Trust and its Shareholders in resolving conflicts of interest;
- The Trust's bitcoin is valued, and the Trust's NAV is calculated, using the Gemini Exchange Auction Price, and the Gemini Exchange Auction Price as provided by the Sponsor will be used by the Administrator to calculate the amount of the Sponsor's Fee due to the Sponsor;
- The Sponsor's relationship with the Gemini Exchange creates an incentive for the Sponsor to sell the bitcoin it collects as its Sponsor's fee for U.S. dollars on the Gemini Exchange, which benefits the Sponsor's affiliates through increased volume on the Gemini Exchange and which may negatively impact the value of the Trust's remaining bitcoin;
- The Sponsor, its affiliates and their officers and employees may own and trade bitcoin and are not prohibited from engaging in other businesses or activities, including those that might be in direct competition with the Trust; and
- The Sponsor decides whether to retain separate counsel, accountants or others to perform services for the Trust.

Although the Trust has taken steps to mitigate these conflicts of interest, including having the Administrator calculate the Trust's NAV and determine the amount of the Sponsor's Fee (based on the publicly-available Gemini Exchange Auction Price, which will be provided to the Administrator by the Sponsor each business day), it may not be possible to entirely eliminate these conflicts of interest.

Gemini Exchange Auction Price

The Trust values its bitcoin using the Gemini Exchange Auction Price on each Business Day. At 4:00 p.m. Eastern Time every day, the Gemini Exchange conducts a two-sided auction which is open to all exchange customers. Similar to the closing auction on the Exchange and other U.S. equities exchanges, the auction process incorporates both auction-only and continuous trading book orders to find a single price at which the most interest is eligible to trade (sometimes called ''Walrasian equilibrium''). Because indicative auction pricing is published publicly throughout the ten (10) minutes prior to the auction, this mechanism allows participants to engage in thorough price discovery while concentrating liquidity and trading volume at a single moment each day. The Gemini Exchange Auction Price is the clearing price of this auction. The Gemini Exchange has been conducting these auctions since September 21, 2016.

The Sponsor believes that the Gemini Exchange Auction Price is representative of the accurate price of bitcoin because of the positive price discovery attributes of the Gemini Exchange marketplace, and because the two-sided auction process was specifically designed to maximize price discovery and liquidity. According to publicly available market data for U.S-based Bitcoin Exchanges as of October 1, 2016 for the prior six months:

- The Gemini Exchange was the third biggest by volume.
- The Gemini Exchange had the second tightest bid/ask spread as a percentage of price.
- The Gemini Exchange had the tightest spread ten (10) bitcoin deep and the second tightest spread one hundred (100) bitcoin deep.
- The Gemini Exchange had the lowest volatility (*i.e.,* smallest standard deviation of daily prices).

In addition, since opening in October 2015 and as of October 1, 2016, pricing on the Gemini Exchange differed from the median price of all U.S.-based Bitcoin Exchanges on Business Days by 0.23% on average and 0.48% at most; that difference dropped to 0.15% on average in the third quarter of 2016.[32]

Since launching on September 21, 2016 and through October 14, 2016, on Business Days, the Gemini Exchange Auction Price has deviated from the Gemini Exchange midpoint price (the midrange of the highest bid and lowest offer prices) by 0.17% on average and 0.71% at most, and it has deviated from the median price of all U.S.-based Bitcoin Exchanges by 0.12% on average and 0.52% at most. On business days between September 21 and October 14, 2016, the volume has averaged more than 1,900 bitcoin (worth $1.2 million notional) representing more than 16% of all U.S.-based Bitcoin Exchange volume during that period. Additionally, the Gemini Exchange's auction market bolstered its share of the U.S.-based Bitcoin Exchange market to almost $1.7 million of notional daily volume for the six-month period ending October 1, 2016, representing almost 32% of such market, since it was first instituted on September 21, 2016. In addition, transactions on the Gemini Exchange appear to be substantially larger than typical daily transaction sizes on other Bitcoin Exchanges. These facts, taken together, suggest that the Gemini Exchange Auction Price is representative and indicative of the larger Bitcoin marketplace, and that it can support the liquidity and volume necessary to maintain an efficient arbitrage mechanism.

As discussed above, the Gemini Exchange is uniquely positioned because of its regulatory status and licensing as a venue on which traditional financial institutions may be comfortable transacting in bitcoin. These institutions provide a vital bridge to the equities markets and other capital markets, serving to enrich price discovery, liquidity, and transparency. The Trust has entered into preliminary conversations with a number of potential Authorized Participants as

[30] Gemini Trust Company, LLC, successfully completed an independent third-party opening day Balance Sheet audit for October 2, 2015 as well as an independent third-party year-end Financial Statements audit for December 31, 2015. No material issues, weaknesses or concerns were raised.

[31] Gemini Trust Company, LLC, successfully completed and filed its first FFIEC Call Report with the NYSDFS on February 1, 2016.

[32] *Id.*

well as market makers, each of which is an experienced participant in the ETP [33] marketplace and is actively engaged in trading ETPs. A number of these potential Authorized Participants, currently trade bitcoin and are already registered participants that trade on the Gemini Exchange. Authorized Participants will not be required to use the Gemini Exchange to trade their bitcoin, and the Gemini Exchange is not the only venue on which Authorized Participants can purchase bitcoin for delivery to the Trust. However, the Gemini Exchange may provide a convenient and stable venue in which to purchase bitcoin, as well as an efficient way to trade bitcoin, given its regulatory oversight and superior liquidity characteristics. See ''Bitcoin Value—The Gemini Exchange'' above.

Bitcoin Market

Global Bitcoin Market

Global trade in bitcoin consists of individual end-user-to-end-user transactions, together with facilitated exchange-based bitcoin trading on ''lit'' markets as well as ''dark pools''. A limited market currently exists for bitcoin-based derivatives. The Trust represents the first Digital Asset ETP. Securitized instruments have been created for other marketplaces, but have encountered limited success due to their lack of transparency and thorough regulatory oversight. Three notable examples are the Grayscale Investment Trust, which trades under the ticker GBTC on OTC Markets (formerly the ''Pink Sheets'') and does not qualify as an exchange-listed product, Bitcoin Tracker One, which trades under the ticker COINXBT on the Stockholm Stock Exchange, and the euro-denominated BitcoinETI Exchange Traded Instrument, which has been approved for admission to the Gibraltar Stock Exchange and will be co-listed on Deutsche Boerse. None of these instruments are held to the same regulatory scrutiny and oversight as a security listed under the Securities Act. Because of the high standards pursued in the creation and listing of the Trust, it will finally provide investors with a reliable and transparent vehicle for access to bitcoin as an asset class.

End-User-to-End-User

The Bitcoin end-user-to-end-user ecosystem operates on a continuous, 24-hour per day basis. This is accomplished through decentralized peer-to-peer transactions between parties on a principal-to-principal basis. All risks and issues of credit are between the parties directly involved in the transaction. Liquidity can change from time to time during the course of a 24-hour trading day. The Bitcoin Network rules that require transaction fees are generally not enforced; therefore transaction costs, if any, are negotiable between the parties and may vary widely, although, where transaction fees are included, they are paid by the spending party in a Bitcoin transaction. These transactions occur remotely through the Internet or in-person through forums such as Satoshi Square (an open-air bitcoin trading market held in New York City) and bulletin boards such as LocalBitcoins. Marketplaces like LocalBitcoins and ICBIT are intended to bring together counterparties trading in bitcoin but do not provide any clearing or intermediary function and may or may not report transaction data such as price and volume.

Bitcoin Exchange ''Lit'' Market

U.S.-based Bitcoin Exchanges traded approximately $20 million of notional value daily throughout the six months ending October 1, 2016. Although it has been operating for only one year, the Gemini Exchange has traded approximately $1.2 million of notional daily volume over the same period, representing nearly 6 percent of the market. Moreover, on business days between September 21 and October 14, 2016, the volume has averaged more than 1,900 bitcoin (worth $1.2 million notional), representing more than 16% of all U.S.-based daily Bitcoin Exchange volume during that period. Additionally, the Gemini Exchange's auction bolstered its share of the U.S.-based Bitcoin Exchange market to almost $1.7 million of notional daily volume for the six-month period ending October 1, 2016, representing almost 32% of such market, since it was first instituted on September 21, 2016. These marketplaces provide significant data with respect to prevailing valuations of bitcoin. Most Bitcoin Exchanges operate through pooled account systems, whereby the users of the Bitcoin Exchange send bitcoin and/or fiat currency to an account of the Bitcoin Exchange, which records user sub-account balances in a ledger entry system. Trades on pooled account exchanges are typically conducted ''off-Blockchain,'' meaning that they are settled by reallocating bitcoin and money to and from users on the balanced ledger of the Bitcoin Exchange. Therefore, a trade on a pooled account exchange will not result in a Bitcoin transaction being transmitted and subsequently recorded on the Blockchain, or of a money transfer going from one bank account to another. For a pooled-account Bitcoin Exchange, Bitcoin transactions and money transfers typically only occur during the withdrawal or deposit of bitcoin or fiat currency by an exchange customer, or if the Bitcoin Exchange needs to shift bitcoin or fiat currency between its pooled accounts for internal purposes. Nevertheless, Bitcoin Exchanges typically publish trade data including last price, bid and ask information, and trade volume, among other data, on their respective Web sites and through application programming interfaces (''APIs'').

As noted above, Gemini Exchange, an affiliate of the Sponsor and the source of the Gemini Exchange Auction Price used by the Trust to calculate its NAV, operates the Web site *www.gemini.com.* Gemini Exchange is owned and operated by Gemini Trust Company, LLC, the Trust's Custodian. As a facility of a New York State-chartered limited liability trust company, Gemini Exchange operates under the direct supervision and regulatory authority of the NYSDFS. The Gemini Trust Company is a fiduciary and must meet the capitalization, compliance, anti-money laundering, consumer protection and cyber security requirements as set forth by the NYSDFS. Gemini Exchange's principal business is to provide an electronic trading platform and associated online presence to allow customers to exchange fiat currency (*e.g.,* U.S. Dollars) for Digital Assets (*e.g.,* bitcoin or ether) and vice versa.

Bitcoin Exchange Market ''Dark Pools'' and OTC Trading

In addition to transparent or ''lit'' online Bitcoin Exchanges with a traditional central limit order book structure, some trading in bitcoin takes place on an on-demand or over-the-counter (''OTC'') basis. Similar to mature securities, there are also private request for quote (RFQ) venues and ''dark pools,'' which are bitcoin trading platforms that do not publicly report limit order book data. Market participants have the ability to execute large block trades in a dark pool without revealing those trades and the related price data to the public Bitcoin Exchange Market; however, any withdrawal from or deposit to a dark pool platform must ultimately be recorded on the Blockchain, as must OTC transactions. Genesis Trading also operates a form of dark pool through a trading desk that buys and sells blocks of bitcoin without publicly reporting trade data. In June 2015, Kraken, a

[33] For purposes of this filing, the term ETP means any product that may be listed on the Exchange pursuant to Rule 14.11.

Bitcoin Exchange, launched a dark pool for bitcoin trades separate from its public central limit order book. Informal dark pools are currently believed to exist, particularly among wholesale buyers of bitcoin and Bitcoin Network mining groups that obtain bitcoin through mining. Such informal dark pools function as a result of the peer-to-peer nature of the Bitcoin Network, which allows direct transactions between any seller and buyer. As the Bitcoin Exchange Market and bitcoin dark pools have a limited history and no publicly available limit order book data, it is difficult to estimate the impact of dark pools on the Bitcoin Exchange Market.

Global Bitcoin Derivatives Markets

Nascent derivatives markets for bitcoin now exist. For example, certain types of options, futures contracts for differences and other derivative instruments are available in certain jurisdictions; however, many of these are not available in the United States and generally are not regulated to the degree that U.S. investors expect derivative instruments to be regulated. The U.S. Commodity Futures Trading Commission (''CFTC'') has approved TeraExchange, LLC as a swap execution facility (''SEF''), on which bitcoin swap contracts may be entered into. On October 9, 2014, TeraExchange announced that it had hosted the first executed bitcoin swap traded on a CFTC-regulated platform. Additionally, in September 2015, the CFTC issued an order temporarily registering LedgerX LLC as a SEF. LedgerX also previously applied for registration as a derivatives clearing organization (''DCO'') although its application is still in the process of CFTC approval. Other parties have acknowledged submitting applications for registration to the CFTC, though no other bitcoin-focused derivatives platform has been approved for registration by the CFTC. Various platforms and Bitcoin Exchanges also offer trading on margin. Currently, the open interest in these bitcoin derivative instruments is quite limited in comparison to the volume of actual bitcoin trades. CFTC commissioners have previously expressed publicly that derivatives based on Digital Assets such as bitcoin are subject to regulation by the CFTC, including oversight to prevent market manipulation of the price of bitcoin. As previously noted, in the September 2015 *Coinflip* case, the CFTC instituted and settled administrative proceedings that involved a bitcoin derivatives trading platform and its chief executive officer. In *Coinflip*,[34] the CFTC determined that bitcoin and other ''virtual currencies'' (aka Digital Assets) are properly defined as commodities under the CEA and CFTC regulations, and applied CEA provisions and CFTC regulations that apply to transactions in commodity options and swaps to the conduct of the bitcoin derivatives trading platform. The CFTC affirmed its approach to the regulation of bitcoin and bitcoin-related enterprises on June 2, 2016, when the CFTC settled charges against Bitfinex, a Bitcoin Exchange based in Hong Kong. In its Order, the CFTC found that Bitfinex engaged in ''illegal, off-exchange commodity transactions and failed to register as a futures commission merchant'' when it facilitated borrowing transactions among its users to permit the trading of bitcoin on a ''leveraged, margined or financed basis'' without first registering with the CFTC.[35] While the Commission has not opined on the legal characterization of bitcoin as a security, it has taken various actions against persons or entities misusing bitcoin in connection with fraudulent schemes (*i.e.,* Ponzi schemes), inaccurate and inadequate publicly disseminated information, and the offering of unregistered securities.[36]

Goods and Services

Bitcoin can also be used to purchase goods and services, either online or at physical locations, although reliable data is not readily available about the retail and commercial market penetration of the Bitcoin Network. In January 2014, U.S. national online retailers Overstock.com and TigerDirect began accepting Bitcoin payments. Over the course of 2014, computer hardware and software company Microsoft began accepting bitcoin as online payment for certain digital content, online retailer NewEgg began accepting bitcoin, and computer hardware company Dell began accepting bitcoin. Additionally, Apple, Inc. approved the inclusion of certain approved bitcoin wallet applications on the Apple App Store. There are thousands of additional online merchants that accept bitcoin, and the variety of goods and services for which bitcoin can be exchanged is increasing. Currently, local, regional and national businesses, including Time Inc., Wikimedia, WordPress, Expedia and Foodler, accept bitcoin. Bitcoin service providers such as BitPay and Coinbase provide means to spend bitcoin for goods and services at additional retailers. There are also many real-world locations that accept bitcoin throughout the world.

As of October 2016, it was estimated that as many as one hundred thousand (100,000) merchants or businesses accept, or have the technological infrastructure to choose to accept (*e.g.,* Shopify merchants), bitcoin as payment. In September 2014, payments giant PayPal announced a partnership with merchant processors including BitPay and Coinbase and to expand their Bitcoin-related services to PayPal's merchant customers, thereby significantly expanding the reach of bitcoin-accepting merchants. To date, the rate of consumer adoption and use of bitcoin in paying merchants has trailed the broad expansion of retail and commercial acceptance of bitcoin. Nevertheless, there will likely be a strong correlation between continued expansion of the Bitcoin Network and its retail and commercial market penetration.

Market Participants

Miners

Miners range from Bitcoin enthusiasts to professional mining operations that design and build dedicated machines and data centers, but the vast majority of mining is now undertaken by participants in mining pools. See ''Bitcoin Mining & Creation of New Bitcoin'' above.

Investment and Speculative Sector

This sector includes the investment and trading activities of both private and professional investors and speculators. These participants range from exchange-traded products, such as

[34] *See supra* note 13 [sic].

[35] *See In re* BFXNA Inc., No. 16–19 (CFTC June 2, 2016), *available at: http://www.cftc.gov/idc/groups/public/@lrenforcementactions/documents/legalpleading/enfbfxnaorder060216.pdf.*

[36] *See, e.g., SEC* v. *Homero Joshua Garza, GAW Miners, LLC and ZenMiner, LLC,* Complaint and Demand for Jury Trial, Case 3:15–cv–01760 (D. Conn. Dec. 1, 2015) (The Commission brought charges in connection with a bitcoin-related Ponzi scheme); *In re* Erik T. Voorhees, Securities Act Release No. 9592 (June 3, 2014), *available at: https://www.sec.gov/litigation/admin/2014/33-9592.pdf* (The Commission brought an administrative action in connection with the offering of unregistered securities of two bitcoin-related entities.); *In re* BTC Trading, Corp. and Ethan Burnside, Securities Act Release No. 9685 (Dec. 8, 2014), *available at: http://www.sec.gov/litigation/admin/2014/33-9685.pdf* (The Commission brought an administrative action in connection with the operation and offering of securities of two online exchanges, neither of which were registered with the Commission, that accepted payment in bitcoin and primarily listed virtual currency-related companies.); *In re* Sand Hill Exchange, et al., Securities Act Release No. 9809 (June 17, 2015), *available at: https://www.sec.gov/litigation/admin/2015/33-9809.pdf* (The Commission took legal action against an online exchange that accepted payment in bitcoin in connection with disseminating fraudulent information, among other matters.).

ARK Web x.0 ETF, or hedge funds such as the Pantera Bitcoin Fund Ltd. to day-traders who invest in bitcoin by trading on Bitcoin Exchanges. See ''Uses of Bitcoin—Bitcoin Exchange Market'' below.

Historically, larger financial services institutions are publicly reported to have limited involvement in investment and trading in bitcoin. In December 2013, Wedbush Securities and Bank of America Merrill Lynch released preliminary research reports on Bitcoin as both a payment tool and investment vehicle. Additionally in December, the Federal Reserve Bank of Chicago released a primer on Bitcoin prepared by a senior economist. In early 2014, Fitch Ratings, Goldman Sachs, JPMorgan Chase, PricewaterhouseCoopers, UBS Securities and Wedbush Securities, among others, released additional research reports analyzing the Bitcoin Network on the basis of bitcoin value, technological innovation or payment system mechanics. In December 2014, the Federal Reserve Board's Divisions of Research & Statistics and Monetary Affairs released an analysis of the Bitcoin Network's transaction system and the Bitcoin Exchange Market's economics. Additionally, institutions including Fortress Investment Group and Pantera Capital made, or proposed to make, direct or indirect investments in bitcoin or the Bitcoin ecosystem. In addition, in October 2015, the Congressional Research Service, at the request of one (1) or more Members, released a report detailing the background and regulatory landscape of Bitcoin.

Retail Sector

The retail sector includes users transacting in direct peer-to-peer Bitcoin transactions through the direct sending of bitcoin over the Bitcoin Network. The retail sector also includes transactions between consumers paying for goods or services from commercial or service businesses through direct transactions or third-party service providers such as BitPay, Coinbase and GoCoin. BitPay, Coinbase and GoCoin each provide a merchant platform for instantaneous transactions whereby the consumer sends bitcoin to BitPay, Coinbase, or GoCoin, which then provides either the bitcoin or the cash value thereof to the commercial or service business utilizing the platform. PayPal, Square and Shopify are examples of traditional merchant payment processors or merchant platforms that have also added Bitcoin payment options for their merchant customers. Payment processing through the Bitcoin Network typically reduces the transaction cost for merchants, relative to the costs paid for credit card transaction processing. Consumers can now purchase goods or services through retail companies such as Overstock.com, DISH, Dell, Expedia, Microsoft, and Time, Inc.

Service Sector

This sector includes companies that provide a variety of services including the buying, selling, payment processing and storing of bitcoin. Coinbase and Circle are each multi-service financial institutions that provide digital wallets that store bitcoin for users and also serve as a retail gateway whereby users can purchase bitcoin for fiat currency. Coinbase, BitPay, BitPagos, and GoCoin are examples of Bitcoin payment processors that allow merchants to accept bitcoin as payment. As the Bitcoin Network continues to grow in acceptance, it is anticipated that service providers will expand the currently available range of services and that additional parties will enter the service sector for the Bitcoin Network.

Competition

Bitcoin is not the only Digital Asset founded on math-based algorithms and cryptographic security, although it is considered the most prominent. Approximately seven hundred (700) other Digital Assets or ''altcoins'' have been developed since the Bitcoin Network's inception, including Litecoin, Ether and Ripple. The Bitcoin Network, however, possesses the ''first-to-market'' advantage and thus far has the largest market capitalization and is secured by a mining network with significantly more aggregate hashrate than the networks of any other Digital Assets.

Description of the Trust and the Shares

According to the Registration Statement, the investment objective of the Trust is for the Shares to track the price of bitcoin using the Gemini Exchange Auction Price on each Business Day, less the Trust's liabilities (which include accrued but unpaid fees and expenses).[37] The Shares are designed for investors seeking a cost-effective and convenient means of gaining investment exposure to bitcoin similar to a direct investment in bitcoin. A substantial direct investment in bitcoin may require expensive and sometimes complicated arrangements in connection with the acquisition, security, and safekeeping of the bitcoin and may involve the payment of substantial fees to acquire such bitcoin from third-party facilitators through cash payments of U.S. Dollars. Although the Shares will not be the exact equivalent of a direct investment in bitcoin, they provide investors with an alternative that allows them to gain investment exposure to bitcoin. In addition, the Trust will provide its investors with other advantages including easy accessibility, relative cost efficiencies and minimal credit risk as the Trust will wholly-own all of its bitcoin assets, as discussed below. The Shares offer an investment that is:

- *Easily Accessible and Relatively Cost Efficient.* Investors in the Shares can also directly access bitcoin through the Bitcoin Exchange Market. The Sponsor believes that investors will be able to more effectively implement strategic and tactical asset allocation strategies that use bitcoin by using the Shares instead of directly purchasing and holding bitcoin, and for many investors, transaction costs related to the Shares will be lower than those associated with the direct purchase, storage and safekeeping of bitcoin.
- *Exchange-Traded and Transparent.* The Shares will be listed on BZX, providing investors with an efficient means to implement various investment strategies. Upon effectiveness of the registration statement of which this prospectus is a part, the Shares will be eligible for margin accounts and will be backed by the assets of the Trust. The Trust will not hold or employ any derivative securities. The value of the Trust's holdings will be reported each day on the Trust's Web site, located at *www.coin-etf.com.* Furthermore, the fact that the Trust will be regulated by the Exchange and by the Commission under the Act provides a level of oversight not

[37] According to the Registration Statement, the activities of the Trust will be limited to (1) issuing Baskets in exchange for the actual bitcoin deposited by the Authorized Participants with the Custodian as consideration, (2) transferring actual bitcoin as necessary to cover the Sponsor's Fee and as necessary to pay Trust expenses not assumed by the Sponsor and other liabilities, (3) transferring actual bitcoin in exchange for Baskets surrendered for redemption by the Authorized Participants, (4) causing the Trustee to sell bitcoin on the termination of the Trust, and (5) engaging in all administrative and custodial procedures necessary to accomplish such activities in accordance with the provisions of the Trust Agreement, the Administration Agreement, the Transfer Agency and Services Agreement, the Custody Agreement, the License Agreement, and Authorized Participant Agreements. The Trust will not be actively managed. It will not engage in any activities designed to obtain a profit from, or to ameliorate losses caused by, changes in the market prices of bitcoin. The Trust seeks to achieve its investment objective by directly owning bitcoin and will not speculate with regard to short-term changes in bitcoin prices. The Trust will not invest in bitcoin derivatives, futures, swaps, or other financial instruments that represent bitcoin or that may be exchanged for bitcoin. The Trust does not expect to make any cash distributions to shareholders.

provided by any other current Bitcoin Exchanges or service providers. The Sponsor represents that the Trust will enter into an information sharing agreement with the Gemini Exchange enabling it to obtain and publish the Gemini Exchange Auction Price on the Trust's Web site. In addition, the Sponsor will arrange for the Gemini Exchange to share data regarding the Gemini Exchange Spot Price and other trading data with the Exchange. See ''Overview of the Bitcoin Industry and Market—Bitcoin Value—Gemini Exchange Spot Price'' above. Lastly, the Exchange has the ability to halt trading and delist the Shares of the Trust under certain circumstances and, more generally, retains broad discretionary authority over the continued listing of securities on the Exchange, as further described below.

• *Proprietary Cold Storage System.* The Custodian has been appointed to store and safekeep the Trust's bitcoin using a state-of-the-art, proprietary Cold Storage System. Similar hardware, software, administration and continued technological development may not be available or cost-efficient for many investors. Winklevoss IP, LLC (''WIP'') is the owner of certain intellectual property and it has licensed such intellectual property to the Sponsor for use by the Custodian and its service providers in the safekeeping of the Trust's bitcoin.

Using the precious metals exchange-traded trusts currently trading on U.S. exchanges[38] as design paradigms, the Sponsor has structured the Trust to be a similar passive investment vehicle holding a single asset. Like the precious metals exchange traded trusts cited above, the Trust will only own and store bitcoin and will not be permitted to hold cash or any other Digital Asset.

The Custodian has been appointed to store and safekeep the Trust's bitcoin using a state-of-the-art, proprietary Cold Storage System.[39] Similar hardware, software, administration and continued technological development may not be available or cost-efficient for many investors. As such, the logistics of accepting, transferring and safekeeping of actual bitcoin are dealt with by the Custodian using the Cold Storage System, and the related expenses are built into the price of the Shares. Therefore, the investor does not have any additional tasks or costs over and above those associated with dealing in any other publicly traded security. The Shares are intended to provide investors with a cost-efficient and convenient means of gaining exposure to bitcoin similar to a direct investment in bitcoin.

All bitcoin is recorded on the Blockchain, the decentralized transaction ledger of the Bitcoin Network. The Blockchain is a canonical record of every bitcoin, every Bitcoin transaction (including the mining of new bitcoin) and every Bitcoin address associated with a quantity of bitcoin. In order to transfer or ''spend'' bitcoin, one must control the private key that is mathematically associated with a given Bitcoin address. The private keys that control the Trust's bitcoin are secured by the Custodian and stored completely offline (*i.e.,* air-gapped) using the Custodian's state-of-the-art, proprietary Cold Storage System. The Custodian's Cold Storage System is founded on the principles of (i) building defense-in-depth against external threats; (ii) protecting against human error; and (iii) guarding against misuse of insider access.

In order to accomplish these principles, the Custodian's Cold Storage System generates, stores and manages the private keys that control the Trust's bitcoin onboard hardware security modules (''HSMs'') for the lifetime of each private key. HSMs (each, a ''Signer'') are tamper-resistant computers used by the Custodian to digitally sign (*i.e.,* authenticate) any transfer of the Trust's bitcoin. All Signers are stored, as well as backed up, in various geographically distributed, access-controlled facilities throughout the United States. In addition, the Custodian's Cold Storage System utilizes multiple-signature (''Multisig'') technology with a ''2 of 3'' signing design that requires a signature from at least two (2) of three (3) potential Signers in order to move the Trust's bitcoin. This provides both security against attacks and tolerance to losing access to a minority of facilities or private keys, thereby eliminating single points of failure. In addition, the operation of a Signer requires the coordinated actions of multiple employees (each a ''Signatory'') to protect against insider malfeasance. All Signatories have undergone background checks by a third-party vendor and are subject to, with or without the Signatory's knowledge, ongoing background checks at the discretion of the Custodian. All Signatories have been fingerprinted, and all fingerprint cards and accompanying information are retained by the Custodian for the duration of the Signatory's tenure and for a minimum of three (3) years thereafter. Lastly, the Cold Storage System is comprised of hardware that is sourced from multiple, diverse manufacturers to guard against supply-chain risks.

The Custodian's Cold Storage System was purpose-built to demonstrate ''proof of control'' of the private keys associated with its public Bitcoin addresses. More specifically, the Custodian can use Signers to sign a specific message that references a current event (*i.e.,* to prove recency), thereby proving control of the private keys associated with the public Bitcoin addresses in which the Trust's bitcoin are held. This allows the Custodian to periodically evidence control of the Trust's assets without necessitating the transfer of any of the Trust's bitcoin. In fact, such ''proof of control'' exercises will be conducted monthly and audited by the Trust's Auditor; the results will be made publicly available on the Trust's Web site along with an attestation from the Trust's Auditor.

The Trust does not currently intend to insure its bitcoin, but may elect to do so in the future if a viable insurance market for bitcoin is established. The Custodian does, however, maintain insurance in the form of a fidelity bond with regard to its custodial business on such terms and conditions as it considers appropriate in connection with its custodial obligations and is responsible for all costs, fees and expenses arising from the insurance policy or policies. The Custodian's statutorily required fidelity bond coverage includes, among other things, insurance against employee theft, computer fraud, and funds transfer fraud; this coverage is subject to certain

[38] *See, e.g.,* SPDR Gold Trust: See Securities Exchange Act Release No. 50603 (October 28, 2004), 69 FR 64614 (November 5, 2004) (SR–NYSE–2004–22) (approving listing of the SPDR Gold Trust); iShares Gold Trust: See Securities Exchange Act Release No. 51058 (January 19, 2005), 70 FR 3749 (January 26, 2005) (SR–Amex–2004–38) (approving listing of the iShares Gold Trust); ETFS Gold Trust: See Securities Exchange Act Release No. 59895 (May 8, 2009), 74 FR 22993 (May 15, 2009) (SR–NYSEArca–2009–40) (approving listing of the ETFS Gold Trust); ETFS Silver Trust: See Securities Exchange Act Release No. 59781 (April 17, 2009), 74 FR 18771 (April 24, 2009) (SR–NYSEArca–2009–95) (approving listing of the ETFS Silver Trust); ETFS Platinum Trust: *See* Securities Exchange Act Release No. 61219 (December 22, 2009), 74 FR 68886 (December 29, 2009) (SR–NYSEArca–2009–94) (approving listing of the ETFS Platinum Trust); and ETFS Palladium Trust: See Securities Exchange Act Release No. 61220 (December 22, 2009), 74 FR 68895 (December 29, 2009) (SR–NYSEArca–2009–94) (approving listing of the ETFS Palladium Trust).

[39] WIP is the owner of certain intellectual property and it has licensed such intellectual property to the Sponsor for use by the Custodian and its service providers in the safekeeping of the Trust's bitcoin. The Sponsor believes that the use of this Cold Storage System and other security features described below, the technological experience of the Custodian's employees and the Sponsor's management team, as well as the use of independent auditors for periodic reviews, will provide a level of security not available through other Digital Asset custodians.

terms, conditions, and exclusions. This fidelity bond has been in effect since October 1, 2015. The Trust will not be a beneficiary of any such insurance and does not have the ability to dictate the existence, nature or amount of coverage. Therefore, Shareholders cannot be assured that the Custodian will maintain adequate insurance or any insurance with respect to the bitcoin held by the Custodian on behalf of the Trust. Furthermore, Shareholders' recourse against the Trust, Custodian and Sponsor under New York law governing their custody operations is limited. Similarly, Shareholders' recourse against the Administrator and Transfer Agent for the services they provide to the Trust is limited. Consequently, a loss may be suffered with respect to the Trust's bitcoin which is not covered by insurance and for which no person is contractually liable in damages.

The Custodian is the custodian of the Trust's bitcoin in accordance with the terms and provisions of the Trust Custody Agreement and utilizes its Cold Storage System in the administration and operation of the Trust and the safekeeping of its bitcoin. The Custodian segregates the Trust's bitcoin which are held in unique Bitcoin addresses with balances that can be directly verified on the Bitcoin Blockchain. Under the Trust Custody Agreement, the Custodian is also responsible for the maintenance of, and periodic updates to, the Cold Storage System.

Acting on standing instructions specified in the Trust Custody Agreement, the Custodian will accept, on behalf of the Trust, delivery of bitcoin from Authorized Participants into the Trust Custody Account in the creation of a Basket. In order for an Authorized Participant to redeem a Basket and receive a distribution of bitcoin from the Trust, the Custodian, upon receiving instructions from the Transfer Agent, will sign transactions necessary to transfer bitcoin out of the Trust Custody Account and distribute to the Bitcoin address specified by the Authorized Participant. See ''Net Asset Value—Creation and Redemption of Shares.''

The Custodian will engage an independent audit firm to periodically audit the Custodian's Cold Storage System protocols and internal controls (''Internal Controls Audit''), and report to the Custodian at least annually on such matters. Additionally, as noted above, the Sponsor and the Custodian have engaged an independent audit firm to verify that the Custodian can demonstrate ''proof of control'' of the private keys that control the Trust's bitcoin on a monthly basis. Other Digital Asset ETPs may not be able to or willing to provide ''proof of control'' of the private keys that control their bitcoin.

Net Asset Value

According to the Registration Statement, on each Business Day, the Administrator will use the Gemini Exchange Auction Price to calculate the Trust's NAV at 4:00 p.m. Eastern Time (the ''Evaluation Time'').

At the Evaluation Time, the Administrator will value the bitcoin held by the Trust using the Gemini Exchange Auction Price which is publicly available and will be provided to the Administrator by the Sponsor each Business Day. In the event that the Sponsor determines that the Gemini Exchange Auction Price is not an appropriate basis for evaluation of the Trust's bitcoin on a given Business Day, the Sponsor will instruct the Administrator to use the 4:00 p.m. Eastern Time spot price on the Gemini Exchange or the itBit bitcoin exchange (the ''itBit Exchange'') [40] as an alternative basis for calculating the Trust's NAV on that Business Day. The itBit Exchange is operated by the itBit Trust Company, LLC, a New York State-chartered limited liability trust company that, like the Gemini Exchange, operates under the direct supervision and regulatory oversight of the NYSDFS. Any determination that the Gemini Exchange Auction Price is unavailable or otherwise not an appropriate basis for calculating the Trust's NAV on a given Business Day would be based upon extraordinary criteria in which the operation of the Gemini Exchange is disrupted or otherwise experiencing material calculation or reporting irregularities. If the Sponsor determines in good faith that none of the Gemini Exchange Auction Price, the spot price on the Gemini Exchange, or the spot price on the itBit Exchange are reliable for calculating the Trust's NAV on a particular Business Day, including but not limited to situations where it does not reflect material information or events occurring between the time of calculation of such prices and the time the Trust's Shares are valued, bitcoin will be valued by the Sponsor using fair market value pricing as determined in good faith by the Sponsor and calculated by the Administrator . Determining the fair market value of bitcoin involves the consideration of a number of subjective factors and thus the prices for bitcoin may differ from the Gemini Exchange Auction Price or the spot price on the Gemini Exchange or the itBit Exchange. Factors the Sponsor may consider include the market price for bitcoin on other Bitcoin Exchanges, or in other forums for which bitcoin prices are published publicly, recent significant transactions on the Blockchain where the USD-bitcoin exchange rate can be readily ascertained (*e.g.,* sales of items with widely available USD prices where the cost in bitcoin can be readily determined), movements in the price of other Digital Assets or fiat currencies, movements in the price of other Digital Asset ETPs, global or regional political, economic or financial events, and other factors determined by the Sponsor in good faith. The Sponsor shall not be liable to any person for the determination that the Gemini Exchange Auction Price or an alternative basis for a fair market value of bitcoin is not appropriate as a basis for calculation of the Trust's NAV provided that such determination is made in good faith.

In order to calculate the Trust's NAV, the Administrator will first determine the value of the Trust's bitcoin and then subtract all of the Trust's liabilities (including accrued but unpaid fees and expenses) to determine the Trust's net assets. The Administrator will calculate the Trust's NAV by dividing the net assets of the Trust by the number of the Shares outstanding as of the close of trading on the Exchange (which includes the net number of any of the Shares created or redeemed on such Business Day).

The Sponsor will publish the Trust's NAV on the Trust's Web site as soon as practicable after determination by the Administrator. To the extent that the NAV has been calculated using a price per bitcoin other than the Gemini Exchange Auction Price for such Business Day, the publication on the Trust's Web site will note the valuation methodology and the price per bitcoin resulting from such calculation.

Creation and Redemption of Shares

The Trust is expected to issue and redeem Shares from time to time only in one or more whole Baskets. The Trust will issue and redeem the Shares in Baskets only to certain Authorized Participants on an ongoing basis. On a creation, Baskets will be distributed to the Authorized Participants by the Trust in exchange for the delivery to the Trust of the appropriate number of bitcoin (*i.e.,* bitcoin equal in value to the value of the Shares being purchased). On a

[40] The itBit Exchange is operated by the itBit Trust Company, LLC, a New York State-chartered limited liability trust company that, like the Gemini Exchange, operates under the direct supervision and regulatory oversight of the NYSDFS.

redemption, the Trust will distribute bitcoin equal in value to the value of the Shares being redeemed to the redeeming Authorized Participant in exchange for the delivery to the Trust of one or more Baskets. On each Business Day, the value of each Basket accepted by the Transfer Agent in a creation or redemption transaction will be the same (*i.e.,* each Basket will consist of 10,000 Shares and the value of the Basket will be equal to the value of 10,000 Shares at their net asset value per Share on that day). The Trust will not issue or redeem fractions of a Basket.

Only Authorized Participants will be able to place orders to create or redeem Baskets. Authorized Participants must be (i) registered broker-dealers or other securities market participants, such as banks and other financial institutions, which are not required to register as broker-dealers to engage in securities transactions, and (ii) DTC Participants. A Transaction Fee may be imposed to offset the transfer and other transaction costs associated with creation or redemption. Authorized Participants or their affiliated market makers are expected to have the facility to participate directly on one or more Bitcoin Exchanges.

The Trust currently expects that prior to the commencement of trading on the Exchange, at least two Authorized Participants will have signed an Authorized Participant Agreement with the Trust and may create and redeem Baskets as described above. Persons interested in placing orders to create or redeem Baskets should contact the Sponsor or the Transfer Agent to obtain the contact information for the Authorized Participants. Shareholders who are not Authorized Participants will only be able to redeem their Shares through an Authorized Participant.

Bitcoin will be (i) delivered to the Trust Custody Account from an Authorized Participant in connection with the creation of one or more Baskets and (ii) distributed by the Custodian from the Trust Custody Account to the Authorized Participant in connection with the redemption of one or more Baskets.

Under the Authorized Participant Agreement, the Sponsor has agreed to indemnify the Authorized Participants against certain liabilities, including liabilities under the Securities Act.

The following description of the procedures for the creation and redemption of Baskets is only a summary and an investor should refer to the relevant provisions of the Trust Agreement, the Trust Servicing Agreement and the form of Authorized Participant Agreement for more detail, each of which is attached as an exhibit to the Registration Statement of which the prospectus is a part.

Creation Procedures

On any Business Day, an Authorized Participant may place an order with the Transfer Agent to create one or more Baskets (each a ''Creation Basket''). The settlement of Creation Basket orders, including the delivery of bitcoin by the Authorized Participant and distribution of Shares to the Authorized Participant, will occur only on days BZX is open for regular trading.

Creation Basket Order Requirements

The quantity of bitcoin required to be delivered to the Trust in exchange for a Creation Basket is determined by the Administrator, and all questions as to the quantity of bitcoin necessary to deliver to purchase a Creation Basket will be conclusively determined by the Administrator. The Administrator's determination of the cost of a Creation Basket shall be final and binding on all persons interested in the Trust.

Creation Basket Distribution

An Authorized Participant who places a Creation Basket order with the Transfer Agent is responsible for delivering the bitcoin to the Trust required to purchase the Creation Basket on the order date. Bitcoin delivered by an Authorized Participant will be considered settled upon the completion of the Confirmation Protocol. Under the Confirmation Protocol, the Custodian must wait until the bitcoin delivery transaction has been confirmed by six (6) consecutive blocks on the Blockchain before it is considered settled. The confirmation process should take approximately one (1) hour depending upon the speed with which Bitcoin Network miners add new blocks to the Blockchain. See ''Overview of the Bitcoin Industry and Market—Cryptographic Security Used in the Bitcoin Network—Double-Spending and the Bitcoin Network Confirmation System,'' above. An Authorized Participant shall not be deemed to have fulfilled its bitcoin delivery requirement until the completion of the Confirmation Protocol.

Following confirmation of the receipt of bitcoin into the Trust Custody Account by the Custodian, the Transfer Agent will direct DTC to credit the Authorized Participant's DTC account with the Shares representing the number of Creation Baskets purchased. The expense and risk of delivery, ownership and safekeeping of a bitcoin delivery until it has been received by the Trust in the Trust Custody Account shall be borne by the Custodian.

The Custodian may accept delivery of bitcoin by such other means as the Sponsor, from time to time, may determine to be acceptable for the Trust, provided that the same is disclosed in a prospectus relating to the Trust filed with the Commission pursuant to Rule 424 under the Securities Act. If bitcoin is to be delivered other than as described above, the Sponsor is authorized to establish such procedures and to appoint such custodians and establish such custody accounts in addition to those described in this prospectus, as the Sponsor determines to be desirable.

Suspension or Rejection of Creation Basket Orders

The Administrator or the Sponsor may suspend the right to place Creation Basket orders, or postpone the Creation Basket settlement date, (i) for any period during which BZX is closed other than customary weekend or holiday closings, or trading on BZX is suspended or restricted; or (ii) for any period during which an emergency exists as a result of which receipt or evaluation of bitcoin delivery is not reasonably practicable or presents, in the judgment of the Custodian or the Sponsor or their agents, a security risk to the Cold Storage System. The inability of the Custodian to operate the Cold Storage System because of a failure of hardware, software or personnel or an inability to access the Cold Storage System (*e.g.,* because of power failure or acts of God) are examples of such emergencies. None of the Custodian, the Sponsor, or their agents will be liable to any person or in any way for any loss or damages that may result from any such suspension or postponement.

The Sponsor may also reject a Creation Basket order if (i) such order is not presented in proper form as described in the Authorized Participant Agreements, (ii) such order is incorrect, (iii) if the Creation Basket Order presents, in the opinion of the Custodian, the Sponsor, or their agents, a security risk to the Cold Storage System, (iv) the fulfillment of the Creation Basket order, in the opinion of counsel, might be unlawful, or (v) circumstances outside the control of the Sponsor, the Transfer Agent or the Custodian, as applicable, make it, for all practical purposes, not feasible to process the Creation Basket Order. None of the Custodian, Sponsor, or their agents will be liable for the rejection of any Creation Basket order.

Redemption Procedures

The procedures by which an Authorized Participant can redeem one or more Baskets (each a ''Redemption Basket'') will mirror the procedures for the creation of Baskets. On any Business Day, an Authorized Participant may place a Redemption Basket order with the Transfer Agent. The settlement of Redemption Baskets orders, including the delivery of Shares to the Trust and distribution of bitcoin to the Authorized Participant, will only occur when BZX is open for regular trading. Settlement of Redemption Baskets may be delayed only in the instance of administrative or custodial delays in the processing of a distribution of bitcoin from the Trust Custody Account, whether by reason of Bitcoin Network delays, mechanical or clerical error or by act of God. Settlement of a Redemption Basket will occur only on Business Days. Redemption Basket orders must be placed no later than 3:00 p.m. Eastern Time on a Business Day. A Redemption Basket order so received will be effective on the date it is received if the Sponsor finds it to be in satisfactory form. The redemption procedures allow only Authorized Participants to place Redemption Basket orders and do not entitle an Authorized Participant to receive a distribution of bitcoin in a quantity that is different than the value of a Redemption Basket.

By placing a Redemption Basket order, an Authorized Participant agrees to deliver the number of Shares in the Redemption Basket through DTC's book-entry system to the Transfer Agent's DTC account not later than the next Business Day following the effective date of the Redemption Basket order.

Redemption Basket Order Requirements

The Redemption Basket distribution from the Trust will consist of a transfer to the redeeming Authorized Participant of the quantity of the bitcoin held by the Trust in the Trust Custody Account evidenced by the Shares being delivered. Redemption distributions will be subject to the deduction of any applicable taxes or other governmental charges that may be due.

Redemption Basket Distribution

The distribution of bitcoin representing a Redemption Basket will be transferred to the Authorized Participant on the third Business Day following the Redemption Basket order date if, by 3:00 p.m. Eastern Time on the next Business Day, the Transfer Agent's DTC account has been credited with the Redemption Baskets to be redeemed. Subsequently, the Transfer Agent will instruct the Custodian to transfer bitcoin from the Trust Custody Account and distribute it to the redeeming Authorized Participant. If the Transfer Agent's DTC account has not been credited with all of the Shares representative of the Redemption Baskets to be redeemed by such time, the delivery will be considered unfulfilled.

In order to facilitate the distribution of the bitcoin representing a Redemption Basket order, the Administrator will calculate the number of bitcoin representing the value of the Redemption Basket order and instruct the Custodian to distribute that quantity of bitcoin to the redeeming Authorized Participant.

Suspension or Rejection of Redemption Basket Orders

The Administrator, the Transfer Agent, or the Sponsor may suspend the right to place Redemption Basket orders, or postpone the Redemption Basket order settlement date, (i) for any period during which BZX is closed other than customary weekend or holiday closings, or trading on BZX is suspended or restricted; or (ii) for any period during which an emergency exists as a result of which the distribution or evaluation of bitcoin is not reasonably practicable or presents, in the judgment of the Custodian, the Sponsor, or their agents a security risk to the Cold Storage System. The inability of the Custodian to operate the Cold Storage System because of a failure of hardware, software or personnel or an inability to access the Cold Storage System (*e.g.,* because of power failure or acts of God) are examples of such emergencies. None of the Custodian, the Sponsor, or their agents will be liable to any person or in any way for any loss or damages that may result from any such suspension or postponement.

The Sponsor will also reject a Redemption Basket order if, among other things, the order is not in proper form as described in the Authorized Participant Agreement or if the fulfillment of the Redemption Basket order, in the opinion of its counsel, might be unlawful.

Availability of Information

The Trust's Web site, which will be publicly available prior to the public offering of the Shares, will include a form of the prospectus for the Trust that may be downloaded. The Web site will feature additional quantitative information for the Shares updated every 15 seconds throughout the Exchange's Regular Trading Session, including the prior Business Day's reported NAV, the Trust's Intraday Indicative Value or IIV (as defined below), the national best bid for the Trust's Shares (''NBB''), the national best offer for the Trust's Shares (''NBO''), the midpoint of the NBB and the NBO, and the discount or premium of this midpoint from the IIV. Daily trading volume information for the Shares will also be available in the financial section of newspapers, through subscription services such as Bloomberg, Thomson Reuters and International Data Corporation, which can be accessed by Authorized Participants and other investors, as well as through other electronic services, including major public Web sites.

In addition, the Sponsor will calculate an estimated fair value of the Shares based on the most recent Gemini Exchange Auction Price (the ''Intraday Indicative Value'' or ''IIV''), which will be updated and widely disseminated by one or more major market data vendors at least every fifteen (15) seconds during the Exchange's regular trading hours.[41] The dissemination of the Intraday Indicative Value will provide investors with an estimate of the fair value of the Shares throughout the trading day.

Investors may obtain bitcoin pricing information twenty-four (24) hours a day or from various financial information service providers or Bitcoin Network information sites such as BitcoinCharts or bitcoinity. Bloomberg financial terminals include pricing data in USD and in Euro from several Bitcoin Exchanges. Recently, the CME and the ICE announced bitcoin pricing indices. Current Bitcoin market prices are also generally available with bid/ask spreads directly from Bitcoin Exchanges. In addition, on each Business Day, the Trust's Web site will provide pricing information for the Gemini Exchange Auction Price, the 4:00 p.m. Eastern Time spot price on the Gemini Exchange and the Shares. The Gemini Exchange itself provides comprehensive last trade information as well as the aggregate quantity available at each price level within its limit order book, all through its public Web site (*www.gemini.com*) and public market data feeds.

Additional information regarding the Trust and its Shares, including risks, creation and redemption procedures, fees, distributions and taxes, is included in the Registration Statement.

[41] Currently, it is the Exchange's understanding that several major market data vendors display and/or make widely available Intraday Indicative Values published via the Consolidated Tape Association (''CTA'') or other data feeds.

Arbitrage Mechanism

Similar to other ETPs listed and traded on the Exchange, the Trust will rely on the Basket creation and redemption process to reduce any premium or discount that may occur in the Share trading prices on the Exchange relative to the NAV. Baskets may be created or redeemed only by Authorized Participants who have entered into an Authorized Participant Agreement with the Trust and the Sponsor, subject to acceptance by the Transfer Agent. The Basket creation and redemption process is important for the Trust in providing Authorized Participants with an arbitrage mechanism through which they may keep Share trading prices in line with the NAV. See ''Overview of the Bitcoin Industry and Market—Bitcoin Value—Gemini Exchange Spot Price'' above.

As the Shares trade intraday on the Exchange, their market prices will fluctuate due to supply and demand, which will be driven in large part by the price of bitcoin. The following examples generally describe the conditions surrounding Basket creation and redemption:

- If the market price of the Shares is greater than the NAV, an Authorized Participant can purchase sufficient bitcoin to create a Basket, and then sell the new Shares on the secondary market at a profit. This process increases the selling interest of the Shares and is expected to decrease the market price of the Shares such that their market price will be closer to the NAV.
- If the NAV is greater than the market price of the Shares, an Authorized Participant can purchase Shares on the secondary market in an amount equal to a Basket and redeem them for bitcoin, and then sell the bitcoin at a profit. This process increases the buying interest for the Shares and is expected to increase the market price of the Shares such that their market price will be closer to the NAV.

This process is referred to as the arbitrage mechanism (''Arbitrage Mechanism''). The Arbitrage Mechanism helps to minimize the difference between the trading price of a Share and the NAV. Over time, these buying and selling pressures should balance, and a Share's market trading price is expected to remain at a level that is at or close to the NAV. The Arbitrage Mechanism provided by the Basket creation and redemption process is designed, and required, in order to maintain the relationship between the market trading price of the Shares and the NAV. The Exchange expects that arbitrageurs will take advantage of price variations between the Shares' market price and the NAV and that the Arbitrage Mechanism will be facilitated by the transparency and simplicity of the Trust's holdings, the availability of the Intraday Indicative Value, the liquidity of the bitcoin market, each Authorized Participant's ability to access the bitcoin market, and each Authorized Participant's ability to create workable hedges.

Rule 14.11(e)(4)—Commodity-Based Trust Shares

The Shares will be subject to BZX Rule 14.11(e)(4), which sets forth the initial and continued listing criteria applicable to Commodity-Based Trust Shares. The Exchange will obtain a representation that the Trust's NAV will be calculated daily and that these values and information about the assets of the Trust will be made available to all market participants at the same time. The Exchange notes that, as defined in Rule 14.11(e)(4)(C)(i), the Shares will be: (a) Issued by a trust that holds a specified commodity [42] deposited with the trust; (b) issued by such trust in a specified aggregate minimum number in return for a deposit of a quantity of the underlying commodity; and (c) when aggregated in the same specified minimum number, may be redeemed at a holder's request by such trust which will deliver to the redeeming holder the quantity of the underlying commodity. The Trust currently expects that there will be at least 100,000 Shares outstanding at the time of commencement of trading on the Exchange. Upon termination of the Trust, the Shares will be removed from listing. The Trustee, Delaware Trust Company, is a trust company having substantial capital and surplus and the experience and facilities for handling corporate trust business, as required under Rule 14.11(e)(4)(E)(iv)(a) and that no change will be made to the trustee without prior notice to and approval of the Exchange. The Exchange also notes that, pursuant to Rule 14.11(e)(4)(F), neither the Exchange nor any agent of the Exchange shall have any liability for damages, claims, losses or expenses caused by any errors, omissions or delays in calculating or disseminating any underlying commodity value, the current value of the underlying commodity required to be deposited to the Trust in connection with issuance of Commodity-Based Trust Shares; resulting from any negligent act or omission by the Exchange, or any agent of the Exchange, or any act, condition or cause beyond the reasonable control of the Exchange, its agent, including, but not limited to, an act of God; fire; flood; extraordinary weather conditions; war; insurrection; riot; strike; accident; action of government; communications or power failure; equipment or software malfunction; or any error, omission or delay in the reports of transactions in an underlying commodity. Finally, as required in Rule 14.11(e)(4)(G), the Exchange notes that any registered market maker (''Market Maker'') in the Shares must file with the Exchange in a manner prescribed by the Exchange and keep current a list identifying all accounts for trading in an underlying commodity, related commodity futures or options on commodity futures, or any other related commodity derivatives, which the registered Market Maker may have or over which it may exercise investment discretion. No registered Market Maker shall trade in an underlying commodity, related commodity futures or options on commodity futures, or any other related commodity derivatives, in an account in which a registered Market Maker, directly or indirectly, controls trading activities, or has a direct interest in the profits or losses thereof, which has not been reported to the Exchange as required by this Rule. In addition to the existing obligations under Exchange rules regarding the production of books and records (see, *e.g.,* Rule 4.2), the registered Market Maker in Commodity-Based Trust Shares shall make available to the Exchange such books, records or other information pertaining to transactions by such entity or registered or non-registered employee affiliated with such entity for its or their own accounts for trading the underlying physical commodity, related commodity futures or options on commodity futures, or any other related commodity derivatives, as may be requested by the Exchange.

Trading Halts

With respect to trading halts, the Exchange may consider all relevant factors in exercising its discretion to halt or suspend trading in the Shares. The Exchange will halt trading in the Shares under the conditions specified in BZX 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

[42] For purposes of Rule 14.11(e)(4), the term commodity takes on the definition of the term as provided in the Commodity Exchange Act. As noted above, the CFTC has opined that Bitcoin is a commodity as defined in Section 1a(9) of the Commodity Exchange Act. *See* Coinflip, *supra* note 13 [sic].

in the bitcoin underlying the Shares; 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(e)(4)(E)(ii), which sets forth circumstances under which trading in the Shares may be halted.

Trading Rules

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. BZX will allow trading in the Shares from 8:00 a.m. until 5:00 p.m. Eastern Time. The Exchange has appropriate rules to facilitate transactions in the Shares during all trading sessions. As provided in BZX Rule 11.11(a) the minimum price variation for quoting and entry of orders in securities traded on the Exchange is $0.01 where the price is greater than $1.00 per share or $0.0001 where the price is less than $1.00 per share.

Surveillance

The Exchange believes that its surveillance 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. Trading of the Shares through the Exchange will be subject to the Exchange's surveillance procedures for derivative products, including Commodity-Based Trust Shares. The issuer has represented to the Exchange that it will advise the Exchange of any failure by the Trust or the Shares to comply with the continued listing requirements, and, pursuant to its obligations under Section 19(g)(1) of the Exchange Act, the Exchange will surveil for compliance with the continued listing requirements. If the Trust or the Shares are not in compliance with the applicable listing requirements, the Exchange will commence delisting procedures under Exchange Rule 14.12. The Exchange may obtain information regarding trading in the Shares via the Intermarket Surveillance Group (''ISG''), from other exchanges who are members or affiliates of the ISG, or with which the Exchange has entered into a comprehensive surveillance sharing agreement.[43] In addition, the Exchange may obtain information about bitcoin transactions, trades and market data from Bitcoin Exchanges with which the Exchange has entered into a comprehensive surveillance sharing agreement as well as certain additional information that is publicly available through the Blockchain. The Exchange notes that it has entered into a comprehensive surveillance sharing agreement with Gemini Exchange.

Information Circular

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: (i) The procedures for the creation and redemption of Baskets (and that the Shares are not individually redeemable); (ii) BZX Rule 3.7, which imposes suitability obligations on Exchange members with respect to recommending transactions in the Shares to customers; (iii) how information regarding the Intraday Indicative Value and the Trust's NAV are disseminated; (iv) the risks involved in trading the Shares during the Pre-Opening[44] and After Hours Trading Sessions[45] when an updated Intraday Indicative Value will not be calculated or publicly disseminated; (v) the requirement that members deliver a prospectus to investors purchasing newly issued Shares prior to or concurrently with the confirmation of a transaction; and (vi) trading information.

In addition, the Information Circular will advise members, prior to the commencement of trading, of the prospectus delivery requirements applicable to the Shares. Members purchasing the Shares for resale to investors will deliver a prospectus to such investors. The Information Circular will also discuss any exemptive, no-action and interpretive relief granted by the Commission from any rules under the Act.

In addition, the Information Circular will reference that the Trust is subject to various fees and expenses described in the Registration Statement. The Information Circular will also reference the fact that, apart from the CFTC, the Financial Crimes Enforcement Network of the U.S. Department of the Treasury (''FinCEN'') and the U.S. Internal Revenue Service (''IRS''), most major U.S. regulators, including the Commission, have yet to make official pronouncements or adopt rules providing guidance with respect to the classification and treatment of bitcoin and other Digital Assets for purposes of commodities, tax and securities laws. The Information Circular will also contain information regarding the CFTC's determination that bitcoin and other ''virtual currencies'' (aka Digital Assets) are properly defined as commodities under the CEA,[46] and will reference the fact that the CFTC has applied CEA provisions and CFTC regulations that apply to transactions in commodity options and swaps to the conduct of the bitcoin derivatives trading platform.

2. Statutory Basis

The Exchange believes that the proposal is consistent with Section 6(b) of the Act[47] in general and Section 6(b)(5) of the Act[48] in particular in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest.

The Exchange believes that the proposed rule change is designed to prevent fraudulent and manipulative acts and practices in that the Shares will be listed on the Exchange pursuant to the initial and continued listing criteria in Exchange Rule 14.11(e)(4), which as noted above includes all statements and representations made in this filing regarding the description of the portfolio and limitations on portfolio holdings or reference assets. The Exchange believes that its surveillance 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. The Exchange may obtain information regarding trading in the Shares via the ISG from other exchanges who are members or affiliates of the ISG, or with which the Exchange has entered into a comprehensive surveillance sharing agreement.[49] In addition, the Exchange may obtain information about Bitcoin transactions, trades, and market data from Bitcoin Exchanges with which the Exchange has entered into a comprehensive surveillance sharing agreement, which includes the Gemini

[43] For a list of the current members and affiliate members of ISG, *see www.isgportal.com.*

[44] The Pre-Opening Session is from 8:00 a.m. to 9:30 a.m. Eastern Time.

[45] The After Hours Trading Session is from 4:00 p.m. to 5:00 p.m. Eastern Time.

[46] *See* Coinflip, *supra* note 13 [sic].

[47] 15 U.S.C. 78f.

[48] 15 U.S.C. 78f(b)(5).

[49] For a list of the current members and affiliate members of ISG, *see www.isgportal.com.*

Exchange, as well as certain additional information that is publicly available through the Blockchain.

According to the Registration Statement, the Trust will only own and store bitcoin and will not be permitted to hold cash or any other Digital Asset. The proposal also promotes market transparency in that large amount of information is publicly available regarding the Trust and the Shares, thereby promoting market transparency. The Exchange will obtain a representation from the Sponsor that the Trust's NAV will be determined by the Administrator and published by the Sponsor at 4:00 p.m. Eastern Time each Business Day (using the Gemini Exchange Auction Price) on the Trust's Web site and that such information will be made available to all market participants at the same time. Furthermore, the Trust's Web site will provide an Intraday Indicative Value during regular trading hours on each Business Day. The Trust's Web site will also provide its current prospectus, as well as the two (2) most recent reports to shareholders. The Web site will feature additional quantitative information for the Shares updated every 15 seconds throughout the Exchange's Regular Trading Session, including the prior Business Day's reported NAV, the Trust's IIV, the NBB, the NBO, the midpoint of the NBB and the NBO, and the discount or premium of this midpoint from the IIV. This information will be retained by the Trust. In addition, the Exchange will publish (via the CTA) quotation information, trading volume, closing prices, and the prior Business Day's NAV. The IIV, which is the pricing on the Gemini Exchange prior to the Gemini Exchange Auction Price, will be widely disseminated by one (1) or more major market data vendors, such as Reuters or Bloomberg, and broadly displayed on at least a 15-second basis during regular trading hours. In addition, information regarding market price and trading volume of the Shares will be continually available on a real-time basis throughout the Business Day on brokers' computer screens and other electronic services, and quotation and last sale information will also be available via the Exchange's data feeds.

The proposed rule change is further designed to promote just and equitable principles of trade and to protect investors and the public interest and to promote market transparency in that there is a considerable amount of bitcoin price and market information available for free on public Web sites and through financial, professional and subscription services. Investors may obtain bitcoin pricing information twenty-four (24) hours a day or from various financial information service providers or Bitcoin Network information sites such as *www.BitcoinCharts.com* or *www.bitcoinity.org.* Bloomberg financial terminals include pricing data in USD and in Euro from several Bitcoin Exchanges. Recently, the CME and the ICE announced bitcoin pricing indices. Current Bitcoin market prices are also generally available with bid/ask spreads directly from various Bitcoin Exchanges.

The Exchange also believes that the widespread availability of information regarding bitcoin, the Trust, and the Shares, combined with the ability of Authorized Participants to create and redeem Baskets each Business Day, thereby utilizing the Arbitrage Mechanism, will be sufficient for market participants to value and trade the Shares in a manner that will not lead to significant deviations between the NBB/NBO midpoint and the Intraday Indicative Value as well as between the NBB/NBO midpoint and the NAV. In addition, the numerous options for buying and selling bitcoin will both provide Authorized Participants with many options for hedging their positions and provide market participants generally with potential arbitrage opportunities, further strengthening the Arbitrage Mechanism as it relates to the Shares. Furthermore, the Trust has discussed with several prominent market participants the possibility of acting as an Authorized Participant and/or a Market Maker, each of which is an experienced participant in the ETP marketplace and is actively engaged in trading ETPs. A number of these potential Authorized Participants and Market Makers currently trade bitcoin and are already registered participants that trade on the Gemini Exchange. Based on their experience in ETPs and in the Bitcoin marketplace, these market participants have indicated that they believe that they will be able to make efficient and liquid markets in the Shares at prices generally in line with the NAV.

Authorized Participants will be able to acquire bitcoin for delivery to the Trust by a variety of means. Authorized Participants will not be required to use the Gemini Exchange to trade their bitcoin and the Gemini Exchange is not the only venue on which Authorized Participants can purchase bitcoin for delivery to the Trust. However, as discussed above, the ability to transact in bitcoin on the Gemini Exchange may provide (i) a convenient and stable venue with superior liquidity characteristics in which to purchase or sell bitcoin, (ii) an efficient way to trade bitcoin, and (iii) a safe place to store purchased bitcoin for future use in the creation of Baskets given the regulatory oversight to which the Gemini Exchange is subject.

The Exchange may consider all relevant factors in exercising its discretion to halt or suspend trading in the Shares. The Exchange will halt trading in the Shares under the conditions specified in BZX 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: (i) The extent to which trading is not occurring in the financial instruments underlying the Shares; or (ii) 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(e)(4)(E)(ii), which sets forth circumstances under which trading in the Shares may be halted.

The proposed rule change is designed to perfect the mechanism of a free and open market and, in general, to protect investors and the public interest in that it will facilitate the listing and trading of Commodity-Based Trust Shares that will enhance competition among market participants, to the benefit of investors and the marketplace. As noted above, the Exchange has in place surveillance procedures relating to trading in the Shares and may obtain information from other Bitcoin Exchanges with which the Exchange has entered into a comprehensive surveillance sharing agreement. In addition, as noted above, investors will have ready access to information regarding bitcoin pricing and bitcoin information, as well as equitable access to the Trust's Intraday Indicative Value, NAV, and quotation and last sale information for the Shares.

For the above reasons, the Exchange believes that the proposed rule change is consistent with the requirements of Section 6(b)(5) of the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purpose of the Act. The Exchange notes that the proposed rule change will facilitate the listing and trading of an additional Commodity-Based Trust Share product that will enhance competition among market participants, to the benefit of investors and the marketplace.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange has neither solicited nor received written comments on the proposed rule change.

III. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change, as amended, is consistent with the Section 6(b)(5) of the Act, the other provisions of the Act, and the rules and regulations thereunder. In particular, the Commission invites the written views of interested persons concerning the sufficiency of the Exchange's statements in support of Amendment No. 1 to the proposed rule change, which are set forth above; the statements made in comment letters submitted to the Commission; [50] and the specific requests for comment set forth in the Order Instituting Proceedings.[51]

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–BatsBZX–2016–30 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–BatsBZX–2016–30. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing will also 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–BatsBZX–2016–30 and should be submitted on or before November 25, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[52]

Brent J. Fields,

Secretary.

[FR Doc. 2016–26513 Filed 11–2–16; 8:45 am]

BILLING CODE 8011–01–P

[50] *See supra* note 8.

[51] *See* Order Instituting Proceedings, *supra* note 7. The Commission notes that, consistent with certain changes made in Amendment No. 1 to the proposed rule change, with respect to Question No. 2 in the Order Instituting Proceedings, commenters are asked to address the sufficiency of the Exchange's statements as they pertain to the Gemini Exchange Auction Price. *See id.,* 81 FR at 71781.

[52] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. IC–32342]

Notice of Applications for Deregistration Under Section 8(f) of the Investment Company Act of 1940

October 28, 2016.

The following is a notice of applications for deregistration under section 8(f) of the Investment Company Act of 1940 for the month of October 2016. A copy of each application may be obtained via the Commission's Web site by searching for the file number, or for an applicant using the Company name box, at *http://www.sec.gov/search/search.htm* or by calling (202) 551–8090. An order granting each application will be issued unless the SEC orders a hearing. Interested persons may request a hearing on any application by writing to the SEC's Secretary at the address below and serving the relevant applicant with a copy of the request, personally or by mail. Hearing requests should be received by the SEC by 5:30 p.m. on November 22, 2016, and should be accompanied by proof of service on applicants, in the form of an affidavit or, for lawyers, a certificate of service. Pursuant to Rule 0–5 under the Act, hearing requests should state the nature of the writer's interest, any facts bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Commission's Secretary.

ADDRESSES: The Commission: Secretary, U.S. Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

FOR FURTHER INFORMATION CONTACT: Jessica Shin, Attorney-Adviser, at (202) 551–5921 or Chief Counsel's Office at (202) 551–6821; SEC, Division of Investment Management, Chief Counsel's Office, 100 F Street NE., Washington, DC 20549–8010.

Arden Investment Series Trust [File No. 811–22701]

Summary: Applicant seeks an order declaring that it has ceased to be an investment company. On March 31, 2016 and September 20, 2016, applicant made liquidating distributions to its shareholders, based on net asset value. Applicant's custodian is holding remaining assets of approximately $816,214 in cash and $105,662 in tax reclaims receivables to cover current and anticipated liabilities and expenses in connection with applicant's liquidation and dissolution as well as to cover any unexpected liabilities. Expenses of approximately $611,038 incurred in connection with the liquidation were paid by the applicant and the applicant's investment advisers.

Filing Dates: The application was filed on April 20, 2016, and amended on September 21, 2016 and October 26, 2016.

Applicant's Address: 375 Park Avenue, 32nd Floor, New York, New York 10152.

Roge Partners Fund [File No. 811–21571]

Summary: Applicant seeks an order declaring that it has ceased to be an investment company. The series of applicant has transferred its assets to a corresponding series of Northern Lights Fund Trust III, and, on April 24, 2014, made a final distribution to its shareholders based on net asset value. Expenses of approximately $9,084 incurred in connection with the reorganization were paid by the applicant's investment adviser.

Filing Dates: The application was filed on September 23, 2016 and amended on October 20, 2016.

Applicant's Address: 630 Johnson Avenue, Suite 103, Bohemia, New York 11716.

Dreyfus New York AMT-Free Municipal Money Market Fund [File No. 811–05160]

Summary: Applicant seeks an order declaring that it has ceased to be an investment company. On October 28, 2015, applicant made a liquidating distribution to its shareholders, based on net asset value. Expenses of approximately $2,016 incurred in connection with the liquidation were paid by the applicant's investment adviser.

Filing Dates: The application was filed on August 5, 2016, and amended on September 8, 2016 and October 7, 2016.

Applicant's Address: 200 Park Avenue, New York, New York 10166.

Little Harbor MultiStrategy Composite Fund [File No. 811–22891]

Summary: Applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. On July 11, 2016 and August 26, 2016, applicant made a liquidating distribution to its shareholders, based on net asset value. Applicant is retaining remaining assets of approximately $9,708 in cash to cover current and anticipated liabilities and expenses in connection with applicant's liquidation. Expenses of approximately $69,863 incurred in connection with the liquidation were paid by the applicant.

Filing Date: The application was filed on October 7, 2016.

Applicant's Address: c/o Little Harbor Advisors, LLC, 30 Doaks Lane, Marblehead, Massachusetts 01945.

Dreyfus Worldwide Dollar Money Market Fund, Inc. [File No. 811–05717]

Summary: Applicant seeks an order declaring that it has ceased to be an investment company. The applicant has transferred its assets to Dreyfus Liquid Assets, Inc. and, on September 18, 2016, made a final distribution to its shareholders based on net asset value. Expenses of $131,250 incurred in connection with the reorganization were paid by the applicant's investment adviser.

Filing Dates: The application was filed on August 30, 2016, and amended on October 13, 2016.

Applicant's Address: c/o The Dreyfus Corporation, 200 Park Avenue, New York, New York 10166.

Dreyfus One Hundred Percent US Treasury Money Market Fund [File No. 811–04430]

Summary: Applicant seeks an order declaring that it has ceased to be an investment company. The applicant has transferred its assets to General Treasury Securities Money Market Fund (formerly, General Treasury Prime Money Market Fund), a series of General Government Securities Money Market Funds Inc. and, on December 4, 2015, made a final distribution to its shareholders based on net asset value. Expenses of approximately $199,495 incurred in connection with the reorganization were paid by the applicant's investment adviser.

Filing Date: The application was filed on October 17, 2016.

Applicant's Address: c/o The Dreyfus Corporation, 200 Park Avenue, New York, New York 10166.

Western Asset Inflation Management Fund Inc. [File No. 811–21533]

Summary: Applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. On May 30, 2014, applicant made a liquidating distribution to its shareholders, based on net asset value. Expenses of $137,100 incurred in connection with the liquidation were paid by the applicant.

Filing Date: The application was filed on October 20, 2016.

Applicant's Address: 620 Eighth Avenue, 49th Floor, New York, New York 10018.

Western Asset 2008 Worldwide Dollar Government Term Trust Inc. [File No. 811–07740]

Summary: Applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. On November 30, 2008, applicant made a liquidating distribution to its shareholders, based on net asset value. Expenses of $20,000 incurred in connection with the liquidation were paid by the applicant.

Filing Date: The application was filed on October 20, 2016.

Applicant's Address: 55 Water Street, New York, New York 10041.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

Brent J. Fields,

Secretary.

[FR Doc. 2016–26508 Filed 11–2–16; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–79189; File No. SR–C2–2016–020]

Self-Regulatory Organizations; C2 Options Exchange, Incorporated; Notice of Filing of a Proposed Rule Change Relating to Price Protection Mechanisms and Risk Controls

October 28, 2016.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on October 25, 2016, C2 Options Exchange, Incorporated (''Exchange'' or ''C2'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The 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 enhance current and adopt new price protection mechanisms and risk controls for orders and quotes. The text of the proposed rule change is available on the Exchange's Web site (*http://www.c2exchange.com/Legal/*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange has in place various price check mechanisms and risk

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

controls that are designed to prevent incoming orders and quotes from automatically executing at potentially erroneous prices or to assist Trading Permit Holders (''TPHs'' or ''Participants'') with managing their risk.[3] These mechanisms and controls are designed to help maintain a fair and orderly market by mitigating potential risks associated with orders trading at prices that are extreme and potentially erroneous, or in extremely large and potentially erroneous volumes, that may be harmful to market participants. The Exchange proposes to amend Rules 6.17 and 8.12 to add new, as well as enhance current, price protection mechanisms and risk controls to further prevent potentially harmful and disruptive trading.[4]

Limit Order Price Parameter for Simple Orders

The proposed rule change amends the limit order price parameter for simple orders in Rule 6.17(b). This price parameter currently states the Exchange will not accept for execution eligible limit orders if:

- Prior to the opening of a series (including before a series is opened following a halt), the order is to buy (sell) at more than an acceptable tick distance (''ATD'') above (below) the Exchange's previous day's close; however, this is not applicable to limit orders of C2 Market-Makers or away Market-Makers, or to intermarket sweep orders (''ISO''s), which cannot be entered prior to the opening on the System; or
- once a series has opened, the order is to buy (sell) at more than an ATD above (below) the disseminated Exchange offer (bid).

The proposed rule change states the System rejects back to a TPH an order to buy (sell) at more than an acceptable tick distance above (below) if:

- Prior to the opening of a series (including during any pre-opening period and opening rotation), (1) the last disseminated national best offer (''NBO'') (national best bid (''NBB'')), if a series is open on another exchange(s), or (2) the Exchange's previous day's closing price, if a series is not yet open on any other exchange; if the NBBO is locked, crossed or unavailable; [5] or if there is no NBO (NBB) and the previous day's closing price is greater (less) than or equal to the NBB (NBO). However, this does not apply to orders of C2 or away market-makers, or to ISOs; if there is no NBO (NBB) and the Exchange's previous day's closing price is less (greater) than the NBB (NBO); or if there is no NBBO and no Exchange previous day's closing price;
- intraday, the last disseminated NBO (NBB), or the Exchange's best offer (bid) if the NBBO is locked, crossed or unavailable. However, this does not apply if there is no NBBO and no Exchange best bid or offer (''BBO''); or
- during a trading halt (including during any pre-opening period or opening rotation prior to re-opening following the halt), the last disseminated NBO (NBB). However, this does not apply to a buy (sell) order if the NBBO is locked, crossed or unavailable; to ISOs; or if there is no NBO (NBB).

Prior to a series opening on C2, the series may already be open on another exchange(s), in which case that exchange(s) would be disseminating an NBBO. The NBBO would more accurately reflect the then-current market, rather than the previous day's closing price, and thus the Exchange believes it would be a better measure to use for purposes of determining the reasonability of the prices of orders. If the series is not yet open on any other exchange, the System will continue to use the Exchange's previous day's closing price as the comparison figure. Additionally, the System will use the Exchange's previous day's closing price if the NBBO is locked, crossed or unavailable (and thus unreliable) or if there is no NBO (NBB) and the Exchange's previous day's closing price is greater (less) than or equal to the NBB (NBO). The check will continue to not apply to orders of C2 or away market-makers, or to ISOs,[6] and will also not apply to orders entered when there is no NBO (NBB) and the Exchange's previous day's closing price is less (greater) than the NBB (NBO) or if there is no NBBO and no Exchange previous day's closing price (for example, if the order is in a newly listed series) (and thus no reliable measure against which to compare the price of the order to determine its reasonability). Prior to the opening of a series, and the NBBO is unavailable, the previous day's closing price is the most relevant pricing information to determine the price at which an investor may want to buy or sell within a series, and the Exchange believes it is a reasonable substitute for the NBB or NBO when not available. With respect to the proposed provisions regarding the applicability of the check when there is no NBO (NBB) against which the price of the buy (sell) order can be compared to determine price reasonability, the Exchange believes using the previous day's closing price is appropriate if that price is greater (less) than or equal to the NBB (NBO) because it does not cross the disseminated NBB (NBO). On the contrary, if that price is less (greater) than the NBB (NBO), and thus would cross the disseminated NBB (NBO), the Exchange believes that closing price is too far away from what an NBO (NBB) would be if an offer (bid) quote or sell (buy) order were to be entered and essentially creates a crossed, unreliable market.

Once a series has opened on C2, this check will compare the price of a buy (sell) order to the last disseminated NBO (NBB) rather than the Exchange best offer (bid). The NBBO would more accurately reflect the then-current market, rather than the Exchange BBO, and thus the Exchange believes it would be a better measure to use for purposes of determining the reasonability of the prices of orders. The System will continue to use the Exchange BBO if the NBBO is locked, crossed or unavailable (and thus unreliable). This check will not apply intraday if there is no NBBO and no BBO (and thus no reliable measure against which to compare the price of the order to determine its reasonability).

With respect to orders entered during a trading halt (including during any pre-opening period or opening rotation prior to re-opening following a halt), the proposed rule change states the System will use the last disseminated NBO (NBB) rather than the Exchange's previous day's closing price (as the current rule states). If a halt occurs during the trading day, the NBO (NBB) would more accurately reflect the then-current market rather than the previous day's closing price, which would be stale by that time. This check will not apply to orders if the NBBO is locked, crossed or unavailable (and thus unreliable); to ISOs; or if there is no NBO (NBB) (and thus no reliable measure against which to compare the price of the order to determine its reasonability).

The rule currently states the Exchange determines the ATD on a series-by-

[3] *See, e.g.,* 6.13, Interpretation and Policy .04 (price check parameters for complex orders), 6.17(a) (market-width and drill through price check parameters), Rule 6.17(b) (simple limit order price parameters), 6.17(d) and (e) (price protections), and 8.12 (Quote Risk Monitor Mechanism (''QRM'')).

[4] The proposed rule change makes conforming changes to other rules, as further discussed below.

[5] If the NBBO (or BBO) is not currently being disseminated, the NBBO (or BBO) will be considered ''unavailable.''

[6] The proposed rule change moves this rule provision to subparagraphs (b)(1) and (b)(3). The proposed rule change also deletes the language stating subparagraph (b)(2) applies to ISOs, because it is unnecessary to explicitly state this given the rules clarify when a provision does not apply to a specific order type.

series [7] and premium basis and will be no less than five minimum increment ticks. The proposed rule change amends the minimum ATD to be two minimum increment ticks rather than five. The Exchange believes it may be appropriate to set the ATD for certain classes (depending on the minimum increment and premium) to be fewer than five to ensure that the ATD price is not so far away from the market price and thus this price check is effective given the market model or market conditions.[8] Additionally, because market conditions during pre-opening periods, trading rotations, and trading halts are different than those present when the exchange is open for trading, the proposed rule change provides the Exchange with flexibility to apply a different ATD during those times (which the Exchange may want to be less than the current minimum of five). The Exchange believes it is appropriate to have the ability to apply a different ATD during the pre-open period or opening rotation so the check does not impact the Exchange's ability to open an option or determination of the opening price. The Exchange may also want to apply a different ATD during a halt, as pricing during those times may be volatile and inaccurate.[9]

The proposed rule change deletes the Exchange's flexibility to not apply this price parameter to immediate-or-cancel orders, as the Exchange believes these orders are also at risk of execution at extreme and potentially erroneous prices and thus will benefit from applicability of these checks.

The proposed rule change also states this price parameter does not apply to orders with a stop contingency. By definition, the stop contingency [10] is triggered for a buy order if there is a last sale or bid at or above the stop price and for a sell order if there is a last sale or offer at or below the stop price. As a result, buy orders with a stop contingency are generally submitted at a triggering price that is above the NBO, and sell orders with a stop contingency are generally submitted at a triggering price that is below the NBB. Because these orders are expected to be priced outside the NBBO, the Exchange will not apply this check to not interfere with the application of the stop contingency.[11]

Drill Through Price Check Parameter

The proposed rule change amends the drill through price check parameter in Rule 6.17(a)(2). Currently, the System will not automatically execute eligible orders that are marketable if the execution would follow an initial partial execution on the Exchange and would be at a subsequent price not within an ATD from the initial execution (determined by the Exchange on a series-by-series and premium basis for market orders and/or marketable limit orders).[12] An ATD may be no less than two minimum increment ticks. Pursuant to paragraph (c), if an execution is suspended because executing the remaining unexecuted portion of an order would exceed the drill through ATD, then such unexecuted portion will be cancelled.

Pursuant to the proposed rule change, if a buy (sell) order not yet exposed via HAL (pursuant to Rule 6.18) partially executes, and the System determines the unexecuted portion would execute at a subsequent price higher (lower) than the price that is an ATD above (below) the NBO (NBB) (the ''drill through price''), the System will not automatically execute that portion and will expose [13] that portion via HAL at the better of the NBBO and the drill through price (if eligible for HAL). The Exchange will determine the ATD on a class and premium basis (which may be no less than two minimum increment ticks),[14] which the Exchange will announce via Regulatory Circular. If a buy (sell) order is exposed via HAL (other than pursuant to the previous sentence) or SAL [15] and, following the exposure period pursuant to Rule 6.18 or 6.14, respectively, the System determines the order (or any unexecuted portion) would execute at a price higher (lower) than the drill through price, the System will not automatically execute the order (or unexecuted portion).[16]

Under the proposed rule change, rather than be cancelled, these orders (or unexecuted portions) will rest in the book (based on the time at which they enter the book for priority purposes) for a time period in milliseconds (which the Exchange will determine and announce via Regulatory Circular and will not exceed three seconds) [17] with a price equal to the drill through price.[18] This time period will provide an additional opportunity for execution for these orders (or unexecuted portions) at a price that does not appear to be erroneous. If the order (or any unexecuted portion) does not execute during that time period, the System cancels it. Buy (sell) orders (or any unexecuted portion) not eligible for

[7] The proposed rule change amends this to be class-by-class rather than series-by-series. The Exchange generally sets parameters on a class-by-class basis. The proposed rule change also moves this provision from subparagraph (c)(1) to paragraph (b).

[8] The Exchange notes current Rule 6.17(c)(1) sets the minimum ATD at two minimum increments for the drill through protection.

[9] Note current Rule 6.17(c)(2) (which becomes proposed Rule 6.17(c)) permits a senior official on the Exchange Help Desk to grant intra-day relief by widening or inactivating one or more of the applicable acceptable price range (''APR'') and/or ATD parameters settings in the interest of a fair and orderly market. The Exchange makes additional nonsubstantive changes to paragraph (c), including to clarify it applies to paragraphs (a) and (b) of the Rule. The provisions for the checks in paragraphs (d) and (e) specify when those checks do and do not apply.

[10] *See* Rule 6.10.

[11] The proposed rule change also makes nonsubstantive changes to Rule 6.17(b), including moving a provision from current paragraph (c) into proposed paragraph (b) regarding the precedence of the limit order price parameter that applies only to proposed paragraph (b). The proposed rule change also deletes the language in current paragraph (c) regarding returning an order to the order entry firm, as the proposed language in paragraph (b) more directly states the order will be rejected, which is consistent with System functionality.

[12] Pursuant to the rule filing of Chicago Board Options Exchange, Incorporated, upon which this rule was based and which proposed this language, the intent of this provision is to allow the Exchange to determine to apply the drill through price check parameter, as well as the market-width price check parameter, to market orders and/or marketable limit orders. *See* Securities Exchange Act Release No. 34–63191 (October 27, 2010), 75 FR 67411 (November 2, 2010) (SR–CBOE–2010–094) (notice of filing and immediate effectiveness of proposed rule change related to the automatic execution feature, including a change to allow CBOE to determine ''to apply these price check parameters to market and/or marketable limit orders''). Currently, the Exchange applies the market-width check to market orders and the drill through check to market and marketable limit orders. The proposed rule change merely removes this flexibility from the Rules and codifies the current practice (which is permitted under the current Rule).

[13] Currently, the Exchange has not activated HAL in any class.

[14] The proposed rule change amends this to be class-by-class rather than series-by-series. The Exchange generally sets parameters on a class-by-class basis.

[15] The proposed rule change expands this to include SAL, a similar price improvement auction the Exchange may activate in classes in which it did not activate HAL. In classes in which SAL is activated, an order eligible for SAL will be exposed immediately and would not partially execute prior to being exposed via SAL. For this reason, SAL is not included in proposed Rule 6.17(a)(2)(A). Currently, the Exchange has not activated SAL in any class.

[16] The proposed rule change makes corresponding changes to Rules 6.14 and 6.18 to clarify orders (or portions) that do not execute following the applicable exposure process are subject to the drill through price check parameter in proposed Rule 6.17(a)(2). The proposed rule change also amends Rule 6.18 to provide orders (or any unexecuted portions) may initiate a HAL at the better of the drill through price and NBBO and make other nonsubstantive changes.

[17] Because the Exchange currently has not activated HAL in any class, no initial time period will be set.

[18] Any order (or unexecuted portion) that by its terms cancels if it does not execute immediately (including immediate-or-cancel, fill-or-kill, intermarket sweep, and market-maker trade prevention orders) will be cancelled rather than rest in the book for this time period in accordance with the definition of those order types.

HAL or SAL that would execute at a price higher (lower) than the drill through price will continue to be cancelled. To avoid any confusion, the proposed rule change also clarifies this drill through check does not apply to executions of orders following exposure at the open pursuant to Rule 6.11(g)(2) and Interpretation and Policy .04, which instead are subject to a separate drill through protection set forth in that rule.[19]

The following examples illustrate the new functionality to briefly rest orders in the book in connection with the drill through price check parameter. As noted above, C2 has not activated HAL or SAL on C2, and thus this new functionality will apply to orders on C2 only if C2 activates those auctions for any classes. Upon approval of this proposed rule change, unless C2 activates these auctions at this time, the drill through price check parameter will apply to orders in the same manner as it does today (as described in proposed Rule 6.17(a)(2)(D))—buy (sell) orders (or any unexecuted portion) that would execute at a subsequent price higher (lower) than the drill through price will be cancelled.

Example #1

Suppose C2's market for a series in a class with a 0.05 minimum increment is 0.90–1.00, represented by a quote for 10 contracts on each side (the quote offer is Quote A). The following sell orders or quote offers also rest in the series: 10 contracts at 1.05 (Order A), 10 contracts at 1.10 (Quote B), 10 contracts at 1.15 (Order B), and 100 contracts at 1.20 (Order C). The market for away exchanges is 0.80–1.25. The Exchange's drill through amount for the class is three ticks (or 0.15), and the drill through resting time period is two seconds. The System receives an incoming order to buy 100 at 1.30, which executes against resting orders and quotes as follows: 10 against Quote A at 1.00, 10 against Order A at 1.05, 10 against Quote B at 1.10, and 10 against Order B at 1.15. The System will not automatically execute the remaining 60 contracts from the incoming order against Order C, because 1.20 is more than 0.15 away from the initial execution price of 1.00 and thus exceeds the drill through price check. The 60 unexecuted contracts are then exposed pursuant to HAL at 1.15 (which is the drill through price, and better than the NBO). No responses to trade against the remaining 60 contracts are entered during the auction, so the 60 contracts remain unexecuted. These contracts then rest in the book for two seconds at a price of 1.15. No incoming orders are entered during that time period to trade against the remaining 60 contracts, so the System cancels that remaining portion of the original incoming order.

Example #2

Suppose C2's market for a series in a class with a 0.05 minimum increment is 0.90–1.00, represented by a quote for 10 contracts on each side (the quote offer is Quote A). The following sell orders or quote offers also rest in the series: 10 contracts at 1.05 (Order A), 10 contracts at 1.10 (Quote B), 10 contracts at 1.15 (Order B), and 100 contracts at 1.20 (Order C). The market for away exchanges is 0.80–1.10, with 5 contracts available on each side. The Exchange's drill through amount for the class is three ticks (or 0.15), and the drill through resting time period is two seconds. The System receives an incoming order to buy 100 at 1.30, which executes against resting orders and quotes as follows: 10 against Quote A at 1.00, 10 against Order A at 1.05, and 10 against Quote B at 1.10. The System will not automatically execute the remaining 70 contracts from the incoming order against Orders B and C, because C2 no longer has size available at the NBBO. The 70 unexecuted contracts are then exposed pursuant to HAL at 1.10 (which is the NBO). No responses to trade against the remaining 70 contracts are entered during the auction, so 5 contracts route away to trade at 1.10 against the 5 contracts available at an away exchange. The best offer from an away exchange then changes to 1.25. Of the remaining 65 unexecuted contracts from the incoming order, 10 trade against Order B at 1.15. The System will not automatically execute the remaining 55 contracts from the incoming order against Order C, because 1.20 is more than 0.15 away from the initial execution price of 1.00 and thus exceeds the drill through price check. These contracts will not be exposed pursuant to HAL again, and instead will rest in the book for two seconds at a price of 1.15. An incoming order to buy 20 at 1.15 is entered after one second, which trades against 20 of the 55 resting contracts. No other incoming orders are entered during that time period to trade against the remaining 35 contracts, so the System cancels that remaining portion of the original incoming order.

TPH-Designated Risk Settings

The proposed rule change amends Rule 6.17 to authorize the Exchange to share any TPH-designated risk settings in the system with a Clearing TPH that clears Exchange transactions on behalf of the TPH. Rule 3.1 states Trading Permits confer the ability to transact on the Exchange, and only CBOE Trading Permit Holders in good standing or non-CBOE Trading Permit Holders whose applications to become C2 Permit Holders are approved by the Exchange are eligible to receive Trading Permits. All Exchange transactions must be submitted for clearance to the Options Clearing Corporation (the ''Clearing Corporation'') and are subject to the Clearing Corporation's rules. For each Exchange transaction in which it participates, a Participant must immediately give up the name of the Clearing Participant through which the Exchange transaction will be cleared.[20] Each TPH must provide a letter of guarantee or authorization for the TPH's trading activities on the Exchange from a Clearing Participant.[21]

Thus, while not all TPHs are Clearing TPHs, all TPHs require a Clearing TPH's consent to clear Exchange transactions on their behalf in order to conduct business on the Exchange. The letter of authorization or guarantee describes the relationship between the TPH and Clearing TPH and provides the Exchange with notice of which Clearing TPHs have relationships with which TPHs. The Clearing TPH that guarantees the TPH's Exchange transactions has a financial interest in understanding the risk tolerance of the TPH. This proposed rule change would provide the Exchange with authority to provide Clearing TPHs directly with information that may otherwise be available to such Clearing TPHs by virtue of their relationship with respective TPHs.[22]

The risk settings that the Exchange may share with Clearing TPHs include, but are not limited to, settings under Rule 8.12 (related to QRM, as further described below), and will include

[19] The proposed rule change amends the market width price check parameter in Rule 6.17(a)(1) to be determined on a class-by-class basis rather than series-by-series. The Exchange generally sets parameters on a class-by-class basis. The proposed rule change makes additional nonsubstantive changes to Rule 6.17(a)(1), including moving provisions from current paragraph (c) applicable only to the market-width parameter (including the provision regarding setting the APR and the provision stating an order that does not meet the APR width will be cancelled) to proposed subparagraph (a)(1). The proposed rule change also amends Rule 6.11(g)(2) and Interpretation and Policy .04 to update the cross-reference to the drill through price check parameter and indicate the Exchange will determine the ATD for the opening drill through protection on a class-by-class rather than series-by-series basis consistent with the proposed rule change described above.

[20] *See* Rule 6.30.

[21] *See* Rule 3.10.

[22] The Exchange will share a TPH's risk settings with its Clearing TPH(s) upon request from the Clearing TPH(s).

settings under proposed Rule 6.17(g) (related to order entry and execution rate checks, as described below) and (h) (related to maximum contract size, as described below). To the extent the Exchange proposes additional rules providing for TPH-designated risk settings other than those in current rules and this rule filing, the Exchange will be able to share those settings with Clearing TPHs under this proposed change as well.[23] Other options exchanges have similar rules permitting them to share member-designated risk settings with other members that clear transactions on the member's behalf.[24]

Put Strike Price/Call Underlying Value Checks

The proposed rule change amends the put strike price and call underlying value checks in Rule 6.17(d). Pursuant to these checks, the System rejects back to the TPH a quote or buy limit order for (1) a put if the price of the quote bid or order is greater than or equal to the strike price of the option, or (2) a call if the price of the quote bid or order is greater than or equal to the consolidated last sale price of the underlying security, with respect to equity and exchange-traded fund options, or the last disseminated value of the underlying index, with respect to index options.[25] The proposed rule change extends this check to apply to market orders (or any remaining size after partial execution).

With respect to put options, a TPH seeks to buy an option that could be exercised into the right to sell the underlying. The value of a put can never exceed the strike price of the option, even if the underlying goes to zero. For example, one put for stock ABC with a strike price of $50 gives the holder the right to sell 100 shares of ABC for $50, no more or less. Therefore, it would be illogical to pay more than $50 for the right to sell shares of ABC, regardless of the price of ABC. Under this check, the Exchange deems any put bid or buy limit order with a price that equals or exceeds the strike price of the option to be erroneous and rejects it, and the Exchange believes it would be appropriate to similarly reject a market order (or remaining size after partial execution) that would execute at that erroneous price.

With respect to call options, a TPH seeks to buy an option that could be exercised into the right to buy the underlying. The Exchange does not believe a derivative product that conveys the right to buy the underlying should ever be priced higher than the prevailing value of the underlying itself. In that case, a market participant could purchase the underlying at the prevailing value rather than pay a larger amount for the call. Accordingly, under this check, the Exchange rejects bids or buy limit orders for call options with prices that are equal to or in excess of the value of the underlying. As an example, suppose a TPH submits an order to buy an ABC call for $11 when the last sale price for stock ABC is $10. The System rejects this order. The Exchange believes it would be appropriate to similarly reject a market order (or remaining size after partial execution) that would execute at that erroneous price.

The proposed rule change also states the put and call checks will not apply to market orders that execute during the opening process as set forth in Rule 6.11 to avoid impacting the determination of the opening price. Separate price protections apply during the opening process, including the drill through protection in Rule 6.11.[26]

Quote Inverting NBBO Check

The proposed rule change amends Rule 6.17(e) regarding the quote inverting NBBO check. Pursuant to this check, if C2 is at the NBO (NBB), the System rejects a quote back to a Market-Maker if the quote bid (offer) crosses the NBO (NBB) by more than a number of ticks specified by the Exchange. If C2 is not at the NBO (NBB), the System rejects a quote back to a Market-Maker if the quote bid (offer) locks or crosses the NBO (NBB).[27] If the NBBO is unavailable, locked or crossed, then this check compares the quote to the BBO (if available). The rule is currently silent on what happens if the BBO is also unavailable. Therefore, the proposed rule change clarifies the System does not apply this check to incoming quotes when the BBO is also unavailable, as there is no then-current price to use as a comparison to determine the reasonability of the quote. The proposed rule change also clarifies this is true when a series is open for trading.

The proposed rule change further clarifies the times when this check applies. Current Rule 6.17(e)(ii) provides the Exchange may not apply the check during the pre-opening, a trading rotation, or trading halt. Proposed Rule 6.17(e)(2) states prior to the opening of a series (including during any pre-opening period and opening rotation), the System does not apply this check to incoming quotes if the series is not open on another exchange. This is consistent with flexibility in the current rule permitting the Exchange to apply (or not apply) the check prior to the open. The Exchange believes without inputs of pricing from other exchanges, it is appropriate to not apply the check if a series is not yet open on another exchange to avoid rejecting quotes that may be consistent with market pricing not yet available in the System. Proposed Rule 6.17(e)(3) deletes the Exchange's flexibility to apply the quote inverting NBBO check during a trading halt. The Exchange currently does not apply the check to quotes entered during these times and does not expect to do so. The proposed rule change moves the provision permitting a senior official at the Exchange's Help Desk to determine not to apply this check in the interest of maintaining a fair and orderly market to proposed Rule 6.17(e)(4).

Execution of Quotes That Lock or Cross NBBO

The proposed rule change amends the provision related to the execution of quotes that lock or cross the NBBO in current Rule 6.17(e)(iii). As this is a separate limitation on execution than the quote inverting NBBO check in Rule 6.17(e),[28] the proposed rule change moves this limitation to proposed Rule 6.17(f) (and makes other nonsubstantive changes to the numbering and lettering within that paragraph, as well as adding a name to the paragraph). The rule currently states if the System accepts a quote that locks or crosses the NBBO, the System executes the quote bid (offer) against quotes and orders in the book at a price(s) that is the same or better than

[23] The proposed rule change also makes nonsubstantive changes to Rule 6.17, including adding risk controls to the name of the rule and an introductory sentence that the System's acceptance and execution of orders and quotes are subject to the price protection mechanisms and risk controls in Rule 6.17 and other rules.

[24] *See, e.g.,* Miami International Securities Exchange, LLC (''MIAX'') Rule 500; NASDAQ OMX BX, Inc. (''BX'') Chapter VI, Section 20; NYSE Arca, Inc. (''Arca'') Rule 6.2A(a); NYSE MKT LLC (''MKT'') Rule 902.1NY(a); and NASDAQ OMX PHLX LLC (''PHLX'') Rule 1016.

[25] Note the current rule states the check does not apply if market data for the underlying is unavailable. If the value of the underlying is not currently being disseminated, market data for the underlying will be considered ''unavailable.''

[26] The Exchange also makes a nonsubstantive change to Rule 6.17(d) so the language reads ''greater than or equal to'' rather than ''equal to or greater than,'' which is the standard phrase, as well as to re-letter and re-number subparagraphs to be consistent with other subparagraphs in the rule.

[27] The System also cancels any resting quote of the Market-Maker in the same series.

[28] The quote inverting NBBO check rejects quotes back to a Market-Maker if the quote bid (offer) crosses the NBO (NBB) by more than a specified number of ticks. The limitation on execution of quote that lock or cross the NBBO describes how the System will handle quotes that lock or cross the NBBO (but not by more than the specified number of ticks and thus are accepted).

the best price disseminated by an away exchange(s) up to the size available on the Exchange and either (1) cancels any remaining size of the quote, if the price of the quote locks or crosses the price disseminated by the away exchange(s), or (2) books any remaining size of the quote, if the price of the quote does not lock or cross the price of the away exchange(s).

In addition, the current rule is silent regarding the applicability of this limitation on execution to quotes when the NBBO is locked, crossed or unavailable. The purpose of this provision is to prevent trade-throughs and displays of locked and crossed markets in accordance with the Options Linkage Plan. However, when the NBBO is locked or crossed, it is unreliable for comparison purposes. Additionally, if there is no NBBO available, then there is no measure against which the System can compare the price of an incoming quote. Therefore, the proposed rule change states if the NBBO is locked, crossed or unavailable, the System does not apply this check to incoming quotes. The linkage rules similarly provide exceptions to the prohibitions on trade-throughs and crossed markets when there is a crossed market or systems or equipment malfunctions.[29] The proposed rule change adds a senior official at the Exchange's Help Desk may determine not to apply this check in the interest of maintaining a fair and orderly market.[30] The Exchange may believe it is appropriate to disable this check in response to a market event or market volatility to avoid inadvertently cancelling quotes not erroneously priced but rather priced to reflect potentially rapidly changing prices.

Order Entry, Execution and Price Parameter Rate Checks

The proposed rule change adopts order entry, execution and price parameter rate checks in proposed Rule 6.17(g). Currently, QRM (described below) provides Market-Makers with functionality to help manage their risk by limiting the number of quotes they may execute in a specified period of time (based on several parameters). The proposed order entry and execution rate checks will provide similar risk-management functionality for orders. These order risk protections are designed to aid TPHs in their risk management by supplementing current and proposed price reasonability checks with activity-based order protections that protect against entering too many orders, executing too many contracts, and having too many orders rejected because of price protection parameters in a short time, based on parameters entered by TPHs.

Specifically, the proposed rule change states each TPH must provide to the Exchange parameters for an acronym or, if the TPH requests, a login,[31] for each of the following rate checks. The System will count each of the following over rolling time intervals, which the Exchange will set and announce via Regulatory Circular:

(1) The total number of orders (of all order types) and auction responses entered and accepted by the System (''orders entered'');

(2) the total number of contracts (from orders and auction responses) executed on the System, which does not count stock contracts executed as part of stock-option orders (''contracts executed'');

(3) the total number of orders the System books or cancels (except orders (or any unexecuted portions) that by their terms cancel if they do not execute immediately (such as immediate-or-cancel, fill-or-kill, intermarket sweep, and market-maker trade prevention orders)) [32] pursuant to the drill through price check parameter (as amended by this proposed rule change) in proposed Rule 6.17(a)(2) (''drill through events''); and

(4) the total number of orders the System cancels pursuant to the limit order price parameters in Rules 6.13, Interpretation and Policy .04(f) and (g) and 6.17(b) (''price reasonability events'').

When the System determines the orders entered, contracts executed, drill through order [sic] events or price reasonability events within the applicable time interval exceeds a TPH's parameter, the System (1) rejects all subsequent incoming orders and quotes, (2) cancels all resting quotes (if the acronym or login is for a Market-Maker), and (3) for the orders entered and contracts executed checks, if the TPH requests (*i.e.,* this part of the proposed functionality is optional), cancels resting orders (either all orders, orders with time-in-force of day, or orders entered on that trading day) for the acronym or login, as applicable.

The System will not accept new orders or quotes from a restricted acronym or login, as applicable, until the Exchange receives the TPH's manual notification (in a form and manner determined by the Exchange, which will be announced by Regulatory Circular) to reactivate its ability to send orders and quotes for the acronym or login. While an acronym or login is restricted, a TPH may continue to interact with any resting orders (*i.e.,* orders not cancelled pursuant to this protection) entered prior to its acronym or login becoming restricted, including receiving trade execution reports and canceling resting orders.

While these order entry and execution rate checks are mandatory for all TPHs, the Exchange is not proposing to establish minimum or maximum values for the parameters described in (1) through (4) above. The Exchange believes this approach will give TPHs the flexibility needed to appropriately tailor these checks to their respective risk management needs. In this regard, the Exchange notes each TPH is in the best position to determine risk settings appropriate for its firm based on its trading activity and business needs. The Exchange will set the values of the time intervals; [33] however, the Exchange believes the amount of flexibility provided to TPHs by having no minimum or maximum values, or default values, for the parameters, as well as by permitting the parameters to be set at the acronym or login level, sufficiently allows TPHs to adjust their parameter inputs to these intervals in accordance with their business models and risk management needs.

The Exchange believes these proposed order entry and execution rate checks will assist TPHs in better managing their risk when trading on C2. In particular,

[29] *See* CBOE Rules 6.81 and 6.82 (which are incorporated by reference into the C2 Rules).

[30] Pursuant to Exchange procedures, any decision to not apply the quote inverting NBBO check, as well as the reason for the decision, will be documented, retained, and periodically reviewed.

[31] A TPH firm may have multiple acronyms. For each Trading Permit a TPH purchases, it receives up to three log-ins (the TPH may elect to use fewer than the three). Additionally, a TPH may purchase additional bandwidth packets, each of which comes with three log-ins. The TPH determines which log-ins will be used under which acronym. While not required, TPH firms, for example, may use one acronym, or log-in, for its proprietary business and another for its customer agency business (if the firm conducts both). Additionally, TPH firms sometimes use different log-ins for different customers. Allowing TPHs to set parameters for these protection mechanisms will allow TPHs to minimize the possibility of these mechanisms from affecting multiple businesses, if they choose to set up acronyms and log-ins in a manner that keeps these business separate.

[32] As discussed above, orders (or unexecuted portions) that by their terms cancel if they do not execute immediately will be cancelled rather than rest in the book for a period of time (as proposed in this filing) pursuant to the drill through price check parameter is [sic] triggered. Because these orders will not book or be cancelled pursuant to the drill through price check parameter (but rather because of their terms), these orders will not be included in the count for the drill through event check.

[33] The Exchange expects the initial time intervals for all these checks to be set at one and five minutes. The time intervals set by the Exchange will apply to all TPHs, who will not be able to change these time intervals.

the proposed rule change provides functionality that allows TPHs to set risk management thresholds for the number of orders entered or contracts executed on the Exchange during a specified period. This is similar to how other options exchanges have implemented activity-based risk management protections, and the Exchange believes this functionality will likewise benefit TPHs.[34] Additionally, similar to QRM, which includes a parameter for the maximum number of QRM incidents that will trigger cancellation of their orders and quotes once reached, the proposed rule change includes parameters for a maximum number of orders that book or cancel pursuant to the drill through check and cancel pursuant to the limit order price check. This could occur, for example, if a system issue is causing many orders to be submitted at prices that are too far away from the market and likely erroneous; this protection will help prevent execution of these erroneous orders.

The below examples illustrate how these order entry and execution rate checks will work:

Example #1—Order Entry Rate Check

A TPH designates an allowable orders entered rate of 9 orders/1 minute for acronym ABC.[35] The TPH enters three orders for acronym ABC, then enters nine additional orders one minute and thirty seconds later (for the same acronym). Because the orders entered did not exceed the TPH's designated rate for acronym ABC within one minute (the second batch of orders was entered more than one minute after the first batch of orders), acronym ABC is not restricted from submitting additional orders. Thirty seconds later, the TPH enters one additional order for acronym ABC. Entry of this order triggers the rate check because the TPH entered 10 orders in less than one minute for acronym ABC. At this time, acronym ABC becomes restricted,[36] and the System will reject all orders (and quotes, if acronym ABC is a Market-Maker), cancel any resting quotes (if acronym ABC is a Market-Maker), and cancel resting orders (if the TPH opted to enable that functionality). The TPH must contact the Exchange to resume trading for acronym ABC.

Example #2—Contracts Executed Rate Check

A TPH designates an allowable contracts executed rate of 999 contracts/1 minute for acronym DEF. The TPH enters an order to buy 600 contracts for acronym DEF, which immediately executes against a resting quote offer. One minute and 15 seconds after that execution, the TPH enters an order to sell 500 contracts for acronym DEF, which immediately executes against a resting quote bid. Because the two executions did not exceed the TPH's designated rate for acronym DEF within one minute (the second execution occurred more than one minute after the first execution), acronym DEF is not restricted from submitting additional orders. Forty-five seconds after the second execution, the TPH enters an order to buy 500 contracts for acronym DEF, which immediately executes against a resting sell order. Execution of this third order triggers the rate check because the TPH executed 1,000 contracts in less than one minute for acronym DEF. At this time, acronym DEF becomes restricted,[37] and the System will reject all orders (and quotes, if acronym DEF is a Market-Maker), cancel any resting quotes (if acronym DEF is a Market-Maker), and cancel resting orders (if the TPH opted to enable that functionality). The TPH must contact the Exchange to resume trading for acronym DEF.

Example #3—Drill Through Event Rate Check

A TPH designates an allowable drill through event rate of 1 event/1 minute for acronym GHI. The ATD for the class, whose minimum increment is 0.05, is 0.10 (*i.e.,* two minimum increments). The market for the XYZ Dec 50 call is 1.00–1.20, represented by an order for 100 contracts on each side. There are also resting orders to buy 100 at 0.90 and buy 100 at 0.80. The TPH enters a market order to sell 300 contracts for acronym GHI. One hundred contracts from the order execute against the resting order to buy 100 at 1.00 and 100 more contracts from the order execute against the resting order to buy 100 at 0.90. The System cancels the remaining 100 contracts of the order (pursuant to the drill through protection).[38] Thirty seconds later, the market for the XYZ Jan 40 call is 2.00–2.20, represented by an order for 100 contracts on each side. There are also resting orders to sell 100 at 2.25, sell 100 at 2.30, and sell 100 at 2.40. The TPH enters a market order to buy 500 contracts for acronym GHI. One hundred contracts from the order execute against the resting order to sell 100 at 2.20, 100 more contracts from the order execute against the resting order to sell 100 at 2.25, and 100 more contracts from the order execute against the resting order to sell 100 at 2.30. The System cancels the remaining 200 contracts (pursuant to the drill through protection). This is the second instance in less than one minute of the remaining portion of an order for acronym GHI being cancelled due to the drill through protection. At this time, acronym GHI becomes restricted, and the System will reject all orders (and quotes, if acronym GHI is a Market-Maker), and cancel any resting quotes (if acronym GHI is a Market-Maker). The TPH must contact the Exchange to resume trading for acronym GHI.

Example #4—Price Reasonability Event Rate Check

A TPH designates an allowable price reasonability event rate of 1 event/1 minute for acronym JKL. The ATD for the class, whose minimum increment is 0.05, is 0.10 (*i.e.,* two minimum increments). The market for the XYZ Dec 50 call is 1.00–1.20. The TPH enters a limit order to sell at 0.85 for acronym JKL. The System rejects the order because it is more than 0.10 below the NBB (pursuant to the limit order price parameter, as proposed to be changed). Thirty seconds later, the market for the XYZ Jan 40 call is 2.00–2.20. The TPH enters a limit order to buy at 2.40 for acronym JKL. The System rejects the order because it is more than 0.10 above the NBO (pursuant to the limit order price parameter, as proposed to be changed). This is the second instance in less than one minute of an order for acronym JKL being rejected due to the limit order price parameter. At this time, acronym JKL becomes restricted, and the System will reject all orders (and quotes, if acronym JKL is a Market-Maker), and cancel any resting quotes (if acronym JKL is a Market-Maker). The TPH must contact the Exchange to resume trading for acronym JKL.

Maximum Contract Size

The proposed rule change adds a maximum contract size risk control.

[34] *See, e.g.,* International Securities Exchange, LLC (''ISE'') Rule 714(d) and MIAX Rule 519A.

[35] As noted above, the Exchange intends to initially set intervals of one minute and five minutes, so the TPH would have a separate entry rate for the five-minute interval, which would be measured in the same manner demonstrated by these examples. This is true for each of the rate checks in proposed Rule 6.17(g).

[36] Note the System accepts the tenth order entered, as the check is not triggered until the orders entered exceeds the TPH's designated rate during a one-minute interval.

[37] Note the System executes this third order, as the check is not triggered until the contracts executed exceeds the TPH's designated rate during a one-minute interval.

[38] This presumes the order is not eligible for HAL or SAL. As discussed above, the Exchange has not activated these auctions on C2, and thus the proposed booking functionality will not be applicable on C2 upon approval of this rule filing.

Specifically, proposed Rule 6.17(h) states the System will reject a TPH's incoming order or quote (including both sides of a two-sided quote) if its size exceeds the TPH's designated maximum contract size parameter. Each TPH must provide a maximum contract size for each of simple orders, complex orders, and quotes applicable to an acronym or, if the TPH requests, a login.[39] The Exchange believes the amount of flexibility provided to TPHs by having no maximum for the contract size parameter, as well as by permitting the parameters to be set at the acronym or login level, sufficiently allows TPH to adjust their parameter inputs to these intervals in accordance with their business models and risk management needs. The Exchange believes this proposed risk control will help prevent executions of orders with size that may be potentially erroneous and mitigate risk associated with such executions. This is similar to how other options exchanges have implemented maximum contract size protections, and the Exchange believes this functionality will likewise benefit TPHs.[40]

If a TPH enters an order or quote to replace a resting order or update a resting quote, respectively, and the System rejects the incoming order or quote because it exceeds the applicable maximum contract size, the System will also cancel the resting order or any resting quote in the same series. The Exchange believes it is appropriate to reject or cancel the resting order or quote because, by submitting a replacement order or quote update because it exceeds the TPH's maximum contract size, the TPH is implicitly instructing the Exchange to cancel the resting order or quote, respectively. Thus, even if the System rejects the replacement order or quote update, the TPH's implicit instruction to cancel the resting order or quote remains valid nonetheless. Additionally, with respect to quotes, the Exchange believes it is appropriate to reject or cancel, as applicable, both sides of a quote (whether submitted as a two-sided quote or resting, respectively) because Market-Makers generally submit two-sided quotes, as their trading strategies and risk profiles are based on the spreads of their quotes. Rejecting and cancelling, as applicable, quotes on both sides of the series is consistent with this practice. The Exchange believes cancellation of resting quotes and orders, and rejection of both sides of a two-sided quote, operate as additional safeguards that cause TPHs to re-evaluate orders and quotes before attempting to submit new orders or quotes.

To the extent a TPH submits a pair of orders to the Automated Improvement Mechanism (''AIM'')[41] or the Solicitation Auction mechanism (''SAM''),[42] this proposed check will apply to both orders in the pair. If the System rejects either order in the pair, then the system will also cancel the paired order. It is the intent of these paired orders to execute against each other. Thus, the Exchange believes it is appropriate to reject both orders if one does not satisfy the maximum contract size check to be consistent with the intent of the submitting TPH. Notwithstanding the foregoing, with respect to A:AIR[43] orders, if the System rejects the agency order pursuant to the maximum contract size check, then the System will also reject the contra-side order. However, if the System rejects the contra-side order pursuant to this check, the System will accept the agency order (assuming it satisfies the check). The purpose of the A:AIR contingency provides the opportunity for the agency order (which is a customer of the submitting TPH) to execute despite not entering an AIM auction pursuant to which the order may execute against a facilitation or solicitation order of the TPH. The Exchange believes the proposed rule change is consistent with that contingency.

Kill Switch

The Exchange proposes to adopt a kill switch in proposed Rule 6.17(i). The kill switch will be an optional tool allowing a TPH to send a message to the System to, or contact the Exchange Help Desk to request that the Exchange, cancel all its resting quotes (if the acronym or login is for a Market-Maker), resting orders (either all orders, orders with time-in-force of day, or orders entered on that trading day), or both for an acronym or login. The System will send a TPH an automated message when the Exchange has processed a kill switch request for any acronym or login.

Once a TPH initiates the kill switch for an acronym or login, the System rejects all subsequent incoming orders and quotes for the acronym or login, as applicable. The System will not accept new orders or quotes from a restricted acronym or login until the Exchange receives the TPH's manual notification (in a form and manner determined by the Exchange, which will be announced by Regulatory Circular) to reactivate its ability to send orders and quotes for the acronym or login. While an acronym or login is restricted, a TPH may continue to interact with any resting orders (*i.e.,* orders not cancelled pursuant to the kill switch) entered prior to its acronym or login becoming restricted, including receiving trade execution reports and canceling resting orders. The proposed kill switch will provide TPHs with a powerful risk management tool for immediate control of their order and quote activity. It will offer TPHs a means to control their exposure through an interface not dependent on the integrity of their own systems, should they experience any type of system failure. This is similar to how other options exchanges have implemented kill switches, and the Exchange believes this functionality will likewise benefit TPHs.[44]

QRM Mechanism

The proposed rule change amends the QRM mechanism in Rule 8.12. QRM is functionality that automatically cancels a Market-Maker's quotes when certain parameter settings are triggered. Specifically, a Market-Maker may establish a (1) maximum number of contracts, (2) a maximum cumulative percentage of the original quoted size of each side of each series, and (3) the maximum number of series for which either side of the quote is fully traded that may trade within a rolling time period in milliseconds also established by the Market-Maker. When these parameters are exceeded within the time interval, the System cancels the Market-Maker's quotes in the class and other classes with the same underlying. Additionally, Rule 8.12 allows Market-Makers or TPH organizations to specify a maximum number of QRM incidents on an Exchange-wide basis. When the Exchange determines that a Market-Maker or TPH organization has reached its QRM incident limit during the rolling time interval, the System will cancel all of the Market-Maker's or TPH organization's electronic quotes and Market-Maker orders resting in the book in all option classes on the Exchange and prevent the Market-Maker or TPH organization from sending additional quotes or orders to the Exchange until the Market-Maker or TPH organization

[39] For purposes of determining the contract size of an incoming order or quote, the proposed rule states the contract size of a complex order will equal the contract size of the largest option leg of the order (*i.e.,* if the order is a stock-option order, this check will not apply to the stock leg of the order).

[40] *See, e.g.,* MIAX Rule 519(b).

[41] *See* Rule 6.51 for a description of the AIM auction process.

[42] *See* Rule 6.52 for a description of the SAM auction process.

[43] *See* Rule 6.51, Interpretation and Policy .10 for a description of the A:AIR functionality.

[44] *See, e.g.,* BOX Options Exchange LLC (''BOX'') Rule 7280 and PHLX Rule 1019(b).

reactivates its ability to send quotes or orders in a manner prescribed by the Exchange.

This functionality allows Market-Makers to provide liquidity across potentially hundreds of options series without being at risk of executing the full cumulative size of all these quotes before being given adequate opportunity to adjust their quotes. Use of this functionality has been voluntary for Market-Makers under the rules. From a technical perspective, Market-Makers currently do not need to enter any values into the applicable fields, and thus effectively can choose not to use these tools. The Exchange proposes to amend Rule 8.12 to make it mandatory for Market-Makers to enter values for each parameter for all classes in which it enters quotes. The purpose of the proposed rule change is to prevent Market-Makers from inadvertently entering quotes without risk-management parameters. The Exchange notes all Market-Makers currently have settings for these parameters. However, it is possible that a Market-Maker could inadvertently enter quotes without populating one or more of the parameters, resulting in the Market-Maker being exposed to much more risk than it intended. The proposed rule change will prevent this from occurring.

While entering values for the QRM parameters will be mandatory to prevent inadvertent exposure to risk, the Exchange notes Market-Makers who prefer to use their own risk-management systems can enter values that assure the Exchange parameters will not be triggered.[45] Accordingly, the proposed rule change provides Market-Makers with flexibility to use their own risk management tools. The Exchange notes other exchanges make similar functionality mandatory for all Market-Makers.[46]

Order of Application of Risk Controls/ Price Protections

Upon approval of this rule filing, the Exchange will have various risk controls and price protection mechanisms in place applicable to quotes and orders. The following lists the ''order'' in which the System will apply these controls and mechanisms to incoming quotes and orders:

Incoming Quotes

- Maximum contract size (proposed Rule 6.17(h));
- put/call check (current Rule 6.17(d), as proposed to be amended by this rule filing);
- execution of quotes that lock or cross the NBBO (current Rule 6.17(e)(iii), proposed to be moved to proposed Rule 6.17(f) in this rule filing); and
- quote inverting NBBO (current Rule 6.17(e), as proposed to be amended by this rule filing).

Note QRM may be triggered after a quote executes.

Incoming Simple Limit Orders

- Maximum contract size (proposed Rule 6.17(h));
- put/call check (current Rule 6.17(d), as proposed to be amended by this rule filing);[47] and
- limit order price parameter (current Rule 6.17(b), as proposed to be amended by this rule filing).

Note the order entry, execution and price parameter rate checks in proposed Rule 6.17(g) and the drill through price check parameter in current Rule 6.17(a)(2) (as proposed to be amended by this rule filing) may be triggered after a limit order executes.

Incoming Simple Market Orders

- Maximum contract size (proposed Rule 6.17(h));
- market-width price check parameter (current Rule 6.17(a)(1), as proposed to be amended (nonsubstantively) by this rule filing); and
- put/call check (current Rule 6.17(d), as proposed to be amended by this rule filing).[48]

Incoming Complex Orders

- Maximum contract size (proposed Rule 6.17(h));
- limit order price parameter (current Rule 6.13, Interpretation and Policy .04(g));
- debit/credit check (current Rule 6.13, Interpretation and Policy .04(c)) or buy-buy (sell-sell) strategy parameter (current Rule 6.13, Interpretation and Policy .04(d)), as applicable;
- maximum value acceptable price range check (current Rule 6.13, Interpretation and Policy .04(h));
- market width parameter (current Rule 6.13, Interpretation and Policy .04(a));
- credit-to-debit parameter (current Rule 6.13, Interpretation and Policy .04(b));
- percentage distance parameter (current Rule 6.13, Interpretation and Policy .04(e)); and
- stock-option derived net market parameter (current Rule 6.13, Interpretation and Policy .04(f)).

Note the order entry, execution and price parameter rate checks in proposed Rule 6.17(g) and the drill through price check parameter in Rule 6.17(a)(2) (as proposed to be amended by this rule filing) may be triggered after a market order executes.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Act and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[49] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[50] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[51] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

In particular, the proposed price protection mechanisms and risk controls will protect investors and the public interest and maintain fair and orderly markets by mitigating potential risks associated with market participants entering orders and quotes at unintended prices or sizes, and risks associated with orders and quotes trading at prices that are extreme and potentially erroneous, which may likely have resulted from human or operational error.

The Exchange believes amending the limit order price parameter for simple orders (current Rule 6.17(b)) to use the

[45] For example, a Market-Maker could set the value for the total number of contracts executed in a class at a level exceeding the total number of contracts it actually quotes in the class.

[46] *See, e.g.,* ISE Rule 804(g).

[47] If a limit order is an order marked to cancel and replace a resting limit order, the maximum contract size check applies after the put/call check. Generally, cancel and replace orders do not modify the size of a resting order, which the System would have already determined did not exceed the TPH's maximum contract size parameter. Therefore, the Exchange believed it was reasonable to apply a price reasonability check to these orders first, as that is the order information likely being changed.

[48] The pricing checks always apply after the maximum size check for market orders, because they apply at the time the System determines at what price these orders will execute, unlike limit orders entered with an execution price.

[49] 15 U.S.C. 78f(b).

[50] 15 U.S.C. 78f(b)(5).

[51] *Id.*

NBBO (rather than the Exchange previous day's closing price or BBO) when available perfects the mechanism of a free and open market and a national market system because it would more accurately reflect the then-current market. Thus, the Exchange believes it would be a better measure to use for purposes of determining the reasonability of the prices of orders and more accurately prevent executions of limit orders at erroneous prices, which ultimately protects investors. Continued use of the Exchange's previous day's closing price or BBO, as applicable, when no NBBO is available or the NBBO is not reliable will still provide continued price protection for orders during those times. The Exchange believes those prices would be the most relevant pricing information to determine the price at which an investor may want to buy or sell within a series, and the Exchange believes it is a reasonable substitute when no NBBO is available. The Exchange believes it is appropriate to have flexibility to determine to apply a different ATD to orders entered during the pre-opening, a trading rotation, or a trading halt to reflect different market conditions during those times. Additionally, the Exchange believes it is appropriate to not apply the check to orders with a stop contingency, because the prices that trigger execution of orders with a stop condition are intended to be outside the NBBO, and nonapplicability of this check is consistent with that condition. Therefore, the Exchange believes it is unnecessary to apply this check to stop-limit orders. This flexibility and non-applicability, as applicable, will further assist the Exchange with its efforts to maintain a fair and orderly market, which will ultimately protect investors. Application of the drill through check to market and marketable limit orders (and of the market width check only to market orders) is consistent with the current Rule and applicability of those checks; the proposed rule change merely deletes the Exchange's flexibility to apply each check to market orders, marketable limit orders, or both.

The proposed rule change to the drill through price check parameter (Rule 6.17(a)(2)) will benefit investors, as it describes how the System handles orders that were and were not previously exposed prior to trading at the drill through price. Additionally, the proposed rule change adds functionality to the drill through price check parameter to expose orders at the better of the NBBO or drill through price, and then rest orders (or any remaining unexecuted portions) in the book for a brief time period (not to exceed three seconds) with a price equal to the drill through price,[52] promotes just and equitable principles of trade and benefits investors by providing an additional opportunity for execution at a price at least as good as the NBBO and that does not appear to be erroneous prior to their cancellation while continuing to protect them against execution at erroneous prices. Excluding orders that by their terms cancel if they do not immediately execute from this proposed change is consistent with the terms of those orders. In addition, the proposed rule change to apply the drill through protection to orders eligible for SAL will prevent erroneous executions of more orders, which assists the Exchange in its efforts to maintain a fair and orderly market. The proposed rule change also clarifies an order will HAL at the better of the NBBO and the drill through price to ensure an order will not be exposed at a price worse than the NBBO (this is consistent with the current HAL rule, which exposes orders at the NBBO).

The proposed rule change to permit the Exchange to share TPH-designated risk settings with Clearing TPHs that clear transactions on the TPH's behalf (proposed introductory paragraph to Rule 6.17) will permit Clearing TPHs who have a financial interest in the risk settings of TPHs with whom they have entered into a letter of authorization or letter of guarantee given by such Clearing TPHs to such TPH to better monitor and manage the potential risks assumed by Clearing TPHs. Because such Clearing TPHs bear the risk associated with Exchange transactions of that TPH, it is appropriate for the Clearing TPHs to have knowledge of what risk settings the TPH may apply within the System. This knowledge will provide Clearing TPHs with greater control and flexibility in managing their own risk tolerance and exposure and aiding Clearing TPHs in complying with the Act. Additionally, to the extent a Clearing TPH might reasonably require a TPH to provide access to its risk settings as a prerequisite to continuing to clear trades on such TPH's behalf, the Exchange's proposed rule change to share those risk settings directly with a Clearing TPH reduces the administrative burden on the TPH and ensures that Clearing TPHs are receiving information that is up to date and conforms to settings active in the System. The Exchange also notes the proposed rule change is consistent with rules of other exchanges.[53]

The proposed rule change to expand the applicability of the put strike price and call underlying value check to market orders (current Rule 6.17(d)) will further assist the Exchange's efforts to maintain a fair and orderly market by mitigating the potential risks associated with additional orders trading at prices that exceed a corresponding benchmark (which may result in executions at prices that are potentially erroneous). The Exchange believes it promotes fair and orderly markets to not apply these checks to market orders executed during an opening rotation to avoid impacting the determination of the opening price (the Exchange notes separate price protections apply to orders during the opening process).

The proposed rule change to the quote inverting NBBO check (current Rule 6.17(e)) benefits investors by clarifying the System does not apply those checks to orders entered when there is no NBBO (or BBO with respect to the quote inverting NBBO check) available, as there is no reliable benchmark during those times against which the System can compare quote prices. This will remove impediments to and perfect the mechanism of a free and open market because these checks would not apply to quotes during times when there is no reliable price benchmark, and thus the check would not erroneously reject otherwise acceptable quotes, which may be disruptive to Market-Makers that provide necessary liquidity to the Exchange. The proposed rule change to delete the Exchange's flexibility regarding when to apply the quote inverting NBBO check and instead state in the Rules it will not apply prior to a series opening if the series is not open on another exchange, and it will not apply during a trading halt is appropriate and consistent with the current rule. The Exchange currently does not apply the check to quotes entered during a halt and does not expect to do so. With respect to quotes entered in series prior to the opening, the Exchange believes it is appropriate to not apply the check if a series is not yet open on another exchange to avoid rejecting quotes that may be consistent with market pricing not yet available in the System.

The proposed changes to the execution of quotes that lock or cross the NBBO (current Rule 6.17(e)(iii) and

[52] As discussed above, this functionality will not be applicable upon approval of this filing, because the Exchange has not activated HAL and SAL for any classes on C2. Unless C2 activates those auctions for a class, the drill through parameter will function in the same manner as it does today.

[53] *See, e.g.,* MIAX Rule 500; BX Chapter VI, Section 20; NYSE Arca Rule 6.2A(a); NYSE MKT Rule 902.1NY(a); and PHLX Rule 1016.

proposed Rule 6.17(f)) to not apply the check when the NBBO is locked, crossed or unavailable, or to allow the Exchange to disable this check in response to a market event or market volatility in the interest of maintaining a fair and orderly market, will prevent the System from inadvertently cancelling quotes when there is no reliable measure against which to compare the price of the order to determine its reasonability, or that are not erroneously priced but rather priced to reflect potentially rapidly changing prices, respectively, which will assist with the maintenance of a fair and orderly market.

The Exchange believes the proposed order entry, execution and price parameter rate checks (proposed Rule 6.17(g)) will assist with the maintenance of a fair and orderly market by establishing new activity based risk protections for orders. The Exchange currently offers QRM, a risk protection mechanism for Market-Maker quotes, which the Exchange believes has been successful in reducing Market-Maker risk, and now proposes to adopt risk protections for orders that would allow other TPHs to similarly manage their exposure to excessive risk. In particular, the proposed rule change implements four new risk protections based on order entry and execution rates as well as rates of orders that trigger the drill through or price reasonability parameters. The Exchange believes these new protections would enable TPHs to better manage their risk when trading on the Exchange by limiting their risk exposure when systems or other issues result in orders being entered or executed, as well as executed at extreme prices, at rates that exceed predefined thresholds. In today's market, the Exchange believes robust risk management is becoming increasingly more important for all TPHs. The proposed rule change would provide an additional layer or risk protection for TPHs. In particular, these rate checks are designed to reduce risk associated with system errors or market events that may cause TPHs to send a large number of orders, receive multiple, automatic executions, or execute a large number of orders at extreme and potentially erroneous prices, before they can adjust their exposure in the market. The proposed order entry and execution rate checks are similar to risk management functionality provided by other options exchanges.[54] While the order entry and contracts executed rate checks apply to all TPHs, it is optional for TPHs to have resting orders (or certain subcategories of resting orders) cancelled when a rate check is triggered and an acronym or login becomes restricted.

The proposed maximum contract size risk control (proposed Rule 6.17(h)) is designed to help TPHs avoid potential submission of erroneously sized orders on the Exchange. Similar to functionality intended to protect against orders and quotes executing at unintended prices, this proposed functionality will assist in the maintenance of a fair and orderly market and protect investors by rejecting orders and quotes that are ''too large'' to prevent executions at unintended sizes and mitigate risks associated with such executions that are potentially erroneous. The Exchange believes the additional risk control feature to reject or cancel the resting order or quote when an incoming replacement order or quote update is rejected pursuant to this proposed risk control is appropriate because, by submitting a replacement order or quote update, the TPH is implicitly instructing the Exchange to cancel the resting order or quote, respectively. Additionally, the Exchange believes it is appropriate to reject or cancel, as applicable, both sides of a quote because Market-Makers generally submit two-sided quotes, as their trading strategies and risk profiles are based on spreads of their quotes, and rejecting and cancelling, as applicable, both sides of a quote is consistent with this practice. The Exchange believes cancellation of resting quotes and orders, and rejection of both sides of a quote, operate as additional safeguards that cause TPHs to re-evaluate orders and quotes before attempting to submit new orders or quotes. This will further protect against erroneous trades, which protects investors. The Exchange also believes the proposed rule change regarding how the proposed check will apply to AIM and SAM orders is reasonable, as the proposed rule change is consistent with the contingencies attached to those types of orders.

With respect to the proposed order entry, execution and price parameter rate checks and maximum contract size check (as well as the existing QRM functionality), the Exchange believes it is appropriate to not have minimum or maximum values, or default values, for the parameters, to provide sufficient flexibility to TPHs to adjust their parameter inputs in accordance with their business and risk management needs. The Exchange believes price protection mechanisms benefits its market and the options industry as a whole, however, ultimately these mechanisms primarily protect TPHs against erroneous executions of their orders and quotes. C2 appreciates the parameter settings determine whether these protections will be meaningful. Based on discussions with TPHs regarding its current and proposed package of risk controls and price protection mechanisms, the Exchange understands TPHs support the implementation of price protection mechanisms such as these and expects TPHs to input settings that are meaningful so they can take full advantage of the benefits these mechanisms are intended to provide.

The proposed kill switch (proposed Rule 6.17(i)) is an optional tool offered to all TPHs. The Exchange represents the proposed kill switch will operate consistently with the firm quote obligations of a broker-dealer pursuant to Rule 602 of Regulation NMS and the functionality is not mandatory. Specifically, any interest executable against a TPH's quotes and orders received by the Exchange prior to the time the kill switch is processed by the Exchange will automatically execute at the price up to the TPH's size. The kill switch message will be accepted by the System in the order of receipt in the queue and will be processed in that order so that interest already in the System will be processed prior to the kill switch message. A Market-Maker's utilization of the kill switch, and subsequent removal of its quotes, does not diminish or relieve the Market-Maker of its obligation to provide continuous two-sided quotes. Market-Makers will continue to be required to provide continuous two-sided quotes on a daily basis, and a Market-Maker's utilization of the kill switch will not prohibit the Exchange from taking disciplinary action against the Market-Maker for failing to meet the continuing quoting obligation each trading day. All TPHs may determine whether a kill switch cancels resting quotes, resting orders (or certain subcategories of resting orders), or both. The Exchange also notes the proposed rule change is consistent with rules of other exchanges.[55]

The Exchange believes requiring Market-Makers to enter values into the risk parameters of the QRM mechanism (current Rule 8.12) will not be unreasonably burdensome, as all Market-Makers currently utilize the functionality. Additionally, the proposed rule change will assist Market-Makers in reducing their risk of inadvertently entering quotes without populating the risk parameters.

[54] *See, e.g.,* ISE Rule 714(d) and MIAX Rule 519A.

[55] *See, e.g.,* BOX Rule 7280 (b) and PHLX Rule 1019(b).

Reducing this risk will enable Market-Makers to enter quotations with larger size, which in turn will benefit investors through increased liquidity for the execution of their orders. Such increased liquidity benefits investors because they receive better prices and because it lowers volatility in the options market.

While entering values for the QRM parameters will be mandatory to prevent inadvertent exposure to risk, the Exchange notes Market-Makers who prefer to use their own risk-management systems can enter values that assure the Exchange parameters will not be triggered. Accordingly, the proposed rule change provides Market-Makers with flexibility to use their own risk management tools. The Exchange notes other exchanges make similar functionality mandatory for all Market-Makers.[56]

The individual firm benefits of enhanced risk protections flow downstream to counterparties both at the Exchange and at other options exchanges, which increases systemic protections as well. The Exchange believes these risk protections will allow TPHs to enter orders and quotes with reduced fear of inadvertent exposure to excessive risk, which will benefit investors through increased liquidity for the execution of their orders, thereby protecting investors and the public interest. Without adequate risk management tools, such as those proposed in this filing, TPHs could reduce the amount of order flow and liquidity they provide. Such actions may undermine the quality of the markets available to customers and other market participants. Accordingly, the proposed rule change is designed to encourage TPHs to submit additional order flow and liquidity to the Exchange, thereby removing impediments to and perfecting the mechanisms of a free and open market and a national market system and, in general, protecting investors and the public interest. In addition, providing TPHs with more tools for managing risk will facilitate transactions in securities because, as noted above, TPHs will have more confidence protections are in place that reduce the risks from potential system errors and market events. As a result, the new functionality as the potential to promote just and equitable principles of trade.

The Exchange notes TPHs must be mindful of their obligations to seek best execution of orders handled on an agency basis. Decisions to use the optional functionality described in this filing (*i.e.,* cancellation of orders when an acronym or log-in becomes restricted after exceeding the orders entered or contracts executed rate, cancellation of orders upon initiation of a kill switch), and decisions on values of parameters (*i.e.,* parameters for the orders entered, contracts executed and price parameter rate check, maximum contract size check), must be made consistent with this duty.

B. Self-Regulatory Organization's Statement on Burden on Competition

C2 does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change adds price protection mechanisms and risk controls for orders and quotes of all Trading Permit Holders submitted to C2 to help further prevent potentially erroneous executions, which benefits all market participants. These mechanisms and controls apply to orders of all TPHs, and quotes of all Market-Makers, in the same manner. The proposed rule changes related to the quote inverting NBBO check, the execution of quotes that lock or cross the NBBO check, and QRM apply only to Market-Makers because only Market-Makers may submit quotes under the Rules, and because similar protections applicable to orders are in place or also proposed in this rule filing. Additionally, the Exchange believes these types of protection for Market-Makers are appropriate given their unique role in the market and may encourage Market-Makers to quote tighter and deeper markets, which will increase liquidity and enhance competition, given the additional protection these price checks will provide. The Exchange believes the proposed rule change would provide market participants with additional protection from risks related to erroneous executions. Certain of the proposed protections are similar to those available on other exchanges.[57]

While the proposed rule change makes entry of parameters into the QRM mechanism mandatory, the Exchange notes all Market-Makers currently avail themselves of this mechanism today. Additionally, the Exchange believes the use of QRM will prevent the inadvertent entry of quotes without risk-management parameters. Market-Makers who prefer to use their own risk-management systems can enter out-of-range values so the Exchange-provided parameters will not be triggered and can function as back-up protection. While entering values for the QRM parameters will be mandatory to prevent inadvertent exposure to risk, the Exchange notes Market-Makers who prefer to use their own risk-management systems can enter values that assure the Exchange parameters will not be triggered. Accordingly, the proposed rule change provides Market-Makers with flexibility to use their own risk management tools. The Exchange notes other exchanges make similar functionality mandatory for all Market-Makers.[58]

With respect to the proposed kill switch functionality, all TPHs may avail themselves of the kill switch, which functionality is optional. The proposed rule change is intended to protect TPHs in the event they experience a systems issue or unusual or unexpected market activity that would require them to withdraw from the market to protect investors. The ability to control risk at either the acronym or login level will permit a TPH to protect itself from inadvertent exposure to excessive risk at each level. Reducing such risk will enable TPHs to enter quotes and orders with protection against inadvertent exposure to excessive risk, which in turn will benefit investors through increased liquidity for the execution of their orders. Such increased liquidity benefits investors because they may receive better prices and because it may lower volatility in the options market. Additionally, the proposed kill switch functionality is similar to that available on other exchanges.[59]

The proposed rule change to permit the Exchange to share TPH-designated risk settings with Clearing TPHs that clear transaction on behalf of the TPH is not designed to address any competitive issues and does not pose any undue burden on non-Clearing TPHs because, unlike Clearing TPHs, non-Clearing TPHs do not guarantee the execution of transactions on the Exchange. The proposed rule change applies the same to all TPHs and Clearing TPHs. Any TPH that does not wish to have the Exchange share designated risk settings with its Clearing TPHs could avoid this by becoming a clearing member of the Clearing Corporation. The Exchange notes other exchanges' rules permit sharing of these settings with clearing members.[60]

[56] *See, e.g.,* ISE Rule 804(g).

[57] *See, e.g.,* ISE Rule 714(d) and MIAX Rule 519A (order entry and execution rate checks); and MIAX Rule 519(b) (order contract size).

[58] *See, e.g.,* ISE Rule 804(g).

[59] *See, e.g.,* BOX Rule 7280(b) and PHLX Rule 1019(b).

[60] *See, e.g.,* MIAX Rule 500; BOX Chapter VI, Section 20; NYSE Arca Rule 6.2A(a); NYSE MKT Rule 901.1NY(a); and PHLX Rule 1016 (sharing TPH-designated risk settings).

The individual firm benefits of enhanced risk protections flow downstream to counterparties both at the Exchange and at other options exchanges, which increases systemic protections as well. The Exchange believes these risk protections will allow TPHs to enter orders and quotes with reduced fear of inadvertent exposure to excessive risk, which will benefit investors through increased liquidity for the execution of their orders. Without adequate risk management tools, such as those proposed in this filing, TPHs could reduce the amount of order flow and liquidity they provide. Such actions may undermine the quality of the markets available to customers and other market participants. Accordingly, the proposed rule change is designed to encourage TPHs to submit additional order flow and liquidity to the Exchange, which may ultimately promote competition. In addition, providing TPHs with more tools for managing risk will facilitate transactions in securities because, as noted above, TPHs will have more confidence protections are in place that reduce the risks from potential system errors and market events.

Based on discussions with TPHs regarding its current and proposed package of risk controls and price protection mechanisms, the Exchange understands TPHs support the implementation of price protection mechanisms such as these and expects TPHs to input settings that are meaningful so they can take full advantage of the benefits these mechanisms are intended to provide.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the Exchange consents, the Commission will:

A. By order approve or disapprove such proposed rule change, or

B. institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–C2–2016–020 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–C2–2016–020. 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–C2–2016–020, and should be submitted on or before November 25, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[61]

Brent J. Fields,

Secretary.

[FR Doc. 2016–26510 Filed 11–2–16; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–79190; File No. SR–FINRA–2016–040]

Self-Regulatory Organizations; Financial Industry Regulatory Authority, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend FINRA Rule 7730 To Establish a Fee for the Academic Corporate Bond TRACE Data Product

October 28, 2016.

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 25, 2016, 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 Substance of the Proposed Rule Change

FINRA is proposing to amend FINRA Rule 7730 to establish a fee for the Academic Corporate Bond TRACE Data product.

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.

[61] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(ii).

[4] 17 CFR 240.19b–4(f)(2).

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, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

FINRA's TRACE data product offerings, set forth in Rule 7730 (Trade Reporting and Compliance Engine (TRACE)), include both real-time as well as historic data for most TRACE-eligible securities. The SEC recently approved a new TRACE data product composed of enhanced historic data available solely to academics (*i.e.,* requests originating from an institution of higher education).[5] The new TRACE data product—Academic Corporate Bond TRACE Data — will contain transaction-level data on historic transactions in corporate bonds and will include masked counterparty information.[6] Specifically, ''Academic Corporate Bond TRACE Data'' means historic transaction-level data on all transactions in corporate bonds reported to TRACE (except a transaction that is a List or Fixed Offering Price Transaction, as defined in Rule 6710(q), or a Takedown Transaction, as defined in Rule 6710(r)), including Rule 144A transactions in corporate bonds, with elements to be determined from time to time by FINRA in its discretion and as stated in a *Regulatory Notice* or other equivalent publication.[7]

The Academic Corporate Bond TRACE Data will be delayed a minimum of 36 months and will not include Market Participant Identifiers (''MPIDs''), but will substitute a masked dealer identifier for each MPID included in the data.[8] Applicants for Academic Corporate Bond TRACE Data will be required to execute appropriate agreements with FINRA.[9]

FINRA is now proposing to amend FINRA Rule 7730 (Trade Reporting and Compliance Engine (TRACE)) to establish fees for the Academic Corporate Bond TRACE Data product. FINRA is proposing to establish a data fee of $500 per calendar year (with a single set-up fee of $500) for receipt of the Academic Corporate Bond TRACE Data product. FINRA believes that this fee is reasonable, and notes that the subscription fee for the Historic TRACE Data Sets is $500 per year (per data set), with a single fee of $1,000 for development and set-up to receive Historic TRACE Data for qualifying tax-exempt organizations.

FINRA has filed the proposed rule change for immediate effectiveness. The effective date of the proposed rule change will be the date of effectiveness of the Academic Corporate Bond TRACE Data product.[10]

2. Statutory Basis

FINRA believes that the proposed rule change is consistent with the provisions of Section 15A(b)(5) of the Act,[11] 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.

Pursuant to the proposal, FINRA will establish fees to make available to institutions of higher education an enhanced historic TRACE data product that will include transaction-level data on corporate bonds on a 36-month delayed basis with masked MPIDs. Academic Corporate Bond TRACE Data will be made available only to institutions of higher education for a fee of $500 per calendar year (with a single set-up fee of $500). FINRA believes that the proposed fees are reasonable, and notes that the fees will be applied equally to all institutions of higher education that choose to subscribe to the data product. Thus, FINRA believes that the proposed rule change is consistent with the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

FINRA does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposal to create a new Academic Corporate Bond TRACE Data product would not impose any additional reporting requirements or costs on firms and, as a result, would have no direct impact on firms. The proposal to establish fees in connection with the new Academic Corporate Bond TRACE Data product applies only to institutions of higher education that choose to subscribe to the data product, and the proposed fees will apply equally to all such subscribers.

C. *Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others*

FINRA solicited comment on a proposal to establish an enhanced historic data product with masked dealer identifiers in *Regulatory Notice* 15–26, including the proposal of a $500 fee per data set and a one-time initial set-up fee of $500. FINRA received four comment letters in response to the *Regulatory Notice.*[12] A copy of the *Regulatory Notice* is attached as Exhibit 2a. A list of comment letters received in response to the *Regulatory Notice* is attached as Exhibit 2b. Copies of the comment letters received in response to the *Regulatory Notice* are attached as Exhibit 2c. Of the four comment letters received, none of the commenters discussed the $500 fee per data set or the single set-up fee of $500.

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 [13] and paragraph (f)(2) of Rule 19b–4 thereunder.[14] 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

[5] *See* Securities Exchange Act Release No. 78759 (September 2, 2016), 81 FR 62222 (September 8, 2016) (''Order Approving File No. SR–FINRA–2016–024'').

[6] *See* Rule 7730(g)(5).

[7] *See supra* note 6.

[8] *See supra* note 6.

[9] *See* Rule 7730(e).

[10] *See* Order Approving File No. SR–FINRA–2016–024. FINRA will announce the effective date of the Academic Corporate Bond TRACE Data product in a *Regulatory Notice* to be published no later than 90 days following Commission approval. The effective date will be no later than 270 days following publication of that *Regulatory Notice.*

[11] 15 U.S.C. 78*o*–3(b)(5).

[12] *See* Letter from Michael Nicholas, Chief Executive Officer, Bond Dealers of America, to Marcia E. Asquith, Corporate Secretary, FINRA, dated August 24, 2015 (''BDA''), letter from Luis Palacios, Director of Research Services, The Wharton School, to Marcia E. Asquith, Corporate Secretary, FINRA, dated September 10, 2015 (''Wharton''), letter from David L. Cohen, Managing Director & Associate General Counsel, and Sean Davy, Managing Director, Securities Industry and Financial Markets Association, to Marcia E. Asquith, Corporate Secretary, FINRA, dated September 11, 2015 (''SIFMA''), and letter from Carrie Devorah, Founder, The Center for Copyrights Integrity, to Marcia E. Asquith, Corporate Secretary, FINRA, dated September 14, 2015 (''CCI'').

[13] 15 U.S.C. 78s(b)(3)(A).

[14] 17 CFR 240.19b–4(f)(2).

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–2016–040 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–FINRA–2016–040. 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 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–2016–040, and should be submitted on or before November 25, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[15]

Brent J. Fields,

Secretary.

[FR Doc. 2016–26509 Filed 11–2–16; 8:45 am]

BILLING CODE 8011–01–P

[15] 17 CFR 200.30–3(a)(12).

DEPARTMENT OF STATE

[Public Notice 9781]

E.O. 13224 Designation of Abu Ali Tabatabai, aka Abu Ali Tabtabai, aka Abu 'Ali Al-Tabataba'i, aka Haytham 'Ali Tabataba'i, as a Specially Designated Global Terrorist

Acting under the authority of and in accordance with section 1(b) of Executive Order 13224 of September 23, 2001, as amended by Executive Order13268 of July 2, 2002, and Executive Order 13284 of January 23, 2003, I hereby determine that the individual known as Abu Ali Tabatabai, aka Abu Ali Tabtabai, aka Abu 'Ali Al-Tabataba'i, aka Haytham 'Ali Tabataba'i,, committed, or poses a significant risk of committing, acts of terrorism that threaten the security of U.S. nationals or the national security, foreign policy, or economy of the United States.

Consistent with the determination in section 10 of Executive Order 13224 that prior notice to persons determined to be subject to the Order who might have a constitutional presence in the United States would render ineffectual the blocking and other measures authorized in the Order because of the ability to transfer funds instantaneously, I determine that no prior notice needs to be provided to any person subject to this determination who might have a constitutional presence in the United States, because to do so would render ineffectual the measures authorized in the Order.

This notice shall be published in the **Federal Register**.

Dated: September 12, 2016.

John F. Kerry,

Secretary of State.

[FR Doc. 2016–26596 Filed 11–2–16; 8:45 am]

BILLING CODE 4710–AD–P

DEPARTMENT OF STATE

[Public Notice: 9783]

60-Day Notice of Proposed Information Collection: Exchange Programs Alumni Web Site Registration

ACTION: Notice of request for public comment.

SUMMARY: The Department of State is seeking Office of Management and Budget (OMB) approval for the information collection described below. In accordance with the Paperwork Reduction Act of 1995, we are requesting comments on this collection from all interested individuals and organizations. The purpose of this notice is to allow 60 days for public comment preceding submission of the collection to OMB.

DATES: The Department will accept comments from the public up to *January 3, 2017.*

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

- *Web:* Persons with access to the Internet may use the Federal Docket Management System (FDMS) to comment on this notice by going to *www.Regulations.gov.* You can search for the document by entering the docket number (DOS–2016–0052) in the Search bar.
- *Email: MessingerCB@state.gov.*
- *Mail:* Bureau of Educational and Cultural Affairs; U.S. Department of State; SA–5, Room C2–C20; Washington, DC 20522–0503.

You must include the DS form number, information collection title, and the OMB control number in any correspondence.

FOR FURTHER INFORMATION CONTACT: Direct requests for additional information regarding the collection listed in this notice, including requests for copies of the proposed collection instrument and supporting documents, to Carlyn Messinger, Alumni Outreach Specialist, Bureau of Educational and Cultural Affairs; U.S. Department of State; SA–5, Room C2–C20; Washington, DC 20522–0503, who may be reached on 202–632–6183 or at *MessingerCB@state.gov.*

SUPPLEMENTARY INFORMATION:

- *Title of Information Collection:* Exchange Programs Alumni Web site Registration.
- *OMB Control Number:* 1405–0192.
- *Type of Request:* Revision of an Approved Request.
- *Originating Office:* Bureau of Educational and Cultural Affairs, ECA/P/A.
- *Form Number:* DS–7006.

• *Respondents:* Exchange program alumni and current participants of U.S. government-sponsored exchange programs.

• *Estimated Number of Respondents:* 5,000 for full form, and 41,000 for expedited form.

• *Estimated Number of Responses:* 46,000.

• *Average Time per Response:* 10 minutes for response to the full form or 2 minutes for response to the expedited form.

• *Total Estimated Burden Time:* 2,200 hours (reduction of approximately 30% since last approval).

• *Frequency:* One time per respondent.

• *Obligation To Respond:* Required to Obtain or Retain a Benefit.

We are soliciting public comments to permit the Department to:

• Evaluate whether the proposed information collection is necessary for the proper functions of the Department.

• Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used.

• Enhance the quality, utility, and clarity of the information to be collected.

• Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Please note that comments submitted in response to this Notice are public record. Before including any detailed personal information, you should be aware that your comments as submitted, including your personal information, will be available for public review.

Abstract of proposed collection: The International Exchange Alumni Web site requires information to process users' voluntary request for participation in the International Exchange Alumni Web site. Other than contact and exchange program information, which is required for Web site registration, all other information is provided on a voluntary basis. Participants also have the option of restricting access to their information.

Respondents to this registration form are U.S. government-sponsored exchange program participants and alumni. Alumni Affairs collects data from users not only to verify their status or participation in a program, but to help alumni network with one another and aid Embassy staff in their alumni outreach. Once a user account is activated, the same information may be used for contests, competitions, and other public diplomacy initiatives in support of Embassy and foreign policy goals.

Methodology: Information provided for registration is collected electronically via the Alumni Web site, *alumni.state.gov.*

Additional Information: Since the previous approval, improvements made to the Web site have decreased the burden to respondents by 30%. International Exchange Alumni is a secure, encrypted Web site.

Dated: October 7, 2016.

Alyson Grunder,

Director, Office of Policy and Evaluation, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2016–26594 Filed 11–2–16; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

[Docket No. PHMSA–2016–0127]

Pipeline Safety: Research and Development Forum

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), DOT.

ACTION: Notice of public forum.

SUMMARY: This notice announces a PHMSA sponsored Pipeline Safety Research and Development Forum. PHMSA periodically holds this public forum to generate a national research agenda that fosters solutions for the many challenges with pipeline safety and with protecting the environment. This forum allows public, government, and industry pipeline stakeholders to develop a consensus on the technical gaps and challenges for future research. It also reduces duplication of programs, factors ongoing research efforts, leverages resources, and broadens synergies. The national research agenda developed through this forum is aligned with the needs of the pipeline safety mission and makes use of the best available knowledge and expertise and considers stakeholder perspectives.

DATES: The public forum will be held on November 16–17, 2016. Name badge pick up and on-site registration will be available starting at 7:00 a.m. on November 16, with the public forum taking place from 8:00 a.m. until approximately 4:30 p.m., November 17 central time.

ADDRESSES: The public forum will be held at the Cleveland Marriott Downtown at Key Center, 127 Public Square, (Driveway Entrance on 1360 West Mall Drive), Cleveland, OH 44114. The hotel can be contacted at 800–228–9290 or 216–696–9200 or at *http://www.marriott.com/hotels/travel/clesc-cleveland-marriott-downtown-at-key-center/.*

FOR FURTHER INFORMATION CONTACT: Robert Smith, Engineering and Research Division, at 919–238–4759 or *robert.w.smith@dot.gov.*

SUPPLEMENTARY INFORMATION:

Registration: Members of the public may attend this free forum. Please note that this public forum will not be available by webcast. Onsite registration will also be available for those attending in person. Event reporting and presentations will be available shortly after the public forum.

Comments: Members of the public may submit written comments either before or after the public forum. Comments should reference Docket No. PHMSA–2016–0127. Comments may be submitted in the following ways:

• *E-Gov Web site: http://www.regulations.gov.* This site allows the public to enter comments on any **Federal Register** notice issued by any agency. Follow the instructions for submitting comments.

• *Fax:* 1–202–493–2251.

• *Mail:* Docket Management System, U.S. Department of Transportation (DOT), 1200 New Jersey Avenue SE., Room W12–140, Washington, DC 20590.

Hand Delivery: DOT Docket Management System, Room W12–140, on the ground floor of the West Building, 1200 New Jersey Avenue SE., Washington, DC between 9:00 a.m. and 5:00 p.m., Monday through Friday, except Federal holidays.

Instructions: Identify the docket number PHMSA–2016–0127 at the beginning of your comments. If you submit your comments by mail, submit two copies. If you wish to receive confirmation that PHMSA has received your comments, include a self-addressed stamped postcard. Internet users may submit comments at *http://www.regulations.gov.*

Note: Comments will be posted without changes or edits to *http://www.regulations.gov* including any personal information provided. Please see the Privacy Act Statement below for additional information.

Privacy Act Statement

Anyone may search the electronic form of all comments received for any of our dockets. You may review DOT's complete Privacy Act Statement in the **Federal Register** published April 11, 2000, (65 FR 19476) or visit *http://dms.dot.gov.*

Information on Services for Individuals With Disabilities

For information on facilities or services for individuals with disabilities, or to request special assistance at the meeting, please contact Robert Smith, Engineering and Research Division, at 919–238–4759 or *robert.w.smith@dot.gov.*

Issued in Washington, DC on October 31, 2016, under authority delegated in 49 CFR 1.97.

Linda Daugherty,

Deputy Associate Administrator for Field Operations.

[FR Doc. 2016–26564 Filed 11–2–16; 8:45 am]

BILLING CODE 4910–60–P

DEPARTMENT OF TRANSPORTATION

[PHMSA–2008–0213 Empire Pipeline, Inc.]

Pipeline Safety; Request for Special Permit

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), Transportation.

ACTION: Notice.

SUMMARY: PHMSA is publishing this notice to seek public comments on a request for special permit, seeking relief from compliance with certain requirements in the federal pipeline safety regulations. At the conclusion of the 30-day comment period, PHMSA will review the comments received from this notice as part of its evaluation to grant or deny the special permit request.

DATES: Submit any comments regarding this special permit request by December 5, 2016.

ADDRESSES: Comments should reference Docket No. PHMSA–2008–0213 and may be submitted in the following ways:

- *E-Gov Web site: http://www.Regulations.gov.* This site allows the public to enter comments on any **Federal Register** notice issued by any agency.
- *Fax:* 1–202–493–2251.
- *Mail:* Docket Management System: U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.
- *Hand Delivery:* Docket Management System: U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9:00 a.m. and 5:00 p.m., Monday through Friday, except Federal holidays.

Instructions: You should identify the docket number for the special permit request you are commenting on at the beginning of your comments. If you submit your comments by mail, please submit two copies. To receive confirmation that PHMSA has received your comments, please include a self-addressed stamped postcard. Internet users may submit comments at *http://www.Regulations.gov.*

Note: Comments are posted without changes or edits to *http://www.Regulations.gov,* including any personal information provided. There is a privacy statement published on *http://www.Regulations.gov.*

FOR FURTHER INFORMATION CONTACT:

General: Ms. Kay McIver by telephone at 202–366–0113, or email at *kay.mciver@dot.gov.*

Technical: Mr. Steve Nanney by telephone at 713–628–7479, or email at *Steve.Nanney@dot.gov.*

SUPPLEMENTARY INFORMATION: PHMSA has received a special permit request from a pipeline operator seeking relief from compliance with certain federal pipeline safety regulations. The request includes a technical analysis and draft Environmental Analysis (EA), provided by the operator and has been filed at *www.Regulations.gov*, in Docket No. PHMSA–2008–0213. PHMSA invites interested persons to participate by reviewing this special permit request and draft EA at *http://www.Regulations.gov*, and by submitting written comments, data or other views. Please include any comments on potential safety and environmental impacts that may result if the special permit is granted.

Before issuing a decision on this special permit request, PHMSA will evaluate all comments received on or before the comment closing date. Comments will be evaluated after this date if it is possible to do so without incurring additional expense or delay. PHMSA will consider each relevant comment we receive in making our decision to grant or deny the request.

PHMSA has received the following special permit request:

Docket No.	Requester	Regulation(s)	Nature of special permit
PHMSA–2008–0213.	Empire Pipeline, Inc., also referred to as Empire State Pipeline (Empire).	49 CFR 192.611 ...	To authorize Empire to include approximately 1,055 feet of 24-inch diameter, 0.257-inch and 0.370-inch wall thickness Grade X–65, (14-mil Encoat fusion-bonded epoxy coated HFERW pipe, manufactured by Stupp Corporation, Baton Rouge, Louisiana) pipeline, as part of the existing special permit originally issued to Empire on May 20, 2010, and renewed on May 20, 2015. Special permit Segment 6 is located approximately 1,190 feet west of the Erie Canal crossing, between mile posts (MP) 99.13 and MP 99.33, in the Town of Macedon, Wayne County, New York. The Empire pipeline has two maximum allowable operating pressure (MAOP) sections. The existing five Special Permit Segments are all located along the western, 1,440 psig MAOP section. Special Permit Segment 6 is sought with respect to one segment of an approximate length of 1,055 feet located in the 1,000 psig MAOP section. Segment 6 was originally classified and designed for a Class 1 location. Construction of a recreational vehicle campground within 100 yards of the pipeline resulted in a class location change of the area from Class 1 to Class 3, as of November 20, 2015. The inclusion of Segment 6 into the current special permit will allow Empire to continue the operation of this segment at its current MAOP of 1,000 psig.

Issued in Washington, DC, on October 31, 2016, under authority delegated in 49 CFR 1.97.

Linda Daugherty,

Deputy Associate Administrator for Field Operations.

[FR Doc. 2016–26565 Filed 11–2–16; 8:45 am]

BILLING CODE 4910–60–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary of Transportation

[Docket No. DOT–OST–2016–0016]

Notice of Funding Opportunity for the Department of Transportation's Nationally Significant Freight and Highway Projects (FASTLANE Grants) for Fiscal Year 2017

AGENCY: Office of the Secretary of Transportation, U.S. Department of Transportation.

ACTION: Notice of funding opportunity.

SUMMARY: The Fixing America's Surface Transportation Act (FAST Act) established the Nationally Significant Freight and Highway Projects (NSFHP) program to provide Federal financial assistance to projects of national or regional significance and authorized the program at $4.5 billion for fiscal years (FY) 2016 through 2020, including $850 million for FY 2017 to be awarded by the Secretary of Transportation. The U.S. Department of Transportation (USDOT/Department) will also refer to NSFHP grants as Fostering Advancements in Shipping and Transportation for the Long-term Achievement of National Efficiencies (FASTLANE) grants. The purpose of this notice is to solicit applications for FY 2017 grants for the FASTLANE program. The Department also invites interested parties to submit comments about this notice's contents to public docket DOT–OST–2016–0016 by December 31, 2016.

DATES: Applications must be submitted by 8:00 p.m. EST on December 15, 2016. The *Grants.gov* ''Apply'' function will open by November 14, 2016.

ADDRESSES: Applications must be submitted through *www.Grants.gov.* Only applicants who comply with all submission requirements described in this notice and submit applications through *www.Grants.gov* will be eligible for award.

FOR FURTHER INFORMATION CONTACT: For further information concerning this notice, please contact the Office of the Secretary via email at *FASTLANEgrants@dot.gov.* For more information about highway projects, please contact Crystal Jones at (202) 366–2976. For more information about maritime projects, please contact Robert Bouchard at (202) 366–5076. For more information about rail projects, please contact Stephanie Lawrence at (202) 493–1376. For all other questions, please contact Howard Hill at (202) 366–0301. A TDD is available for individuals who are deaf or hard of hearing at 202–366–3993. Additionally, the Department will regularly post answers to questions and requests for clarifications as well as information about webinars for further guidance on USDOT's Web site at *https://www.transportation.gov/buildamerica/FASTLANEgrants.*

SUPPLEMENTARY INFORMATION: This notice solicits applications for the FASTLANE program for FY 2017. Each section of this notice contains information and instructions relevant to the application process for FASTLANE grants, and the applicant should read this notice in its entirety to submit eligible and competitive applications.

Table of Contents

A. Program Description

The Nationally Significant Freight and Highway Projects (NSFHP) program, as established by the Fixing America's Surface Transportation Act (FAST Act), Public Law 114–94, section 1105 (23 U.S.C. 117), will provide Federal financial assistance to freight and highway projects of national or regional significance. The Department will also refer to NSFHP grants as Fostering Advancements in Shipping and Transportation for the Long-term Achievement of National Efficiencies (FASTLANE) grants. The FASTLANE program provides dedicated, discretionary funding for projects that address critical freight issues facing our nation's highways and bridges, and for the first time in the U.S. Department of Transportation's 50-year history, establishes broad, multiyear eligibilities for freight infrastructure.

To better adapt to national and regional population growth, compete in the global economy, and meet the needs of consumers and industry, the United States needs a strong multimodal transportation system. *Beyond Traffic 2045: Trends and Choices (Beyond Traffic),*[1] the Department's 30-year framework for the future, outlines changing local and global patterns, including population and employment growth in burgeoning megaregions and significant growth in freight movement by ton and value. The report affirms the need to address freight bottlenecks that severely constrain system performance and capacity. The Department's draft National Freight Strategic Plan,[2] released in October 2015, further

[1] *https://www.transportation.gov/BeyondTraffic.*

[2] *https://www.transportation.gov/freight/NFSP.*

explores these challenges for freight transportation and identifies strategies to address impediments to the flow of goods throughout the nation.

The FASTLANE program provides an opportunity to address nationally or regionally significant challenges across the nation's transportation system including improving the safety, efficiency, and reliability of the movement of freight and people; generating national or regional economic benefits and increasing the United States' global competitiveness; reducing highway congestion and bottlenecks; enabling more efficient intermodal connections; minimizing delays at international borders; improving inadequate first and last mile segments; modernizing port facilities to meet 21st Century demands, including connections between ports and their surface transportation systems; enhancing the resiliency of critical intermodal infrastructure and helping protect the environment; improving grade crossings; improving roadways vital to national energy security; and addressing the impact of population growth on the movement of people and freight. The program also offers resources to advance highway and bridge projects on the National Highway System (NHS), including those that improve mobility through added capacity on the Interstate or address needs in a national scenic area. Recognizing the interconnected and multimodal nature of the nation's transportation system, the Department will give additional consideration to nationally or regionally significant multimodal and multijurisdictional projects.

The Department will also consider whether projects enhance personal mobility and accessibility. Such projects include, but are not limited to, investments that better connect people to essential services such as employment centers, health care, schools and education facilities, healthy food, and recreation; remove physical or operational barriers to access; strengthen communities through neighborhood redevelopment; mitigate the negative impacts of freight movement on communities—such as road or railroad crossing congestion; and support workforce development, particularly for disadvantaged groups, which include low-income groups, persons with visible and hidden disabilities, elderly individuals, and minority persons and populations. The Department may consider whether a project's design is likely to generate benefits for all users of the proposed project, including non-driving members of a community adjacent to or affected by the project.

B. Federal Award Information

1. Amount Available

The FAST Act authorizes the FASTLANE program at $4.5 billion for fiscal years (FY) 2016 through 2020, including $850 million [3] for FY 2017 to be awarded by USDOT on a competitive basis to projects of national or regional significance that meet statutory requirements. The funding described in this notice is authorized for FY 2017 in FAST Act Section 1101(a)(5). The amount that will be available for awards is uncertain because the Department is issuing this notice before full-year appropriations legislation has been enacted for FY 2017. The Department anticipates that up to approximately $787 million will be available for awards. But that estimate may be higher or lower than the final amount, which is dependent on future appropriations legislation. Any award selections under this notice will be subject to the availability of funds.

While the Department is initiating the process of soliciting applications for FY 2017, awards will be subject to the availability of funding; the Department is currently operating under a Continuing Resolution, and the obligation limitation distribution for the balance of the Fiscal Year will depend on Congressional action. However, as obligation limitation associated with this program currently expires at the end of the Fiscal Year, the Department is now beginning the process of soliciting applications to facilitate the possibility of awards with sufficient time for grantees to obligate in advance of peak construction season, while accounting for the requirement that the Department notify Congressional Committees 60 days ahead of awards.

2. Eligible Uses

FASTLANE grants may be used for the construction, reconstruction, rehabilitation, acquisition of property (including land related to the project and improvements to the land), environmental mitigation, construction contingencies, equipment acquisition, and operational improvements directly related to system performance. FASTLANE grants may also fund developmental phase activities, including planning, feasibility analysis, revenue forecasting, environmental review, preliminary engineering, design, and other preconstruction activities, provided the project meets statutory requirements.

The FAST Act allows a FASTLANE grant recipient to use FASTLANE funds granted to pay the subsidy and administrative costs necessary to receive credit assistance for the associated project under the Transportation Infrastructure Finance and Innovation Act of 1998 (''TIFIA'') program.

3. Other Restrictions

The Department will make awards under the FASTLANE program to both large and small projects. (Refer to section C.3.ii.for a definition of large and small projects.) For large projects, the FAST Act specifies that FASTLANE grants must be at least $25 million. For small projects, the grants must be at least $5 million. For both large and small projects, maximum FASTLANE awards may not exceed 60 percent of future eligible project costs. While 10 percent of available funds are reserved for small projects, 90 percent of funds are reserved for large projects. Applicants are strongly encouraged to submit applications only for eligible award amounts.

Pursuant to the FAST Act, not more than $500 million in aggregate of the $4.5 billion authorized for FASTLANE grants over fiscal years 2016 to 2020 may be used for grants to freight rail, water (including ports), or other freight intermodal projects that make significant improvements to freight movement on the National Highway Freight Network. After accounting for FY 2016 FASTLANE awards, approximately $326 million within this constraint remains available. Only the non-highway portion(s) of multimodal projects count toward the $500 million maximum. Improving freight movement on the National Highway Freight Network may include shifting freight transportation to other modes, thereby reducing congestion and bottlenecks on the National Highway Freight Network. The Federal share for projects that count toward the $500 million maximum may fund only elements of the project that provide public benefit. Grade crossing and grade separation projects do not count toward the $500 million maximum for freight rail, port, and intermodal projects.

[3] Funds are subject to the overall Federal-aid highway obligation limitation, and funds in excess of the obligation limitation provided to the program are distributed to the States. While $850 million is authorized for FY 2017, DOT estimates that approximately $787 million will be available for award. For additional information see FAST Act § 1102 (f) and the Transportation, Housing and Urban Development, and Related Agencies Appropriations Act, 2016, Public Law 114–113, div. L § 120. Applicants should note that the provisions of the FY2016 appropriations act are only illustrative and may differ from what will be enacted in a full year FY 2017 appropriations act.

The FAST Act directs at least 25 percent of the funds provided for FASTLANE grants must be used for projects located in rural areas, as defined in Section C.3.iv. If the Department does not receive enough qualified applications to fully award the 25 percent reserved for rural projects, the Department may use the excess funding for non-rural awards. The USDOT must consider geographic diversity among grant recipients, including the need for a balance in addressing the needs of urban and rural areas.

4. Repeat Applications

In response to the FY 2016 FASTLANE solicitation (81 FR 10955), USDOT received applications for more eligible, excellent projects than could be funded in the first year of the program. Because the evaluation criteria described in this notice do not differ from the criteria in the FY 2016 solicitation and because USDOT requires applications to be submitted within 45 days of this notice, USDOT anticipates that some FY 2016 applicants who did not receive FY 2016 awards will resubmit their applications with few or no changes. If an applicant is re-applying for a project for which that applicant applied for FY 2016 funds and was not awarded, the applicant should highlight new or revised information in the application. This will improve the evaluation process by allowing USDOT to avoid redundant evaluations and focus evaluation resources on new information. To the extent that a resubmitted application contains few or no changes, USDOT may rely on previous analysis when considering the project for a FY 2017 award.

C. Eligibility Information

To be selected for an FASTLANE grant, an applicant must be an Eligible Applicant and the project must be an Eligible Project that meets the Minimum Project Size Requirement.

1. Eligible Applicants

Eligible applicants for FASTLANE grants are (1) a State or group of States; (2) a metropolitan planning organization that serves an Urbanized Area (as defined by the Bureau of the Census) with a population of more than 200,000 individuals; (3) a unit of local government or group of local governments; (4) a political subdivision of a State or local government; (5) a special purpose district or public authority with a transportation function, including a port authority; (6) a Federal land management agency that applies jointly with a State or group of States; (7) a tribal government or a consortium of tribal governments; or (8) a multi-State or multijurisdictional group of public entities. Multiple States or jurisdictions that submit a joint application should identify a lead applicant as the primary point of contact. Each applicant in a joint application must be an Eligible Applicant. Joint applications should include a description of the roles and responsibilities of each applicant and should be signed by each applicant.

2. Cost Sharing or Matching

FASTLANE grants may be used for up to 60 percent of future eligible project costs. Other Federal assistance may satisfy the non-Federal share requirement for a FASTLANE grant, but total Federal assistance for a project receiving a FASTLANE grant may not exceed 80 percent of the future eligible project costs. Non-Federal sources include State funds originating from programs funded by State revenue, local funds originating from State or local revenue funded programs, private funds or other funding sources of non-Federal origins. If a Federal land management agency applies jointly with a State or group of States, and that agency carries out the project, then Federal funds that were not made available under titles 23 or 49 of the United States Code may be used for the non-Federal share. Unless otherwise authorized by statute, local cost-share may not be counted as non-Federal share for both the FASTLANE and another Federal program. For any project, the Department cannot consider previously incurred costs or previously expended or encumbered funds towards the matching requirement. Matching funds are subject to the same Federal requirements described in Section F.2 as awarded funds.

3. Other

i. Eligible Project

Eligible projects for FASTLANE grants are: Highway freight projects carried out on the National Highway Freight Network (23 U.S.C. 167); highway or bridge projects carried out on the NHS, including projects that add capacity on the Interstate System to improve mobility or projects in a national scenic area; railway-highway grade crossing or grade separation projects; or a freight project that is (1) an intermodal or rail project, or (2) within the boundaries of a public or private freight rail, water (including ports), or intermodal facility. A project within the boundaries of a freight rail, water (including ports), or intermodal facility must be a surface transportation infrastructure project necessary to facilitate direct intermodal interchange, transfer, or access into or out of the facility and must significantly improve freight movement on the National Highway Freight Network. For a freight project within the boundaries of a freight rail, water (including ports), or intermodal facility, Federal funds can only support project elements that provide public benefits.

ii. Eligible Project Costs

Eligible costs under the FASTLANE program include development phase activities, including planning, feasibility analysis, revenue forecasting, environmental review, preliminary engineering and design work, and other pre-construction activities, as well as construction, reconstruction, rehabilitation, acquisition of real property, environmental mitigation, construction contingencies, acquisition of equipment, and operational improvements directly related to system performance.

iii. Minimum Project Size Requirement

For the purposes of determining whether a project meets the minimum project size requirement, the Department will count all future eligible project costs under the award and some related costs incurred before selection for an FASTLANE grant. Previously incurred costs will be counted toward the minimum project size requirement only if they were eligible project costs under Section C.3.ii. and were expended as part of the project for which the applicant seeks funds. Although those previously incurred costs may be used for meeting the minimum project size thresholds described in this Section, they cannot be reimbursed with FASTLANE grant funds, nor will the count toward the project's required non-Federal share.

a. Large Projects

The minimum project size for large projects is the lesser of $100 million; 30 percent of a State's FY 2016 Federal-aid apportionment if the project is located in one State; or 50 percent of the larger participating State's FY 2016 apportionment for projects located in more than one State. The following chart identifies the minimum total project cost for projects for FY 2017 for both single and multi-State projects.

State	One-State minimum (millions)	Multi-State minimum * (millions)
Alabama	$100	$100
Alaska	100	100

State	One-State minimum (millions)	Multi-State minimum * (millions)
Arizona	100	100
Arkansas	100	100
California	100	100
Colorado	100	100
Connecticut	100	100
Delaware	51	86
Dist. of Col.	49	81
Florida	100	100
Georgia	100	100
Hawaii	51	86
Idaho	87	100
Illinois	100	100
Indiana	100	100
Iowa	100	100
Kansas	100	100
Kentucky	100	100
Louisiana	100	100
Maine	56	94
Maryland	100	100
Massachusetts	100	100
Michigan	100	100
Minnesota	100	100
Mississippi	100	100
Missouri	100	100
Montana	100	100
Nebraska	88	100
Nevada	100	100
New Hampshire	50	84
New Jersey	100	100
New Mexico	100	100
New York	100	100
North Carolina	100	100
North Dakota	76	100
Ohio	100	100
Oklahoma	100	100
Oregon	100	100
Pennsylvania	100	100
Puerto Rico	47	74
Rhode Island	67	100
South Carolina	100	100
South Dakota	86	100
Tennessee	100	100
Texas	100	100
Utah	100	100
Vermont	62	100
Virginia	100	100
Washington	100	100
West Virginia	100	100
Wisconsin	100	100
Wyoming	78	100

** For multi-State projects, the minimum project size is the largest of the multi-State minimums from the participating States.*

b. Small Projects

A small project is an eligible project that does not meet the minimum project size described in Section C.3.iii.a.

iv. Rural/Urban Area

The FASTLANE statute defines a rural area as an area outside an Urbanized Area [4] with a population of over 200,000. In this notice, urban area is defined as inside an Urbanized Area, as a designated by the U.S. Census Bureau, with a population of 200,000 or more.[5] Cost share requirements and minimum grant awards are the same for projects located in rural and urban areas. The Department will consider a project to be in a rural area if the majority of the project (determined by geographic location(s) where the majority of the money is to be spent) is located in a rural area. Rural and urban definitions differ in some other USDOT programs, including TIFIA and the FY 2016 TIGER Discretionary Grants Program.

v. Application Limit

To encourage applicants to prioritize their FASTLANE submissions, each eligible applicant may submit no more than three applications. The three-application limit applies only to applications where the applicant is the lead applicant. There is no limit on applications for which an applicant can be listed as a partnering agency. If a lead applicant submits more than three applications as the lead applicant, only the first three received will be considered.

vi. Project Components

An application may describe a project that contains more than one component, and may describe components that may be carried out by parties other than the applicant. Applicants should clearly identify all highway, bridge, and freight-related components comprising the total project. The USDOT may award funds for a component, instead of the larger project, if that component (1) independently meets minimum award amounts described in Section B and all eligibility requirements described in Section C; (2) independently aligns well with the selection criteria specified in Section E; and (3) meets National Environmental Policy Act (NEPA) requirements with respect to independent utility. Independent utility means that the component will represent a transportation improvement that is usable and represents a reasonable expenditure of USDOT funds even if no other improvements are made in the area, and will be ready for intended use upon completion of that component's construction. All project components that are presented together in a single application must demonstrate a relationship or connection with one another. (See Section D.2.f. for Required Approvals).

Applicants should be aware that, depending upon the relationship between project components and upon applicable Federal law, USDOT funding of only some project components may make other project components subject to Federal requirements as described in Section F.2.

The USDOT strongly encourages applicants to identify in their applications the project components that have independent utility and separately detail costs and requested FASTLANE funding for each component. If the application identifies one or more independent project components, the application should clearly identify how each independent component addresses selection criteria and produces benefits on its own, in addition to describing how the full proposal of which the independent component is a part addresses selection criteria.

D. Application and Submission Information

1. Address

Applications must be submitted through *www.Grants.gov*. Instructions for submitting applications can be found at *https://www.transportation.gov/buildamerica/FASTLANEgrants.*

2. Content and Form of Application

The application must include the Standard Form 424 (Application for Federal Assistance), Standard Form 424C (Budget Information for Construction Programs), cover page, and the Project Narrative. More detailed information about the cover page and Project Narrative follows.

i. Cover Page Including the Following Chart

Project name	
Was a FASTLANE application for this project submitted previously?	Yes/no.
If yes, what was the name of the project in the previous application?	

[4] For Census 2010, the Census Bureau defined an Urbanized Area (UA) as an area that consists of densely settled territory that contains 50,000 or more people. Updated lists of UAs are available on the Census Bureau Web site at *http://www2.census.gov/geo/maps/dc10map/UAUC_RefMap/ua/*. For the purposes of the FASTLANE program, Urbanized Areas with populations fewer than 200,000 will be considered rural.

[5] See *www.transportation.gov/FASTLANEgrants* for a list of Urbanized Areas with a population of 200,000 or more.

Project name	
Previously Incurred Project Cost	$.
Future Eligible Project Cost	$.
Total Project Cost	$.
FASTLANE Request	$.
Total Federal Funding (including FASTLANE)	$.
Are matching funds restricted to a specific project component? If so, which one?	Yes/no.
Is the project or a portion of the project currently located on National Highway Freight Network?	Yes/no.
Is the project or a portion of the project located on the NHS?	Yes/no (for each question).
• Does the project add capacity to the Interstate system?	
• Is the project in a national scenic area?	
Do the project components include a railway-highway grade crossing or grade separation project?	Yes/no.
• If so, please include the grade crossing ID.	
Do the project components include an intermodal or freight rail project, or freight project within the boundaries of a public or private freight rail, water (including ports), or intermodal facility?.	Yes/no.
If answered yes to either of the two component questions above, how much of requested FASTLANE funds will be spent on each of these projects components?.	
State(s) in which project is located	
Small or large project	Small/Large.
Urbanized Area in which project is located, if applicable.	
Population of Urbanized Area	
Is the project currently programmed in the:	
• TIP	Yes/no (*please specify in which plans the project is currently programmed*).
• STIP	
• MPO Long Range Transportation Plan	
• State Long Range Transportation Plan	
• State Freight Plan?	

ii. Summary of Changes

If a FASTLANE application for this project was previously submitted, please describe any changes between the FY 2016 and FY 2017 applications. The changes should be summarized on a single page following the Cover Page AND highlighted throughout the application on a section-by-section basis. Because the evaluation criteria described in this notice do not differ from the criteria in the FY 2016 solicitation and because USDOT requires applications to be submitted within 45 days of this notice, USDOT anticipates that some FY 2016 applicants who did not receive FY 2016 awards will resubmit their applications with few or no changes.

iii. Project Narrative

The USDOT recommends that the project narrative adhere to the following basic outline to clearly address the program requirements and make critical information readily apparent:

I. Project Description	See D.2.iii.a.
II. Project Location	See D.2.iii.b.
III. Project Parties	See D.2.iii.c.
IV. Sources and Uses of all Project Funding.	See D.2.iii.d.
V. Merit Criteria	See E.1.i. a,b,c,d and E.1.ii.a.b.
VI. Large/Small Project Requirements.	See E.1.iii.
VII. Cost Effectiveness.	See D.2.iii.e.
VIII. Project Readiness.	See D.2.iii.f.

The application should include information required for USDOT to determine that the project satisfies project requirements described in Sections B and C and to assess the selection criteria specified in Section E.1. To the extent practicable, applicants should provide data and evidence of project merits in a form that is verifiable or publicly available. The USDOT may ask any applicant to supplement data in its application, but expects applications to be complete upon submission.

In addition to a detailed statement of work, detailed project schedule, and detailed project budget, the project narrative should include a table of contents, maps, and graphics, as appropriate to make the information easier to review. The USDOT recommends that the project narrative be prepared with standard formatting preferences. (*i.e.,* a single-spaced document, using a standard 12-point font such as Times New Roman, with 1-inch margins.) The project narrative may not exceed 25 pages in length, excluding cover pages and table of contents. The only substantive portions that may exceed the 25-page limit are supporting documents to support assertions or conclusions made in the 25-page project narrative. If possible, Web site links to supporting documentation should be provided rather than copies of these supporting materials. If supporting documents are submitted, applicants should clearly identify within the project narrative the relevant portion of the project narrative that each supporting document supports. At the applicant's discretion, relevant materials provided previously to a modal administration in support of a different USDOT financial assistance program may be referenced and described as unchanged. The USDOT recommends using appropriately descriptive final names (*e.g.,* ''Project Narrative,'' ''Maps,'' ''Memoranda of Understanding and Letters of Support,'' etc.) for all attachments. The USDOT recommends applications include the following sections:

a. Project Description including a description of the project size, including previously incurred expenses, to show the project meets minimum project size requirements, a description of what requested FASTLANE and matching funds will support, how the project is nationally or regionally significant, information on the expected users of the project, a description of the transportation challenges the project aims to address, and how the project will address these challenges. The description should include relevant data for before and after the project is built, such as passenger and freight volumes, congestion levels, infrastructure condition, and safety experience, including citations for data sources. Examples of potentially relevant data can be found at *www.transportation.gov/FASTLANEgrants,* but USDOT

encourages applicants to identify the most relevant information for their project.

b. Project Location including a detailed description of the proposed project and geospatial data for the project, as well as a map of the project's location and its connections to existing transportation infrastructure. If the project is located within the boundary of a Census-designated Urbanized Area, the application should identify the Urbanized Area.

c. Project Parties including information about the grant recipient and other affected public and private parties who are involved in delivering the project, such as port authorities, terminal operators, freight railroads, shippers, carriers, freight-related associations, third-party logistics providers, and the freight industry workforce.

d. Grant Funds, Sources and Uses of Project Funds including information to demonstrate the viability and completeness of the project's financing package, assuming the availability of the requested FASTLANE grant funds. The applicant should show evidence of stable and reliable capital and (as appropriate) operating fund commitments sufficient to cover estimated costs; the availability of contingency reserves should planned capital or operating revenue sources not materialize; evidence of the financial condition of the project sponsor; and evidence of the grant recipient's ability to manage grants. At a minimum, applicants should include:

(i) Future eligible cost, as defined in Section C.3.ii–iii.

(ii) Availability and commitment of all committed and expected funding sources and uses of all project funds for future eligible project costs, including the identity of all parties providing funds for the project and their percentage shares; any restrictions attached to specific funds; compliance or a schedule for compliance with all conditions applicable to each funding source, and, to the extent possible, funding commitment letters from non-Federal sources.

(iii) Federal funds already provided and the size, nature, and source of the required match for those funds, as well as pending or past Federal funding requests for the project. This information should demonstrate that the requested FASTLANE funds do not exceed 60 percent of future eligible project costs and that total Federal funding will not exceed 80 percent of future eligible project costs. This information should also show that local share for the FASTLANE grant is not counted as the matching requirement for another Federal program.

(iv) A detailed project budget containing a breakdown of how the funds will be spent. That budget should estimate—both dollar amount and percentage of cost—the cost of work for each project component. If the project will be completed in individual segments or phases, a budget for each individual segment or phase should be included. Budget spending categories should be broken down between FASTLANE, other Federal, and non-Federal sources, and this breakdown should also identify how each funding source will share in each activity.

(v) Amount of requested FASTLANE funds that will be spent on highway, bridge, freight intermodal or freight rail, port, grade crossing or grades separation project components.

e. Cost-Effectiveness analysis should demonstrate that the project is likely to deliver its anticipated benefits at reasonable costs. Applicants should delineate each of their project's expected outputs and costs in the form of a complete Benefit-Cost Analysis (BCA) to enable the Department to consider cost-effectiveness (small projects) or determine whether the project is cost effective (for large projects). The primary economic benefits from projects eligible for FASTLANE grants are likely to include time savings for passenger travel and freight shipments, improvements in transportation safety, reduced damages from emissions of greenhouse gases and criteria air pollutants, and savings in maintenance costs to public agencies. Applicants should submit a BCA in support of each project for which they seek funding that quantifies each of these benefits, provides monetary estimates of their economic value, and compares the properly-discounted present values of these benefits to the project's estimated costs. Where applicants cannot adequately monetize benefits, they are urged to identify non-monetary measures for other categories of benefits (examples below) to assist the Department in making cost-effectiveness and other determinations about projects.

Many projects are likely to generate other categories of benefits that are more difficult to quantify and value in economic terms, but are nevertheless important considerations in determining whether a proposed project is cost-effective. These may include impacts such as improving the reliability of passenger travel times or freight deliveries, improvements to the existing human and natural environments surrounding the project, increased connectivity, access, and mobility, benefits to public health, stormwater runoff mitigation, and noise reduction. Applicants should identify each category of impact or benefits that is not already included in the estimated dollar value of their project's benefits (as described above), and wherever possible provide numerical estimates of the magnitude and timing of each of these additional impacts.

For the purpose of evaluating cost-effectiveness, project costs should include those for constructing, operating, and maintaining the proposed project, including a detailed breakdown of those costs by spending category and the expected timing or schedule for costs in each category.

To assist in USDOT's cost-effectiveness evaluation, applicants should provide all relevant files used for their BCA, including any spreadsheet files and technical memos describing the analysis (whether created in-house or by a contractor). The spreadsheets and technical memos should present the calculations in sufficient detail to allow the analysis to be reproduced by USDOT evaluators. Detailed guidance for estimating some types of quantitative benefits and costs, together with recommended economic values for converting them to dollar terms and discounting to their present values, are available in USDOT's guidance for conducting BCAs for projects seeking funding under the FASTLANE program (see *https://www.transportation.gov/buildamerica/FASTLANEgrants*).

Applicants for freight projects within the boundaries of a freight rail, water (including ports), or intermodal facility should also quantify the benefits of their proposed projects for freight movements on the National Highway Freight Network, and should demonstrate that the Federal share of the project funds only elements of the project that provide public benefits.

f. Project Readiness including information to demonstrate that the project is reasonably expected to begin construction in a timely manner. For a large project, the Department cannot award a project that is not reasonably expected to begin construction within 18 months of obligation of funds for the project. The Department will determine that large projects with an obligation date beyond September 30, 2020 are not reasonably expected to begin construction within 18 months of obligation. Obligation occurs when a selected applicant and USDOT enter a written, project-specific agreement and is generally after the applicant has satisfied applicable administrative requirements, including transportation

planning and environmental review requirements. Depending on the nature of pre-construction activities included in the awarded project, the Department may obligate funds in phases.

Preliminary engineering and right-of-way acquisition activities, such as environmental review, design work, and other preconstruction activities, do not fulfill the requirement to begin construction within 18 months of obligation for large projects.

To assist the Department's project readiness determination, the Department will consider information provided in this Section D.2.ii.d. (Grant Funds, Sources and Uses of Project Funds) in addition to the following information:

(i) Technical Feasibility. The technical feasibility of the project should be demonstrated by engineering and design studies and activities; the development of design criteria and/or a basis of design; the basis for the cost estimate presented in the FASTLANE application, including the identification of contingency levels appropriate to its level of design; and any scope, schedule, and budget risk-mitigation measures. Applicants should include a detailed statement of work that focuses on the technical and engineering aspects of the project and describes in detail the project to be constructed.

(ii) Project Schedule. The applicant should include a detailed project schedule that identifies all major project milestones. Examples of such milestones include State and local planning approvals (programming on the STIP), start and completion of NEPA and other environmental reviews and approvals including permitting; design completion; right of way acquisition; approval of plan, specification and estimate (PS&E); procurement; State and local approvals; project partnership and implementation agreements including agreements with railroads; and construction. The project schedule should be sufficiently detailed to demonstrate that:

(a) All necessary activities will be complete to allow grant funds to be obligated sufficiently in advance of the statutory deadline, and that any unexpected delays will not put the funds at risk of expiring before they are obligated;

(b) the project can begin construction quickly upon receipt of a FASTLANE grant, and that the grant funds will be spent expeditiously once construction starts; and

(c) all property and/or right-of-way acquisition will be completed in a timely manner in accordance with 49 CFR part 24 and other legal requirements or a statement that no acquisition is necessary.

(iii) Required Approvals

(a) Environmental Permits and Reviews: As noted in Section D.2.ii.f.iii above, the application should demonstrate receipt (or reasonably anticipated receipt) of all environmental approvals and permits necessary for the project to proceed to construction on the timeline specified in the project schedule and necessary to meet the statutory obligation deadline, including satisfaction of all Federal, State and local requirements and completion of the NEPA process. Although Section C.3.vi (Project Components) of this notice encourages applicants to identify independent project components, those components may not be separable for the NEPA process. In such cases, the NEPA review for the independent project component may have to include evaluation of all project components as connected, similar, or cumulative actions, as detailed at 40 CFR 1508.25. In addition, the scope of the NEPA decision may affect the applicability of the Federal requirements on the project described in the application. Specifically, the application should include:

(1) Information about the NEPA status of the project. If the NEPA process is completed, an applicant should indicate the date of, and provide a Web site link or other reference to the final Categorical Exclusion, Finding of No Significant Impact, Record of Decision, or any other NEPA documents prepared. If the NEPA process is underway but not complete, the application should detail the type of NEPA review underway, where the project is in the process, and indicate the anticipated date of completion of all milestones and of the final NEPA determination. If the NEPA documents are approaching ten years old, the applicant should include a proposed approach for updating this material.

(2) Information on reviews, approvals, and permits by other agencies. An application should indicate whether the proposed project requires reviews or approval actions by other agencies,[6] indicate the status of such actions, and provide detailed information about the status of those reviews or approvals and or demonstrate compliance with any other applicable Federal, State, or local requirements. Applicants should provide a Web site link or other reference to copies of any reviews, approvals, and permits prepared.

(3) Environmental studies or other documents—preferably through a Web site link—that describe in detail known project impacts, and possible mitigation for those impacts.

(4) A description of discussions with the appropriate USDOT modal administration field or headquarters office regarding compliance with NEPA and other applicable environmental reviews and approvals.

(5) A description of public engagement to date about the project including the degree to which public comments and commitments have been integrated into project development and design.

b. State and Local Approvals. The applicant should demonstrate receipt of State and local approvals on which the project depends, such as local government funding commitments or TIF approval. Additional support from relevant State and local officials is not required; however, an applicant should demonstrate that the project is broadly supported.

c. State and Local Planning. The planning requirements of the operating administration administering the FASTLANE project will apply,[7] including intermodal projects located at airport facilities.[8] Applicants should

[6] Projects that may impact protected resources such as wetlands, species habitat, cultural or historic resources require review and approval by Federal and State agencies with jurisdiction over those resources.

[7] In accordance with 23 U.S.C. 134 and 135, all projects requiring an action by the Federal Highway Administration (FHWA) must be in the metropolitan transportation plan, transportation improvement program (TIP) and statewide transportation improvement program (STIP). Further, in air quality non-attainment and maintenance areas, all regionally significant projects, regardless of the funding source, must be included in the conforming metropolitan transportation plan and TIP. To the extent a project is required to be on a metropolitan transportation plan, TIP, and/or STIP, it will not receive a FASTLANE grant until it is included in such plans. Projects not currently included in these plans can be amended by the State and metropolitan planning organization (MPO). Projects that are not required to be in long range transportation plans, STIPs, and TIPs will not need to be included in such plans in order to receive a FASTLANE grant. Port, freight rail, and intermodal projects are not required to be on the State Rail Plans called for in the Passenger Rail Investment and Improvement Act of 2008. However, applicants seeking funding for freight projects are encouraged to demonstrate that they have done sufficient planning to ensure that projects fit into a prioritized list of capital needs and are consistent with long-range goals. Means of demonstrating this consistency would to include the projects in TIPs or a State Freight Plan that conforms to the requirements Section 70202 of Title 49 prior to the start of construction. Port planning guidelines are available at *StrongPorts.gov*.

[8] Projects at grant obligated airports, must be compatible with the FAA-approved Airport Layout Plan (ALP), as well as aeronautical surfaces associated with the landing and takeoff of aircraft at the airport. Additionally, projects at an airport: must comply with established Sponsor Grant Assurances, including (but not limited to)

demonstrate that a project that is required to be included in the relevant State, metropolitan, and local planning documents has been or will be included. If the project is not included in the relevant planning documents at the time the application is submitted, the applicant should submit a statement from the appropriate planning agency that actions are underway to include the project in the relevant planning document.

To the extent possible, freight projects should be included in a State Freight Plan and supported by a State Freight Advisory Committee (49 U.S.C. 70201, 70202). Applicants should provide links or other documentation supporting this consideration.

Because projects have different schedules, the construction start date for each FASTLANE grant will be specified in the project-specific agreements signed by relevant modal administration and the grant recipients and will be based on critical path items identified by applicants in response to items (iv)(a) through (c) above, and be consistent with other relevant State or local plan, including bicycle and pedestrian plans, economic development plans, local land-use plans, and water and coastal zone management plans.

(iv) Assessment of Project Risks and Mitigation Strategies. Project risks, such as procurement delays, environmental uncertainties, increases in real estate acquisition costs, uncommitted local match, or lack of legislative approval, affect the likelihood of successful project start and completion. The applicant should identify the material risks to the project and the strategies that the lead applicant and any project partners have undertaken or will undertake in order to mitigate those risks. Information provided in response to Section D.2.ii.f.i–iv above should be referenced in developing this assessment. The applicant should assess the greatest risks to the project and identify how the project parties will mitigate those risks. The USDOT will consider projects that contain risks, but expects the applicant to clearly and directly describe achievable mitigation strategies.

The applicant, to the extent it is unfamiliar with the Federal program, should contact USDOT modal field or headquarters offices as found at *www.transportation.gov/FASTLANEgrants* for information on what steps are pre-requisite to the obligation of Federal funds in order to ensure that their project schedule is reasonable and that there are no risks of delays in satisfying Federal requirements.

3. Unique Entity Identifier and System for Award Management (SAM)

Each applicant must: (1) Be registered in SAM before submitting its application; (2) provide a valid unique entity identifier in its application; and (3) continue to maintain an active SAM registration with current information at all times during which it has an active Federal award or an application or plan under consideration by a Federal awarding agency. The USDOT may not make a FASTLANE grant to an applicant until the applicant has complied with all applicable unique entity identifier and SAM requirements and, if an applicant has not fully complied with the requirements by the time USDOT is ready to make an FASTLANE grant, USDOT may determine that the applicant is not qualified to receive an FASTLANE grant and use that determination as a basis for making an FASTLANE grant to another applicant.

4. Submission Dates and Timelines

i. Deadline

Applications must be submitted by 8:00 p.m. EST on December 15, 2016. The *Grants.gov* ''Apply'' function will open by November 14, 2016. The Department has determined that an application deadline fewer than 60 days after this notice is published is appropriate because the accelerated timeline is necessary to satisfy the statutory 60-day Congressional notification requirement, as well as to ensure the timely obligation of available funds.

To submit an application through *Grants.gov*, applicants must:

a. Obtain a Data Universal Numbering System (DUNS) number:

b. Register with the System Award for Management (SAM) at *www.sam.gov;*

c. Create a *Grants.gov* username and password; and

d. The E-business Point of Contact (POC) at the applicant's organization must respond to the registration email from *Grants.gov* and login at *Grants.gov* to authorize the POC as an Authorized Organization Representative (AOR). Please note that there can only be one AOR per organization.

Please note that the *Grants.gov* registration process usually takes 2–4 weeks to complete and late applications that are the result of failure to register or comply with *Grants.gov* applicant requirements in a timely manner will not be considered. For information and instruction on each of these processes, please see instructions at *http://www.grants.gov/web/grants/applicants/applicant-faqs.html*. If interested parties experience difficulties at any point during the registration or application process, please call the *Grants.gov* Customer Service Support Hotline at 1 (800) 518–4726, Monday–Friday from 7:00 a.m. to 9:00 p.m. EST.

ii. Consideration of Application

Only applicants who comply with all submission deadlines described in this notice and submit applications through *Grants.gov* will be eligible for award. Applicants are strongly encouraged to make submissions in advance of the deadline.

iii. Late Applications

Applications received after the deadline will not be considered except in the case of unforeseen technical difficulties outlined in Section 4.iv.

iv. Late Application Policy

Applicants experiencing technical issues with *Grants.gov* that are beyond the applicant's control must contact *FASTLANEgrants@dot.gov* prior to the application deadline with the user name of the registrant and details of the technical issue experienced. The applicant must provide:

a. Details of the technical issue experienced;

b. Screen capture(s) of the technical issues experienced along with corresponding *Grants.gov* ''Grant tracking number'';

c. The ''Legal Business Name'' for the applicant that was provided in the SF–424;

d. The AOR name submitted in the SF–424;

e. The DUNS number associated with the application; and

f. The *Grants.gov* Help Desk Tracking Number.

To ensure a fair competition of limited discretionary funds, the following conditions are not valid reasons to permit late submissions: (1) Failure to complete the registration process before the deadline; (2) failure to follow *Grants.gov* instructions on how to register and apply as posted on its Web site; (3) failure to follow all of the instructions in this notice of funding opportunity; and (4) technical issues experienced with the applicant's computer or information technology environment. After USDOT staff review all information submitted and contact

requirements for non-exclusive use facilities, consultation with users, consistency with local plans including development of the area surrounding the airport, and consideration of the interest of nearby communities, among others; and must not adversely affect the continued and unhindered access of passengers to the terminal.

the *Grants.gov* Help Desk to validate reported technical issues, USDOT staff will contact late applicants to approve or deny a request to submit a late application through *Grants.gov*. If the reported technical issues cannot be validated, late applications will be rejected as untimely.

E. Application Review Information

1. Criteria

i. Merit Criteria

For both large and small projects, the Department will consider the extent to which the project addresses the following criteria:

a. Economic Outcomes

Improving the efficiency and reliability of the surface transportation system at the regional or national level to increase the global economic competitiveness of the United States, including improving connectivity between freight modes of transportation, improving roadways vital to national energy security, facilitating freight movement across land border crossings, and addressing the impact of population growth on the movement of people and freight.

b. Mobility Outcomes

Improving the movement of people and goods by maintaining highways, bridges, and freight infrastructure in a state of good repair, enhancing the resiliency of critical surface transportation infrastructure, and significantly reducing highway congestion and bottlenecks.

c. Safety Outcomes

Achieving a significant reduction in traffic fatalities and serious injuries on the surface transportation system, as well as improving interactions between roadway users, reducing the likelihood of derailments or high consequence events, and improving safety in transporting certain types of commodities.

d. Community and Environmental Outcomes

How and whether the project mitigates harm to communities and the environment, extends benefits to the human and natural environment, or enhances personal mobility and accessibility. This includes reducing the negative effects of existing infrastructure, removing barriers, avoiding harm to the human and natural environment, and using design improvements to enhance access (where appropriate) and environmental quality for affected communities. Projects should also reflect meaningful community input provided during project development.

ii. Other Review Criteria

a. Partnership and Innovation

Demonstrating strong collaboration among a broad range of stakeholders or using innovative strategies to pursue primary outcomes listed above including efforts to reduce delivery delays. Additional consideration will be given for the use of innovative and flexible designs and construction techniques or innovative technologies.

b. Cost Share

FASTLANE grants must have one or more stable and dependable sources of funding and financing to construct, maintain, and operate the project, subject to the parameters in Section C.2. Applicants should provide sufficient information to demonstrate that the project cannot be easily and efficiently completed without other Federal funding or financial assistance available to the project sponsor. Additional consideration will be given to the use of nontraditional financing, as well as the use of non-Federal contributions. The Department may consider the form of cost sharing presented in an application. Firm commitments of cash that indicate a complete project funding package and demonstrate local support for the project are more competitive than other forms of cost sharing.

iii. Large/Small Project Requirements

For a *large* project to be selected, the Department must determine that the project generates national or regional economic, mobility, or safety benefits; is cost-effective; contributes to one or more of the goals described in 23 U.S.C 150; is based on the results of preliminary engineering; has one or more stable and dependable funding or financing sources available to construct, maintain, and operate the project, and contingency amounts are available to cover unanticipated cost increases; cannot be easily and efficiently completed without other Federal funding or financial assistance; and is reasonably expected to begin construction no later than 18 months after the date of obligation. These requirements have been translated into a question format in the table below. If you are applying for an award for a large project, use this section to provide specific evidence on how your project addresses these requirements, or refer to where the evidence can be found elsewhere in your application.

1. Does the project generate national or regional economic, mobility, safety benefits?
2. Is the project cost effective?
3. Does the project contribute to one or more of the Goals listed under 23 USC 150 (and shown below)?
   (b) National Goals.—It is in the interest of the United States to focus the Federal-aid highway program on the following national goals:
   (1) Safety.—To achieve a significant reduction in traffic fatalities and serious injuries on all public roads.
   (2) Infrastructure condition.—To maintain the highway infrastructure asset system in a state of good repair.
   (3) Congestion reduction.—To achieve a significant reduction in congestion on the NHS.
   (4) System reliability.—To improve the efficiency of the surface transportation system.
   (5) Freight movement and economic vitality.—To improve the national freight network, strengthen the ability of rural communities to access national and international trade markets, and support regional economic development.
   (6) Environmental sustainability.—To enhance the performance of the transportation system while protecting and enhancing the natural environment.
   (7) Reduced project delivery delays.—To reduce project costs, promote jobs and the economy, and expedite the movement of people and goods by accelerating project completion through eliminating delays in the project development and delivery process, including reducing regulatory burdens and improving agencies' work practices.
4. Is the project based on the results of preliminary engineering?
5a. With respect to non-federal financial commitments, does the project have one or more stable and dependable funding or financing sources to construct, maintain, and operate the project?
5b. Are contingency amounts available to cover unanticipated cost increases?
6. Is it the case that the project cannot be easily and efficiently completed without other federal funding or financial assistance available to the project sponsor?
7. Is the project reasonably expected to begin construction not later than 18 months after the date of obligation of funds for the project?

In responding to the Large Project Requirements, here are some guidelines

which may assist you in completing your application:

—National or regional economic, mobility, and safety benefits, as well as a contribution to national goals, are often demonstrated in the Merit Criteria section of the application.
—NEPA completion is a sufficient indication the project is based on the results of preliminary engineering. For more information on preliminary engineering activities, please see: *https://www.fhwa.dot.gov/federalaid/150311.cfm.*
—Historical trends, current policy, or future feasibility analyses can be used as evidence to substantiate the stable and dependable nature of the non-federal funding or financing committed to the project construction, operation, and maintenance.
—Contingency amounts are often, but not always, expressly shown in project budgets or the SF–424C. If your project cost estimates include an implicit contingency calculation, please say so directly.
—Discussing the impact that not having *any* federal funding, including a FASTLANE grant, would have on project's schedule, cost, or likelihood of completion, can help convey whether a project can be completed as easily or efficiently without federal funding available to the project sponsor.

2. For a *small* project to be selected, the Department must consider the cost effectiveness of the proposed project and the effect of the proposed project on mobility in the State and region in which the project is carried out. If you are applying for an award for a small project, use this section to provide specific evidence on how your project addresses these requirements, or refer to where the evidence can be found elsewhere in your application.

3. Review and Selection Process

i. USDOT Review

The USDOT will review all eligible applications received before the application deadline. The FASTLANE process consists of a Technical Evaluation phase and Senior Review. In the Technical Evaluation phase teams will, for each project, determine whether the project satisfies statutory requirements and rate how well it addresses selection criteria. The Senior Review Team will consider the applications and the technical evaluations to determine which projects to advance to the Secretary for consideration. Evaluations in both the Technical Evaluation and Senior Review Team phases will place projects into rating categories, not assign numerical scores. The Secretary will select the projects for award. A Quality Control and Oversight Team will ensure consistency across project evaluations and appropriate documentation throughout the review and selection process. The FAST Act requires Congressional notification, in writing, at least 60 days before making a FASTLANE grant.

4. Additional Information

Prior to award, each selected applicant will be subject to a risk assessment required by 2 CFR 200.205. The Department must review and consider any information about the applicant that is in the designated integrity and performance system accessible through SAM (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). An applicant may review information in FAPIIS and comment on any information about itself. The Department will consider comments by the applicant in addition to the other information in FAPIIS, in making a judgment about the applicant's integrity, business ethics, and record of performance under Federal awards when completing the review of risk posed by applicants.

F. Federal Award Administration Information

1. Federal Award Notices

Following the evaluation outlined in Section E, the Secretary will announce awarded projects by posting a list of selected projects at *https://www.transportation.gov/buildamerica/FASTLANEgrants.* Following the announcement, the Department will contact the point of contact listed in the SF 424 to initiate negotiation of a project specific agreement.

2. Administrative and National Policy Requirements

All awards will be administered pursuant to the Uniform Administrative Requirements, Cost Principles and Audit Requirements for Federal Awards found in 2 CFR part 200, as adopted by USDOT at 2 CFR part 1201. Additionally, applicable Federal laws, rules and regulations of the relevant modal administration administering the project will apply to the projects that receive FASTLANE grants, including planning requirements, Stakeholder Agreements, Buy America compliance, and other requirements under USDOT's other highway, transit, rail, and port grant programs. A project carried out under this FASTLANE program will be treated as if the project is located on a Federal-aid highway. For an illustrative list of the applicable laws, rules, regulations, executive orders, policies, guidelines, and requirements as they relate to an FASTLANE, please see *http://www.ops.fhwa.dot.gov/Freight/infrastructure/nsfhp/fy2016_gr_exhbt_c/index.htm.*

3. Reporting

i. Progress Reporting on Grant Activity

Each applicant selected for an FASTLANE grant must submit the Federal Financial Report (SF–425) on the financial condition of the project and the project's progress, as well as an Annual Budget Review and Program Plan to monitor the use of Federal funds and ensure accountability and financial transparency in the FASTLANE program.

ii. Reporting of Matters Related to Integrity and Performance

If the total value of a selected applicant's currently active grants, cooperative agreements, and procurement contracts from all Federal awarding agencies exceeds $10,000,000 for any period of time during the period of performance of this Federal award, then the applicant during that period of time must maintain the currency of information reported to the System for Award Management (SAM) that is made available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)) about civil, criminal, or administrative proceedings described in paragraph 2 of this award term and condition. This is a statutory requirement under section 872 of Public Law 110–417, as amended (41 U.S.C. 2313). As required by section 3010 of Public Law 111–212, all information posted in the designated integrity and performance system on or after April 15, 2011, except past performance reviews required for Federal procurement contracts, will be publicly available.

G. Federal Awarding Agency Contacts

For further information concerning this notice, please contact the Office of the Secretary via email at *FASTLANEgrants@dot.gov.* For more information about highway projects, please contact Crystal Jones at (202) 366–2976. For more information about maritime projects, please contact Robert Bouchard at (202) 366–5076. For more information about rail projects, please contact Stephanie Lawrence at (202) 493–1376. For more information about railway-highway grade crossing

projects, please contact Karen McClure at (202) 493–6417. For all other questions, please contact Howard Hill at (202) 366–0301. A TDD is available for individuals who are deaf or hard of hearing at 202–366–3993. In addition, up to the application deadline, USDOT will post answers to common questions and requests for clarifications on USDOT's Web site at *https://www.transportation.gov/buildamerica/FASTLANEgrants.* To ensure applicants receive accurate information about eligibility or the program, the applicant is encouraged to contact USDOT directly, rather than through intermediaries or third parties, with questions.

H. Other Information

1. Invitation for Public Comment on the FY 2017 Notice

The FAST Act authorized the FASTLANE program through FY 2020. This notice solicits applications for FY2017 only. The Department invites interested parties to submit comments about this notice's contents, the Department's implementation choices, as well as suggestions for clarification in future FASTLANE rounds. The Department may consider the submitted comments and suggestions when developing subsequent FASTLANE solicitations and guidance, but submitted comments will not affect the selection criteria for the FY 2017 round. Applications or comments about specific projects should not be submitted to the docket. Any application submitted to the docket will not be reviewed. Comments should be sent DOT–OST–2016–0016 by December 31, 2016, but, to the extent practicable, the Department will consider late filed comments.

2. Response to Comments on the FY 2016 Notice

The Department received four comments in response to the FY16 Notice of Funding Opportunity, published under docket DOT–OST–2016–0022. The Department appreciates the feedback from our stakeholders.

Two commenters addressed USDOT's intent to prioritize projects that enhance personal mobility and accessibility.[9] Congress established multiple goals for the FASTLANE discretionary grant program, including the improvement of the safety, efficiency, and reliability of movement of both people and freight. It is the view of USDOT that considering the impact that transportation projects have on personal mobility and accessibility, particularly of disadvantaged groups, is entirely compatible with the goals of the program.

Another goal for the program which was incorporated into USDOT's evaluation was the reduction of highway congestion and bottlenecks, including bottlenecks similar to the ''Missing Links'' described by one commenter.[10]

Two commenters requested that the USDOT publish a full list of applications for FASTLANE funding.[11] USDOT has published such a list at *https://www.transportation.gov/buildamerica/FASTLANEgrants.*

Finally, one commenter encouraged DOT to change the population eligibility criteria for Metropolitan Planning Organizations.[12] Under 23 U.S.C. 117(c)(1)(B), an MPO that serves an urbanized area with a population of more than 200,000 is an eligible applicant, and DOT lacks discretion to change that statutory threshold. However, if an MPO is organized as a unit of local government or a political subdivision of a State or local government, then that MPO satisfies other eligibility criteria and the size of the urbanized area that it serves does not affect eligibility.

3. Protection of Confidential Business Information

All information submitted as part of or in support of any application shall use publicly available data or data that can be made public and methodologies that are accepted by industry practice and standards, to the extent possible. If the application includes information the applicant considers to be a trade secret or confidential commercial or financial information, the applicant should do the following: (1) Note on the front cover that the submission ''Contains Confidential Business Information (CBI)''; (2) mark each affected page ''CBI''; and (3) highlight or otherwise denote the CBI portions.

The USDOT protects such information from disclosure to the extent allowed under applicable law. In the event USDOT receives a Freedom of Information Act (FOIA) request for the information, USDOT will follow the procedures described in its FOIA regulations at 49 CFR 7.17. Only information that is ultimately determined to be confidential under that procedure will be exempt from disclosure under FOIA.

Following the completion of the selection process and announcement of awards, the Department intends to publish a list of all applications received along with the names of the applicant organizations and funding amounts requested.

Issued On: October 28, 2016.

Blair C. Anderson,

Under Secretary.

[FR Doc. 2016–26496 Filed 11–2–16; 8:45 am]

BILLING CODE 4910–9X–P

[9] *https://www.regulations.gov/document?D=DOT-OST-2016-0022-0005; https://www.regulations.gov/document?D=DOT-OST-2016-0022-0006.*

[10] *https://www.regulations.gov/document?D=DOT-OST-2016-0022-0003.*

[11] *https://www.regulations.gov/document?D=DOT-OST-2016-0022-0005; https://www.regulations.gov/document?D=DOT-OST-2016-0022-0006.*

[12] *https://www.regulations.gov/document?D=DOT-OST-2016-0022-0002.*

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–NEW]

Proposed Information Collection (Application for Approval of a Program in a Foreign Country) Activity: Comment Request

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: The Veterans Benefits Administration (VBA), Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of a currently approved collection, and allow 60 days for public comment in response to the notice. This notice solicits comments on information needed from foreign educational institutions.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before January 3, 2017.

ADDRESSES: Submit written comments on the collection of information through Federal Docket Management System (FDMS) at *www.Regulations.gov* or to Nancy J. Kessinger, Veterans Benefits Administration (20M33), Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420 or email to *nancy.kessinger@va.gov.* Please refer to ''OMB Control No. 2900–XXXX'' in any correspondence. During the comment period, comments may be viewed online through the FDMS.

FOR FURTHER INFORMATION CONTACT: Nancy J. Kessinger at (202) 632–8924 or FAX (202) 632–8925.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995 (Pub. L. 104–13; 44 U.S.C. 3501–21), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to Section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VBA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of VBA's functions, including whether the information will have practical utility; (2) the accuracy of VBA's estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Title: Application for Approval of a Program in a Foreign Country.

OMB Control Number: 2900–XXXX.

Type of Review: New information collection.

Abstract: This form is used by foreign educational institutions seeking approval for their postsecondary programs. VA uses the information to determine if a program offered by the foreign educational institution is approvable under CFR 21.4260.

Affected Public: Not-for-profit institutions.

Estimated Annual Burden: 50 hours.

Estimated Average Burden per Respondent: 20 minutes.

Frequency of Response: Once.

Estimated Number of Respondents: 150.

By direction of the Secretary.

Cynthia Harvey-Pryor,

Enterprise Records Service (005R1B), Program Specialist, Office of Privacy and Records Management, Office of Information Technology, Department of Veterans Affairs.

[FR Doc. 2016–26523 Filed 11–2–16; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0847]

Proposed Information Collection: (Veterans Employment Pay For Success (VEPFS), Grant Program Application); Activity: Comment Request.

AGENCY: Office of Policy and Planning, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: The Office of Policy and Planning, Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed revision of a currently approved collection, and allow 60 days for public comment in response to the notice.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before January 3, 2017.

ADDRESSES: Submit written comments on the collection of information through Federal Docket Management System (FDMS) at *www.Regulations.gov* or to Patrick Littlefield, Office of Policy and Planning (008), VA Center for Innovation, Department of Veterans Affairs, 810 Vermont Avenue (B–34) NW., Washington, DC 20420 or email to *patrick.littlefield@va.gov.* Please refer to ''OMB Control No. 2900–0847'' in any correspondence. During the comment period, comments may be viewed online through the FDMS.

FOR FURTHER INFORMATION CONTACT: Cynthia Harvey-Pryor (202) 461–5870 or email: *cynthia.harvey-pryor@va.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA of 1995 (Pub. L. 104–13; 44 U.S.C. 3501–21), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to Section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, the Office of Policy and Planning invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of the Office of Policy and Planning's functions, including whether the information will have practical utility; (2) the accuracy of the Office of Policy and Planning's estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Title: Veterans Employment Pay For Success (VEPFS), Grant Program Application.

OMB Control Number: 2900–0847.

Type of Review: Extension of an approved collection.

Abstract: Section 3119 of title 38, United States Code, authorizes the Secretary of Veterans Affairs to make grants to or contract with public or nonprofit agencies, including institutions of higher learning, to advance ''the knowledge, methods, techniques, and resources available for use in rehabilitation programs for veterans.'' Section 3119 specifically authorizes the Secretary to make grants to such agencies to conduct or provide support for projects which are ''designed to increase the resources and potential for accomplishing the rehabilitation of disabled veterans.'' VA has codified these provisions in its regulations at 38 CFR 21.390 Rehabilitation research and special projects. The purpose of the VEPFS program is to provide one or more grants to fund Outcomes Payments for one or more PFS projects that seek to improve employment outcomes for Veterans with a Service-connected Mental Health Disability.

Affected Public: Individuals or households.

Estimated Annual Burden: 2000 hours.

Estimated Average Burden Per Respondent: 80 hours.

Frequency of Response: On occasion.

Estimated Number of Respondents: 25.

By direction of the Secretary:

Cynthia Harvey-Pryor,

Program Specialist, Office of Privacy and Records Management, Department of Veterans Affairs.

[FR Doc. 2016–26494 Filed 11–2–16; 8:45 am]

BILLING CODE 8320–01–P

FEDERAL REGISTER

Vol. 81 Thursday,
No. 213 November 3, 2016

Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 409 and 484

Medicare and Medicaid Programs; CY 2017 Home Health Prospective Payment System Rate Update; Home Health Value-Based Purchasing Model; and Home Health Quality Reporting Requirements; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 409 and 484

[CMS–1648–F]

RIN 0938–AS80

Medicare and Medicaid Programs; CY 2017 Home Health Prospective Payment System Rate Update; Home Health Value-Based Purchasing Model; and Home Health Quality Reporting Requirements

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule updates the Home Health Prospective Payment System (HH PPS) payment rates, including the national, standardized 60-day episode payment rates, the national per-visit rates, and the non-routine medical supply (NRS) conversion factor; effective for home health episodes of care ending on or after January 1, 2017. This rule also: Implements the last year of the 4-year phase-in of the rebasing adjustments to the HH PPS payment rates; updates the HH PPS case-mix weights using the most current, complete data available at the time of rulemaking; implements the 2nd-year of a 3-year phase-in of a reduction to the national, standardized 60-day episode payment to account for estimated case-mix growth unrelated to increases in patient acuity (that is, nominal case-mix growth) between CY 2012 and CY 2014; finalizes changes to the methodology used to calculate payments made under the HH PPS for high-cost ''outlier'' episodes of care; implements changes in payment for furnishing Negative Pressure Wound Therapy (NPWT) using a disposable device for patients under a home health plan of care; discusses our efforts to monitor the potential impacts of the rebasing adjustments; includes an update on subsequent research and analysis as a result of the findings from the home health study; and finalizes changes to the Home Health Value-Based Purchasing (HHVBP) Model, which was implemented on January 1, 2016; and updates to the Home Health Quality Reporting Program (HH QRP).

DATES: These regulations are effective on January 1, 2017.

FOR FURTHER INFORMATION CONTACT:

For general information about the HH PPS, please send your inquiry via email to: *HomehealthPolicy@cms.hhs.gov*.

For information about the HHVBP Model, please send your inquiry via email to: *HHVBPquestions@cms.hhs.gov*.

Michelle Brazil, (410) 786–1648 for information about the HH quality reporting program.

Lori Teichman, (410) 786–6684, for information about Home Health Care CAHPS® Survey (HHCAHPS).

SUPPLEMENTARY INFORMATION:

Table of Contents

Acronyms

In addition, because of the many terms to which we refer by abbreviation in this rule, we are listing these abbreviations and their corresponding terms in alphabetical order below:

ACH LOS Acute Care Hospital Length of Stay
ADL Activities of Daily Living
APU Annual Payment Update
BBA Balanced Budget Act of 1997, Pub. L. 105–33
BBRA Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999, (Pub. L. 106–113)
CAD Coronary Artery Disease
CAH Critical Access Hospital
CASPER Certification and Survey Provider Enhanced Reports
CBSA Core-Based Statistical Area
CBWI Commuting-based Wage Index
CHF Congestive Heart Failure
CMI Case-Mix Index
CMP Civil Money Penalty
CMS Centers for Medicare & Medicaid Services
CoPs Conditions of Participation
COPD Chronic Obstructive Pulmonary Disease
CVD Cardiovascular Disease
CY Calendar Year
DM Diabetes Mellitus
DRA Deficit Reduction Act of 2005, Pub. L. 109–171, enacted February 8, 2006
FDL Fixed Dollar Loss
FI Fiscal Intermediaries
FISS Fiscal Intermediary Shared System
FR Federal Register
FY Fiscal Year
HAVEN Home Assessment Validation and Entry System
HCC Hierarchical Condition Categories
HCIS Health Care Information System
HH Home Health
HHA Home Health Agency

HHCAHPS Home Health Care Consumer Assessment of Healthcare Providers and Systems Survey
HH PPS Home Health Prospective Payment System
HHRG Home Health Resource Group
HHVBP Home Health Value-Based Purchasing
HIPPS Health Insurance Prospective Payment System
HVBP Hospital Value-Based Purchasing
ICD–9–CM International Classification of Diseases, Ninth Revision, Clinical Modification
ICD–10–CM International Classification of Diseases, Tenth Revision, Clinical Modification
IH Inpatient Hospitalization
IMPACT Act Improving Medicare Post-Acute Care Transformation Act of 2014 (P.L. 113–185)
IRF Inpatient Rehabilitation Facility
LEF Linear Exchange Function
LTCH Long-Term Care Hospital
LUPA Low-Utilization Payment Adjustment
MEPS Medical Expenditures Panel Survey
MFP Multifactor productivity
MMA Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. 108–173, enacted December 8, 2003
MSA Metropolitan Statistical Area
MSPB–PAC Medicare Spending Per Beneficiary-Post Acute Care
MSS Medical Social Services
NPWT Negative Pressure Wound Therapy
NQF National Quality Forum
NQS National Quality Strategy
NRS Non-Routine Supplies
OASIS Outcome and Assessment Information Set
OBRA Omnibus Budget Reconciliation Act of 1987, Pub. L. 100–2–3, enacted December 22, 1987
OCESAA Omnibus Consolidated and Emergency Supplemental Appropriations Act, Pub. L. 105–277, enacted October 21, 1998
OES Occupational Employment Statistics
OIG Office of Inspector General
OT Occupational Therapy
OMB Office of Management and Budget
OPPS Outpatient Prospective Payment System
PAMA Protecting Access to Medicare Act of 2014
PAC–PRD Post-Acute Care Payment Reform Demonstration
PEP Partial Episode Payment Adjustment
PT Physical Therapy
PY Performance Year
PRRB Provider Reimbursement Review Board
QAP Quality Assurance Plan
RAP Request for Anticipated Payment
RF Renal Failure
RFA Regulatory Flexibility Act, Pub. L. 96–354
RHHIs Regional Home Health Intermediaries
RIA Regulatory Impact Analysis
SAF Standard Analytic File
SLP Speech-Language Pathology
SN Skilled Nursing
SNF Skilled Nursing Facility
TPS Total Performance Score
TPN Total Parenteral Nutrition
UMRA Unfunded Mandates Reform Act of 1995.
VBP Value-Based Purchasing

I. Executive Summary

A. Purpose

This final rule updates the payment rates for home health agencies (HHAs) for calendar year (CY) 2017, as required under section 1895(b) of the Social Security Act (the Act). This update reflects the final year of the 4-year phase-in of the rebasing adjustments to the national, standardized 60-day episode payment rate, the national per-visit rates, and the NRS conversion factor finalized in the CY 2014 HH PPS final rule (78 FR 72256), as required under section 3131(a) of the Patient Protection and Affordable Care Act of 2010 (Pub. L. 111–148), as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152) (collectively referred to as the ''Affordable Care Act'').

This final rule also updates the case-mix weights under section 1895(b)(4)(A)(i) and (b)(4)(B) of the Act and includes a reduction to the national, standardized 60-day episode payment rate in CY 2017 of 0.97 percent, to account for case-mix growth unrelated to increases in patient acuity (nominal case-mix growth) between CY 2012 and CY 2014 under the authority of section 1895(b)(3)(B)(iv) of the Act. With regards to payments made under the HH PPS for high-cost ''outlier'' episodes of care (that is, episodes of care with unusual variations in the type or amount of medically necessary care), this rule finalizes changes to the methodology used to calculate outlier payments under the authority of section 1895(b)(5) of the Act. Also, in accordance with section 1834(s) of the Act, as amended by the Consolidated Appropriations Act, 2016 (Pub. L. 114–113), this rule implements changes in payment for furnishing Negative Pressure Wound Therapy (NPWT) using a disposable device for patients under a home health plan of care for which payment would otherwise be made under section 1895(b) of the Act. Additionally, this rule finalizes changes to the Home Health Value-Based Purchasing (HHVBP) Model, in which Medicare-certified HHAs in certain states are required to participate as of January 1, 2016, under the authority of section 1115A of the Act; and changes to the home health quality reporting program requirements under the authority of section 1895(b)(3)(B)(v) of the Act.

B. Summary of the Major Provisions

As required by section 3131(a) of the Affordable Care Act, and finalized in the CY 2014 HH PPS final rule (78 FR 77256, December 2, 2013), we are implementing the final year of the 4-year phase-in of the rebasing adjustments to the national, standardized 60-day episode payment amount, the national per-visit rates and the NRS conversion factor in section III.C.3. The rebasing adjustments for CY 2017 will reduce the national, standardized 60-day episode payment amount by $80.95, increase the national per-visit payment amounts by 3.5 percent of the national per-visit payment amounts in CY 2010 with the increases ranging from $1.79 for home health aide services to $6.34 for medical social services, and reduce the NRS conversion factor by 2.82 percent. In addition, in section III.C.3 of this rule, we are implementing a reduction to the national, standardized 60-day episode payment rate in CY 2017 of 0.97 percent to account for estimated case-mix growth unrelated to increases in patient acuity (that is, nominal case-mix growth) between CY 2012 and CY 2014. This reduction was finalized in the CY 2016 HH PPS final rule (80 FR 68624). Section III.A of this rule discusses our efforts to monitor for potential impacts due to the rebasing adjustments mandated by section 3131(a) of the Affordable Care Act.

In the CY 2015 HH PPS final rule (79 FR 66072), we finalized our proposal to recalibrate the case-mix weights every year with more current data. In section III.B of this rule, we are recalibrating the HH PPS case-mix weights, using the most current cost and utilization data available, in a budget neutral manner. In section III.C.1 of this rule, we update the payment rates under the HH PPS by the home health payment update percentage of 2.5 percent (using the 2010-based Home Health Agency (HHA) market basket update of 2.8 percent, minus 0.3 percentage point for productivity), as required by section 1895(b)(3)(B)(vi)(I) of the Act, and in section III.C.2 of this rule, we update the CY 2017 home health wage index using more current hospital wage data. In section III.D, we are finalizing a change to the current methodology used to estimate the cost of an episode of care to determine whether the episode of care would receive an outlier payment. The methodology change includes calculating the cost of an episode of care using a cost-per-unit calculation, which takes into account visit length, rather than the current methodology that uses a cost-per-visit calculation. In section

III.E of this rule, as a result of the Consolidated Appropriations Act, 2016 (Pub. L. 114–113), we are implementing changes in payment for furnishing Negative Pressure Wound Therapy (NPWT) using a disposable device for a patient under a home health plan of care for which payment is otherwise made under the HH PPS.

In section III.F of this rule, we provide an update on our recent research and analysis pertaining to the home health study required by section 3131(d) of the Affordable Care Act. Finally, in section III.G of this rule, we provide an update a process for grouping the HH PPS claim centrally during claims processing.

In section IV of this rule, we are finalizing changes to the HHVBP Model that was implemented January 1, 2016. We are finalizing: the removal of the definition of ''starter set''; a revised definition for ''benchmark''; calculation of benchmarks and achievement thresholds at the state level; a minimum requirement of eight HHAs in a cohort; an increased timeframe for submitting New Measure data; removal of four measures from the set of applicable measures; an annual reporting period and submission date for one of the New Measures; and an appeals process that includes a recalculation and reconsideration process. We are also providing an update on the progress towards developing public reporting of performance under the HHVBP Model.

This final rule also include updates to the Home Health Quality Reporting Program in section V, including removing six quality measures, adopting four new quality measures, mentioning future measures under consideration, following a calendar year schedule for measure and data submission requirements, and aligning quarterly reporting timeframes and quarterly review and correction periods.

C. Summary of Costs and Transfers

The preliminary complete set of benchmarks

TABLE 1—SUMMARY OF COSTS AND TRANSFERS

Provision description	Costs	Transfers
CY 2017 HH PPS Payment Rate Update	.....	The overall economic impact of the HH PPS payment rate update is an estimated −$130 million (−0.7 percent) in payments to HHAs.
CY 2017 HHVBP Model	.....	The overall economic impact of the HHVBP Model provision for CY 2018 through 2022 is an estimated $378 million in total savings from a reduction in unnecessary hospitalizations and SNF usage as a result of greater quality improvements in the HH industry. As for payments to HHAs, there are no aggregate increases or decreases to the HHAs competing in the model.

II. Background

A. Statutory Background

The Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33, enacted August 5, 1997), significantly changed the way Medicare pays for Medicare HH services. Section 4603 of the BBA mandated the development of the HH PPS. Until the implementation of the HH PPS on October 1, 2000, HHAs received payment under a retrospective reimbursement system. Section 4603(a) of the BBA mandated the development of a HH PPS for all Medicare-covered HH services provided under a plan of care (POC) that were paid on a reasonable cost basis by adding section 1895 of the Act, entitled ''Prospective Payment For Home Health Services.'' Section 1895(b)(1) of the Act requires the Secretary to establish a HH PPS for all costs of HH services paid under Medicare.

In accordance with section 1895(b)(3)(A) of the Act, the computation of a standard prospective payment amount must be computed to include all costs for covered HH services paid on a reasonable cost basis and such amounts must be initially based on the most recent reported cost report data. Additionally, section 1895(b)(3)(A) of the Act requires the standardized prospective payment amount to be adjusted to account for the effects of case-mix and wage levels among HHAs.

Section 1895(b)(3)(B) of the Act addresses the annual update to the standard prospective payment amounts by the HH applicable percentage increase. Section 1895(b)(4) of the Act governs the payment computation. Sections 1895(b)(4)(A)(i) and (b)(4)(A)(ii) of the Act require the standard prospective payment amount to be adjusted for case-mix and geographic differences in wage levels, respectively. Section 1895(b)(4)(B) of the Act requires the establishment of an appropriate case-mix change adjustment factor for significant variation in costs among different units of services.

Similarly, section 1895(b)(4)(C) of the Act requires the establishment of wage adjustment factors that reflect the relative level of wages, and wage-related costs applicable to HH services furnished in a geographic area compared to the applicable national average level. Under section 1895(b)(4)(C) of the Act, the wage-adjustment factors used by the Secretary may be the factors used under section 1886(d)(3)(E) of the Act.

Section 1895(b)(5) of the Act gives the Secretary the option to make additions or adjustments to the payment amount otherwise paid in the case of outliers due to unusual variations in the type or amount of medically necessary care. Section 3131(b)(2) of the Patient Protection and Affordable Care Act of 2010 (the Affordable Care Act) (Pub. L. 111–148, enacted March 23, 2010) revised section 1895(b)(5) of the Act so that total outlier payments in a given year would not exceed 2.5 percent of total payments projected or estimated. The provision also made permanent a 10 percent agency-level outlier payment cap.

In accordance with the statute, as amended by the BBA, we published a final rule in the July 3, 2000 **Federal Register** (65 FR 41128) to implement the HH PPS legislation. The July 2000 final rule established requirements for the new HH PPS for HH services as required by section 4603 of the BBA, as subsequently amended by section 5101 of the Omnibus Consolidated and Emergency Supplemental Appropriations Act (OCESAA) for Fiscal Year 1999, (Pub. L. 105–277, enacted October 21, 1998); and by sections 302, 305, and 306 of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act (BBRA) of 1999, (Pub. L. 106–113, enacted November 29, 1999). The requirements include the implementation of a HH PPS for HH services, consolidated billing requirements, and a number of other related changes. The HH PPS described in that rule replaced the retrospective reasonable cost-based system that was used by Medicare for the payment of HH services under Part A and Part B. For a

complete and full description of the HH PPS as required by the BBA, see the July 2000 HH PPS final rule (65 FR 41128 through 41214).

Section 5201(c) of the Deficit Reduction Act of 2005 (DRA) (Pub. L. 109–171, enacted February 8, 2006) added new section 1895(b)(3)(B)(v) to the Act, requiring HHAs to submit data for purposes of measuring health care quality, and links the quality data submission to the annual applicable percentage increase. This data submission requirement is applicable for CY 2007 and each subsequent year. If an HHA does not submit quality data, the HH market basket percentage increase is reduced by 2 percentage points. In the November 9, 2006 **Federal Register** (71 FR 65884, 65935), we published a final rule to implement the pay-for-reporting requirement of the DRA, which was codified at § 484.225(h) and (i) in accordance with the statute. The pay-for-reporting requirement was implemented on January 1, 2007.

The Affordable Care Act made additional changes to the HH PPS. One of the changes in section 3131 of the Affordable Care Act is the amendment to section 421(a) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173, enacted on December 8, 2003) as amended by section 5201(b) of the DRA. Section 421(a) of the MMA, as amended by section 3131 of the Affordable Care Act, requires that the Secretary increase, by 3 percent, the payment amount otherwise made under section 1895 of the Act, for HH services furnished in a rural area (as defined in section 1886(d)(2)(D) of the Act) with respect to episodes and visits ending on or after April 1, 2010, and before January 1, 2016. Section 210 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10) amended section 421(a) of the MMA to extend the rural add-on for 2 more years. Section 421(a) of the MMA, as amended by section 210 of the MACRA, requires that the Secretary increase, by 3 percent, the payment amount otherwise made under section 1895 of the Act, for HH services provided in a rural area (as defined in section 1886(d)(2)(D) of the Act) with respect to episodes and visits ending on or after April 1, 2010, and before January 1, 2018.

Section 2(a) of the Improving Medicare Post-Acute Care Transformation Act of 2014 (the IMPACT Act) (Pub. L. 113–185, enacted on Oct. 6, 2014) amended Title XVIII of the Act, in part, by adding a new section 1899B, which imposes new data reporting requirements for certain post-acute care (PAC) providers, including HHAs. New section 1899B of the Act is titled, ''Standardized Post-Acute Care (PAC) Assessment Data for Quality, Payment, and Discharge Planning''. Under section 1899B(a)(1) of the Act, certain post-acute care (PAC) providers (defined in section 1899B(a)(2)(A) of the Act to include HHAs, SNFs, IRFs, and LTCHs) must submit standardized patient assessment data in accordance with section 1899B(b) of the Act, data on quality measures required under section 1899B(c)(1) of the Act, and data on resource use, and other measures required under section 1899B(d)(1) of the Act. The Act also sets out specified application dates for each of the measures. The Secretary must specify the quality, resource use, and other measures no later than the applicable specified application date defined in section 1899B(a)(2)(E) of the Act.

B. System for Payment of Home Health Services

Generally, Medicare makes payment under the HH PPS on the basis of a national standardized 60-day episode payment rate that is adjusted for the applicable case-mix and wage index. The national standardized 60-day episode rate includes the six HH disciplines (skilled nursing, HH aide, physical therapy, speech-language pathology, occupational therapy, and medical social services). Payment for non-routine supplies (NRS) is no longer part of the national standardized 60-day episode rate and is computed by multiplying the relative weight for a particular NRS severity level by the NRS conversion factor (see section III.C.3.e.). Payment for durable medical equipment covered under the HH benefit is made outside the HH PPS payment system. To adjust for case-mix, the HH PPS uses a 153-category case-mix classification system to assign patients to a home health resource group (HHRG). The clinical severity level, functional severity level, and service utilization are computed from responses to selected data elements in the OASIS assessment instrument and are used to place the patient in a particular HHRG. Each HHRG has an associated case-mix weight which is used in calculating the payment for an episode.

For episodes with four or fewer visits, Medicare pays national per-visit rates based on the discipline(s) providing the services. An episode consisting of four or fewer visits within a 60-day period receives what is referred to as a low-utilization payment adjustment (LUPA). Medicare also adjusts the national standardized 60-day episode payment rate for certain intervening events that are subject to a partial episode payment adjustment (PEP adjustment). For certain cases that exceed a specific cost threshold, an outlier adjustment may also be available.

C. Updates to the Home Health Prospective Payment System

As required by section 1895(b)(3)(B) of the Act, we have historically updated the HH PPS rates annually in the **Federal Register**. The August 29, 2007 final rule with comment period set forth an update to the 60-day national episode rates and the national per-visit rates under the HH PPS for CY 2008. The CY 2008 HH PPS final rule included an analysis performed on CY 2005 HH claims data, which indicated a 12.78 percent increase in the observed case-mix since 2000. Case-mix represents the variations in conditions of the patient population served by the HHAs. Subsequently, a more detailed analysis was performed on the 2005 case-mix data to evaluate if any portion of the 12.78 percent increase was associated with a change in the actual clinical condition of HH patients. We examined data on demographics, family severity, and non-HH Part A Medicare expenditures to predict the average case-mix weight for 2005. We identified 8.03 percent of the total case-mix change as real, and therefore, decreased the 12.78 percent of total case-mix change by 8.03 percent to get a final nominal case-mix increase measure of 11.75 percent ($0.1278 * (1 - 0.0803) = 0.1175$).

To account for the changes in case-mix that were not related to an underlying change in patient health status, we implemented a reduction, over 4 years, to the national, standardized 60-day episode payment rates. That reduction was to be 2.75 percent per year for 3 years beginning in CY 2008 and 2.71 percent for the fourth year in CY 2011. In the CY 2011 HH PPS final rule (76 FR 68532), we updated our analyses of case-mix change and finalized a reduction of 3.79 percent, instead of 2.71 percent, for CY 2011 and deferred finalizing a payment reduction for CY 2012 until further study of the case-mix change data and methodology was completed. In the CY 2012 HH PPS final rule (76 FR 68526), we updated the 60-day national episode rates and the national per-visit rates. In addition, as discussed in the CY 2012 HH PPS final rule (76 FR 68528), our analysis indicated that there was a 22.59 percent increase in overall case-mix from 2000 to 2009 and that only 15.76 percent of that overall observed case-mix percentage increase was due to real

case-mix change. As a result of our analysis, we identified a 19.03 percent nominal increase in case-mix. At that time, to fully account for the 19.03 percent nominal case-mix growth identified from 2000 to 2009, we finalized a 3.79 percent payment reduction in CY 2012 and a 1.32 percent payment reduction for CY 2013.

In the CY 2013 HH PPS final rule (77 FR 67078), we implemented a 1.32 percent reduction to the payment rates for CY 2013 to account for nominal case-mix growth from 2000 through 2010. When taking into account the total measure of case-mix change (23.90 percent) and the 15.97 percent of total case-mix change estimated as real from 2000 to 2010, we obtained a final nominal case-mix change measure of 20.08 percent from 2000 to 2010 (0.2390 * (1 − 0.1597) = 0.2008). To fully account for the remainder of the 20.08 percent increase in nominal case-mix beyond that which was accounted for in previous payment reductions, we estimated that the percentage reduction to the national, standardized 60-day episode rates for nominal case-mix change would be 2.18 percent. Although we considered proposing a 2.18 percent reduction to account for the remaining increase in measured nominal case-mix, we finalized the 1.32 percent payment reduction to the national, standardized 60-day episode rates in the CY 2012 HH PPS final rule (76 FR 68532).

Section 3131(a) of the Affordable Care Act requires that, beginning in CY 2014, we apply an adjustment to the national, standardized 60-day episode rate and other amounts that reflect factors such as changes in the number of visits in an episode, the mix of services in an episode, the level of intensity of services in an episode, the average cost of providing care per episode, and other relevant factors. Additionally, we must phase in any adjustment over a 4 year period in equal increments, not to exceed 3.5 percent of the amount (or amounts) as of the date of enactment of the Affordable Care Act, and fully implement the rebasing adjustments by CY 2017. The statute specifies that the maximum rebasing adjustment is to be no more than 3.5 percent per year of the CY 2010 rates. Therefore, in the CY 2014 HH PPS final rule (78 FR 72256) for each year, CY 2014 through CY 2017, we finalized a fixed-dollar reduction to the national, standardized 60-day episode payment rate of $80.95 per year, increases to the national per-visit payment rates per year as reflected in Table 2, and a decrease to the NRS conversion factor of 2.82 percent per year. We also finalized three separate LUPA add-on factors for skilled nursing, physical therapy, and speech-language pathology and removed 170 diagnosis codes from assignment to diagnosis groups in the HH PPS Grouper. In the CY 2015 HH PPS final rule (79 FR 66032), we implemented the 2nd year of the 4 year phase-in of the rebasing adjustments to the HH PPS payment rates and made changes to the HH PPS case-mix weights. In addition, we simplified the face-to-face encounter regulatory requirements and the therapy reassessment timeframes.

TABLE 2—MAXIMUM ADJUSTMENTS TO THE NATIONAL PER-VISIT PAYMENT RATES

[Not to Exceed 3.5 Percent of the Amount(s) in CY 2010]

	2010 National per-visit payment rates	Maximum adjustments per year (CY 2014 through CY 2017)
Skilled Nursing	$113.01	$3.96
Home Health Aide	51.18	1.79
Physical Therapy	123.57	4.32
Occupational Therapy	124.40	4.35
Speech- Language Pathology	134.27	4.70
Medical Social Services	181.16	6.34

In the CY 2016 HH PPS final rule (80 FR 68624), we implemented the 3rd year of the 4-year phase-in of the rebasing adjustments to the national, standardized 60-day episode payment amount, the national per-visit rates and the NRS conversion factor (as outlined above). In the CY 2016 HH PPS final rule, we also recalibrated the HH PPS case-mix weights, using the most current cost and utilization data available, in a budget neutral manner and finalized reductions to the national, standardized 60-day episode payment rate in CY 2016, CY 2017, and CY 2018 of 0.97 percent in each year to account for estimated case-mix growth unrelated to increases in patient acuity (that is, nominal case-mix growth) between CY 2012 and CY 2014. Finally, section 421(a) of the MMA, as amended by section 210 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10), extended the payment increase of 3 percent for HH services provided in rural areas (as defined in section 1886(d)(2)(D) of the Act) to episodes or visits ending before January 1, 2018.

III. Provisions of the Proposed Rule and Analysis of and Responses to Comments

We received 83 timely comments from the public, including comments from home health agencies, national provider associations, patient and other advocacy organizations, nurses, and device manufacturers. The following sections, arranged by subject area, include a summary of the public comments received, and our responses.

A. Monitoring for Potential Impacts—Affordable Care Act Rebasing Adjustments

In the CY 2017 proposed rule (81 FR 43714), we provided a summary of analysis on FY 2014 HHA cost report data and how such data, if used, would impact our estimate of the percentage difference between Medicare payments and HHA costs used to calculate the Affordable Care Act rebasing adjustments. In addition, we presented information on Medicare home health utilization that included HHA claims data through CY 2015. We will continue to monitor the impacts due to the rebasing adjustments and other future policy changes and will provide the industry with periodic updates on our analysis in future rulemaking and/or announcements on the HHA Center Web page at: *https://www.cms.gov/Center/Provider-Type/Home-Health-Agency-HHA-Center.html*.

B. CY 2017 HH PPS Case-Mix Weights

In the CY 2015 HH PPS final rule (79 FR 66072), we finalized a policy to annually recalibrate the HH PPS case-

mix weights—adjusting the weights relative to one another—using the most current, complete data available. To recalibrate the HH PPS case-mix weights for CY 2017, we will use the same methodology finalized in the CY 2008 HH PPS final rule (72 FR 49762), the CY 2012 HH PPS final rule (76 FR 68526), and the CY 2015 HH PPS final rule (79 FR 66032). Annual recalibration of the HH PPS case-mix weights ensures that the case-mix weights reflect, as accurately as possible, current home health resource use and changes in utilization patterns.

To generate the proposed CY 2017 HH PPS case-mix weights, we used CY 2015 home health claims data (as of December 31, 2015) with linked OASIS data. For this final rule, we used CY 2015 home health claims data (as of June 30, 2016) with linked OASIS data to generate the final CY 2017 HH PPS case-mix weights. These data are the most current and complete data available at this time. The tables below have been revised to reflect the results using the updated data. The process we used to calculate the HH PPS case-mix weights are also outlined below.

Step 1: Re-estimate the four-equation model to determine the clinical and functional points for an episode using wage-weighted minutes of care as our dependent variable for resource use. The wage-weighted minutes of care are determined using the Bureau of Labor Statistics national hourly wage (covering May 2015) plus fringe rates (covering December 2015) for the six home health disciplines and the visit length (reported in 15-minute units) from the claim. The points for each of the variables for each leg of the model, updated with CY 2015 data, are shown in Table 3. The points for the clinical variables are added together to determine an episode's clinical score. The points for the functional variables are added together to determine an episode's functional score.

TABLE 3—CASE-MIX ADJUSTMENT VARIABLES AND SCORES

Case-Mix adjustment variables and scores				
Episode number within sequence of adjacent episodes	1 or 2	1 or 2	3+	3+
Therapy visits	0–13	14+	0–13	14+
Equation:	*1*	*2*	*3*	*4*
Clinical Dimension				
1. Primary or Other Diagnosis = Blindness/Low Vision.				
2. Primary or Other Diagnosis = Blood disorders	.....	2		
3. Primary or Other Diagnosis = Cancer, selected benign neoplasms	.....	5	.....	5
4. Primary Diagnosis = Diabetes	.....	4	.....	2
5. Other Diagnosis = Diabetes	1			
6. Primary or Other Diagnosis = Dysphagia AND Primary or Other Diagnosis = Neuro 3—Stroke	2	18	2	12
7. Primary or Other Diagnosis = Dysphagia AND M1030 (Therapy at home) = 3 (Enteral)	2	6	.....	6
8. Primary or Other Diagnosis = Gastrointestinal disorders.				
9. Primary or Other Diagnosis = Gastrointestinal disorders AND M1630 (ostomy) = 1 or 2	.....	7		
10. Primary or Other Diagnosis = Gastrointestinal disorders AND Primary or Other Diagnosis = Neuro 1—Brain disorders and paralysis, OR Neuro 2—Peripheral neurological disorders, OR Neuro 3—Stroke, OR Neuro 4—Multiple Sclerosis.				
11. Primary or Other Diagnosis = Heart Disease OR Hypertension	1	2	.....	2
12. Primary Diagnosis = Neuro 1—Brain disorders and paralysis	2	12	7	12
13. Primary or Other Diagnosis = Neuro 1—Brain disorders and paralysis AND M1840 (Toilet transfer) = 2 or more	.....	3	.....	3
14. Primary or Other Diagnosis = Neuro 1—Brain disorders and paralysis OR Neuro 2—Peripheral neurological disorders AND M1810 or M1820 (Dressing upper or lower body) = 1, 2, or 3	2	3	1	3
15. Primary or Other Diagnosis = Neuro 3—Stroke	3	12	2	5
16. Primary or Other Diagnosis = Neuro 3—Stroke AND M1810 or M1820 (Dressing upper or lower body) = 1, 2, or 3.				
17. Primary or Other Diagnosis = Neuro 3—Stroke AND M1860 (Ambulation) = 4 or more.				
18. Primary or Other Diagnosis = Neuro 4—Multiple Sclerosis AND AT LEAST ONE OF THE FOLLOWING: M1830 (Bathing) = 2 or more OR M1840 (Toilet transfer) = 2 or more OR M1850 (Transferring) = 2 or more OR M1860 (Ambulation) = 4 or more	3	7	6	11
19. Primary or Other Diagnosis = Ortho 1—Leg Disorders or Gait Disorders AND M1324 (most problematic pressure ulcer stage) = 1, 2, 3 or 4	8	1	7	
20. Primary or Other Diagnosis = Ortho 1—Leg OR Ortho 2—Other orthopedic disorders AND M1030 (Therapy at home) = 1 (IV/Infusion) or 2 (Parenteral)	3	.....	3	4
21. Primary or Other Diagnosis = Psych 1—Affective and other psychoses, depression.				
22. Primary or Other Diagnosis = Psych 2—Degenerative and other organic psychiatric disorders.				
23. Primary or Other Diagnosis = Pulmonary disorders	.....	.....	.....	1
24. Primary or Other Diagnosis = Pulmonary disorders *AND* M1860 (Ambulation) = 1 or more	.....	1		
25. Primary Diagnosis = Skin 1—Traumatic wounds, burns, and post-operative complications	4	20	7	18
26. Other Diagnosis = Skin 1—Traumatic wounds, burns, post-operative complications	7	15	8	15
27. Primary or Other Diagnosis = Skin 1—Traumatic wounds, burns, and post-operative complications OR Skin 2—Ulcers and other skin conditions AND M1030 (Therapy at home) = 1 (IV/Infusion) or 2 (Parenteral)	3			
28. Primary or Other Diagnosis = Skin 2—Ulcers and other skin conditions	2	17	8	17
29. Primary or Other Diagnosis = Tracheostomy	4	17	4	17

TABLE 3—CASE-MIX ADJUSTMENT VARIABLES AND SCORES—Continued

Case-Mix adjustment variables and scores				
Episode number within sequence of adjacent episodes	1 or 2	1 or 2	3+	3+
Therapy visits	0–13	14+	0–13	14+
Equation:	*1*	*2*	*3*	*4*
30. Primary or Other Diagnosis = Urostomy/Cystostomy	.....	18	.....	13
31. M1030 (Therapy at home) = 1 (IV/Infusion) or 2 (Parenteral)	.....	17	6	17
32. M1030 (Therapy at home) = 3 (Enteral)	.....	16	.....	9
33. M1200 (Vision) = 1 or more.				
34. M1242 (Pain) = 3 or 4	3	.....	2	
35. M1311 = Two or more pressure ulcers at stage 3 or 4 [1]	5	10	5	10
36. M1324 (Most problematic pressure ulcer stage) = 1 or 2	4	19	7	16
37. M1324 (Most problematic pressure ulcer stage) = 3 or 4	9	32	11	26
38. M1334 (Stasis ulcer status) = 2	4	15	8	15
39. M1334 (Stasis ulcer status) = 3	7	17	10	17
40. M1342 (Surgical wound status) = 2	2	7	5	11
41. M1342 (Surgical wound status) = 3	.....	6	4	9
42. M1400 (Dyspnea) = 2, 3, or 4.				
43. M1620 (Bowel Incontinence) = 2 to 5	.....	4	.....	3
44. M1630 (Ostomy) = 1 or 2	4	12	2	8
45. M2030 (Injectable Drug Use) = 0, 1, 2, or 3.				
Functional Dimension				
46. M1810 or M1820 (Dressing upper or lower body) = 1, 2, or 3	1	.....	1	
47. M1830 (Bathing) = 2 or more	6	5	5	2
48. M1840 (Toilet transferring) = 2 or more	1	2		
49. M1850 (Transferring) = 2 or more	3	1	2	
50. M1860 (Ambulation) = 1, 2 or 3	7	.....	4	.....
51. M1860 (Ambulation) = 4 or more	8	9	6	8

Source: CY 2015 Medicare claims data for episodes ending on or before December 31, 2015 (as of June 30, 2016) for which we had a linked OASIS assessment. LUPA episodes, outlier episodes, and episodes with SCIC or PEP adjustments were excluded. Note(s): Points are additive; however, points may not be given for the same line item in the table more than once.

In updating the four-equation model for CY 2017, using complete 2015 data as of June 30, 2016 (the last update to the four-equation model for CY 2016 used 2014 data), there were few changes to the point values for the variables in the four-equation model. These relatively minor changes reflect the change in the relationship between the grouper variables and resource use between 2014 and 2015. The CY 2017 four-equation model resulted in 119 point-giving variables being used in the model (as compared to the 124 point-giving variables for the 2016 recalibration). Of those 119 variables, the CY 2017 four-equation model had 113 variables that were also present in the CY 2016 four-equation model. Of those 113 variables, the points for 33 variables increased in the CY 2017 four-equation model compared to CY 2016 and the points for 33 variables decreased in the CY 2017 4-equation model compared to CY 2016. There were 47 variables with the same point values between CY 2016 and CY 2017. There were 6 variables that were added to the model in CY 2017 that weren't in the model in CY 2016. Also, 11 variables were in the model in CY 2016 but dropped in CY 2017 due to the absence of additional resources associated with these variables. In other words, these variables are not associated with additional resources beyond what is captured by the other case-mix adjustment variables in the regression model.

Step 2: Re-define the clinical and functional thresholds so they are reflective of the new points associated with the CY 2017 four-equation model. After estimating the points for each of the variables and summing the clinical and functional points for each episode, we look at the distribution of the clinical score and functional score, breaking the episodes into different steps.

The categorizations for the steps are as follows:

- Step 1: First and second episodes, 0–13 therapy visits.
- Step 2.1: First and second episodes, 14–19 therapy visits.
- Step 2.2: Third episodes and beyond, 14–19 therapy visits.
- Step 3: Third episodes and beyond, 0–13 therapy visits.
- Step 4: Episodes with 20+ therapy visits

We then divide the distribution of the clinical score for episodes within a step such that a third of episodes are classified as low clinical score, a third of episodes are classified as medium clinical score, and a third of episodes are classified as high clinical score. The same approach is then done looking at the functional score. It was not always possible to evenly divide the episodes within each step into thirds due to many episodes being clustered around one particular score.[2] Also, we looked at the average resource use associated with each clinical and functional score and used that to guide where we placed our thresholds. We tried to group scores with similar average resource use within the same level (even if it meant that more or less than a third of episodes were placed within a level). The new

[1] M1308 'Current Number of Unhealed Pressure Ulcers at Each Stage or Unstageable' will be changed to M1311 'Current Number of Unhealed Pressure Ulcers at Each Stage' under the new OASIS C2 format, effective January 1, 2017.

[2] For Step 1, 49.2 percent of episodes were in the medium functional level (All with score 14).

For Step 2.1, 70.7 percent of episodes were in the low functional level (Most with score 5 and 6).

For Step 2.2, 78.7 percent of episodes were in the medium functional level (Most with score 2).

For Step 3, 51.0 percent of episodes were in the medium functional level (Most with score 10).

For Step 4, 51.2 percent of episodes were in the medium functional level (Most with score 5 and 6).

thresholds, based off of the CY 2017 four-equation model points are shown in Table 4.

TABLE 4—CY 2017 CLINICAL AND FUNCTIONAL THRESHOLDS

		1st and 2nd episodes		3rd+ episodes		All episodes
		0 to 13 therapy visits	14 to 19 therapy visits	0 to 13 therapy visits	14 to 19 therapy visits	20+ therapy visits
Grouping Step:		1	2.1	3	2.2	4
Equation(s) used to calculate points: (see Table 3)		1	2	3	4	(2&4)
Dimension	Severity Level					
Clinical	C1	0 to 1	0 to 1	0 to 1	0 to 1	0 to 3
	C2	2 to 3	2 to 7	2	2 to 9	4 to 16
	C3	4+	8+	3+	10+	17+
Functional	F1	0 to 13	0 to 6	0 to 6	0 to 1	0 to 2
	F2	14	7 to 13	7 to 10	2 to 9	3 to 6
	F3	15+	14+	11+	10+	7+

Step 3: Once the clinical and functional thresholds are determined and each episode is assigned a clinical and functional level, the payment regression is estimated with an episode's wage-weighted minutes of care as the dependent variable. Independent variables in the model are indicators for the step of the episode as well as the clinical and functional levels within each step of the episode. Like the four-equation model, the payment regression model is also estimated with robust standard errors that are clustered at the beneficiary level. Table 5 shows the regression coefficients for the variables in the payment regression model updated with CY 2015 data. The R-squared value for the payment regression model is 0.4929 (an increase from 0.4822 for the CY 2016 recalibration).

TABLE 5—PAYMENT REGRESSION MODEL

Variable description	New payment regression coefficients
Step 1, Clinical Score Medium	$22.81
Step 1, Clinical Score High	53.36
Step 1, Functional Score Medium	70.51
Step 1, Functional Score High	108.77
Step 2.1, Clinical Score Medium	32.34
Step 2.1, Clinical Score High	146.99
Step 2.1, Functional Score Medium	11.24
Step 2.1, Functional Score High	64.89
Step 2.2, Clinical Score Medium	42.88
Step 2.2, Clinical Score High	193.55
Step 2.2, Functional Score Medium	0.00
Step 2.2, Functional Score High	57.18
Step 3, Clinical Score Medium	11.50
Step 3, Clinical Score High	91.93
Step 3, Functional Score Medium	53.82
Step 3, Functional Score High	85.08
Step 4, Clinical Score Medium	76.81
Step 4, Clinical Score High	256.77
Step 4, Functional Score Medium	35.45
Step 4, Functional Score High	81.20
Step 2.1, 1st and 2nd Episodes, 14 to 19 Therapy Visits	498.79
Step 2.2, 3rd+ Episodes, 14 to 19 Therapy Visits	506.90
Step 3, 3rd+ Episodes, 0–13 Therapy Visits	−72.76
Step 4, All Episodes, 20+ Therapy Visits	903.44
Intercept	397.53

Source: CY 2015 Medicare claims data for episodes ending on or before December 31, 2015 (as of June 30, 2016) for which we had a linked OASIS assessment.

Step 4: We use the coefficients from the payment regression model to predict each episode's wage-weighted minutes of care (resource use). We then divide these predicted values by the mean of the dependent variable (that is, the average wage-weighted minutes of care across all episodes used in the payment regression). This division constructs the weight for each episode, which is simply the ratio of the episode's predicted wage-weighted minutes of care divided by the average wage-weighted minutes of care in the sample. Each episode is then aggregated into one of the 153 home health resource groups (HHRGs) and the ''raw'' weight for each HHRG was calculated as the average of the episode weights within the HHRG.

Step 5: The weights associated with 0 to 5 therapy visits are then increased by 3.75 percent, the weights associated with 14–15 therapy visits are decreased by 2.5 percent, and the weights associated with 20+ therapy visits are decreased by 5 percent. These adjustments to the case-mix weights were finalized in the CY 2012 HH PPS final rule (76 FR 68557) and were done to address concerns that the HH PPS overvalues therapy episodes and undervalues non-therapy episodes and to better align the case-mix weights with episode costs estimated from cost report data.[3]

Step 6: After the adjustments in step 5 are applied to the raw weights, the weights are further adjusted to create an increase in the payment weights for the therapy visit steps between the therapy thresholds. Weights with the same clinical severity level, functional severity level, and early/later episode status were grouped together. Then within those groups, the weights for each therapy step between thresholds are gradually increased. We do this by interpolating between the main thresholds on the model (from 0–5 to 14–15 therapy visits, and from 14–15 to 20+ therapy visits). We use a linear model to implement the interpolation so the payment weight increase for each step between the thresholds (such as the increase between 0–5 therapy visits and

[3] Medicare Payment Advisory Commission (MedPAC), *Report to the Congress: Medicare Payment Policy*. March 2011, P. 176.

6 therapy visits and the increase between 6 therapy visits and 7–9 therapy visits) are constant. This interpolation is the identical to the process finalized in the CY 2012 HH PPS final rule (76 FR 68555).

Step 7: The interpolated weights are then adjusted so that the average case-mix for the weights is equal to 1.0000.[4] This last step creates the CY 2017 case-mix weights shown in Table 6.

TABLE 6—FINAL CY 2017 CASE-MIX PAYMENT WEIGHTS

Payment group	Step (episode and/or therapy visit ranges)	Clinical and functional levels (1 = low; 2 = medium; 3 = high)	Final CY 2017 case-mix weights
10111	1st and 2nd Episodes, 0 to 5 Therapy Visits	C1F1S1	0.5857
10112	1st and 2nd Episodes, 6 Therapy Visits	C1F1S2	0.7168
10113	1st and 2nd Episodes, 7 to 9 Therapy Visits	C1F1S3	0.8479
10114	1st and 2nd Episodes, 10 Therapy Visits	C1F1S4	0.9790
10115	1st and 2nd Episodes, 11 to 13 Therapy Visits	C1F1S5	1.1100
10121	1st and 2nd Episodes, 0 to 5 Therapy Visits	C1F2S1	0.6896
10122	1st and 2nd Episodes, 6 Therapy Visits	C1F2S2	0.8030
10123	1st and 2nd Episodes, 7 to 9 Therapy Visits	C1F2S3	0.9164
10124	1st and 2nd Episodes, 10 Therapy Visits	C1F2S4	1.0298
10125	1st and 2nd Episodes, 11 to 13 Therapy Visits	C1F2S5	1.1433
10131	1st and 2nd Episodes, 0 to 5 Therapy Visits	C1F3S1	0.7460
10132	1st and 2nd Episodes, 6 Therapy Visits	C1F3S2	0.8630
10133	1st and 2nd Episodes, 7 to 9 Therapy Visits	C1F3S3	0.9800
10134	1st and 2nd Episodes, 10 Therapy Visits	C1F3S4	1.0970
10135	1st and 2nd Episodes, 11 to 13 Therapy Visits	C1F3S5	1.2140
10211	1st and 2nd Episodes, 0 to 5 Therapy Visits	C2F1S1	0.6193
10212	1st and 2nd Episodes, 6 Therapy Visits	C2F1S2	0.7526
10213	1st and 2nd Episodes, 7 to 9 Therapy Visits	C2F1S3	0.8860
10214	1st and 2nd Episodes, 10 Therapy Visits	C2F1S4	1.0193
10215	1st and 2nd Episodes, 11 to 13 Therapy Visits	C2F1S5	1.1526
10221	1st and 2nd Episodes, 0 to 5 Therapy Visits	C2F2S1	0.7232
10222	1st and 2nd Episodes, 6 Therapy Visits	C2F2S2	0.8389
10223	1st and 2nd Episodes, 7 to 9 Therapy Visits	C2F2S3	0.9545
10224	1st and 2nd Episodes, 10 Therapy Visits	C2F2S4	1.0702
10225	1st and 2nd Episodes, 11 to 13 Therapy Visits	C2F2S5	1.1858
10231	1st and 2nd Episodes, 0 to 5 Therapy Visits	C2F3S1	0.7796
10232	1st and 2nd Episodes, 6 Therapy Visits	C2F3S2	0.8988
10233	1st and 2nd Episodes, 7 to 9 Therapy Visits	C2F3S3	1.0181
10234	1st and 2nd Episodes, 10 Therapy Visits	C2F3S4	1.1373
10235	1st and 2nd Episodes, 11 to 13 Therapy Visits	C2F3S5	1.2565
10311	1st and 2nd Episodes, 0 to 5 Therapy Visits	C3F1S1	0.6643
10312	1st and 2nd Episodes, 6 Therapy Visits	C3F1S2	0.8204
10313	1st and 2nd Episodes, 7 to 9 Therapy Visits	C3F1S3	0.9765
10314	1st and 2nd Episodes, 10 Therapy Visits	C3F1S4	1.1325
10315	1st and 2nd Episodes, 11 to 13 Therapy Visits	C3F1S5	1.2886
10321	1st and 2nd Episodes, 0 to 5 Therapy Visits	C3F2S1	0.7682
10322	1st and 2nd Episodes, 6 Therapy Visits	C3F2S2	0.9066
10323	1st and 2nd Episodes, 7 to 9 Therapy Visits	C3F2S3	1.0450
10324	1st and 2nd Episodes, 10 Therapy Visits	C3F2S4	1.1834
10325	1st and 2nd Episodes, 11 to 13 Therapy Visits	C3F2S5	1.3218
10331	1st and 2nd Episodes, 0 to 5 Therapy Visits	C3F3S1	0.8246
10332	1st and 2nd Episodes, 6 Therapy Visits	C3F3S2	0.9666
10333	1st and 2nd Episodes, 7 to 9 Therapy Visits	C3F3S3	1.1086
10334	1st and 2nd Episodes, 10 Therapy Visits	C3F3S4	1.2505
10335	1st and 2nd Episodes, 11 to 13 Therapy Visits	C3F3S5	1.3925
21111	1st and 2nd Episodes, 14 to 15 Therapy Visits	C1F1S1	1.2411
21112	1st and 2nd Episodes, 16 to 17 Therapy Visits	C1F1S2	1.4125
21113	1st and 2nd Episodes, 18 to 19 Therapy Visits	C1F1S3	1.5838
21121	1st and 2nd Episodes, 14 to 15 Therapy Visits	C1F2S1	1.2567
21122	1st and 2nd Episodes, 16 to 17 Therapy Visits	C1F2S2	1.4388
21123	1st and 2nd Episodes, 18 to 19 Therapy Visits	C1F2S3	1.6209
21131	1st and 2nd Episodes, 14 to 15 Therapy Visits	C1F3S1	1.3310
21132	1st and 2nd Episodes, 16 to 17 Therapy Visits	C1F3S2	1.5089
21133	1st and 2nd Episodes, 18 to 19 Therapy Visits	C1F3S3	1.6868
21211	1st and 2nd Episodes, 14 to 15 Therapy Visits	C2F1S1	1.2859
21212	1st and 2nd Episodes, 16 to 17 Therapy Visits	C2F1S2	1.4769
21213	1st and 2nd Episodes, 18 to 19 Therapy Visits	C2F1S3	1.6679
21221	1st and 2nd Episodes, 14 to 15 Therapy Visits	C2F2S1	1.3014
21222	1st and 2nd Episodes, 16 to 17 Therapy Visits	C2F2S2	1.5032

[4] When computing the average, we compute a weighted average, assigning a value of one to each normal episode and a value equal to the episode length divided by 60 for PEPs.

TABLE 6—FINAL CY 2017 CASE-MIX PAYMENT WEIGHTS—Continued

Payment group	Step (episode and/or therapy visit ranges)	Clinical and functional levels (1 = low; 2 = medium; 3 = high)	Final CY 2017 case-mix weights
21223	1st and 2nd Episodes, 18 to 19 Therapy Visits	C2F2S3	1.7049
21231	1st and 2nd Episodes, 14 to 15 Therapy Visits	C2F3S1	1.3757
21232	1st and 2nd Episodes, 16 to 17 Therapy Visits	C2F3S2	1.5733
21233	1st and 2nd Episodes, 18 to 19 Therapy Visits	C2F3S3	1.7708
21311	1st and 2nd Episodes, 14 to 15 Therapy Visits	C3F1S1	1.4446
21312	1st and 2nd Episodes, 16 to 17 Therapy Visits	C3F1S2	1.6636
21313	1st and 2nd Episodes, 18 to 19 Therapy Visits	C3F1S3	1.8826
21321	1st and 2nd Episodes, 14 to 15 Therapy Visits	C3F2S1	1.4602
21322	1st and 2nd Episodes, 16 to 17 Therapy Visits	C3F2S2	1.6899
21323	1st and 2nd Episodes, 18 to 19 Therapy Visits	C3F2S3	1.9197
21331	1st and 2nd Episodes, 14 to 15 Therapy Visits	C3F3S1	1.5345
21332	1st and 2nd Episodes, 16 to 17 Therapy Visits	C3F3S2	1.7601
21333	1st and 2nd Episodes, 18 to 19 Therapy Visits	C3F3S3	1.9856
22111	3rd+ Episodes, 14 to 15 Therapy Visits	C1F1S1	1.2523
22112	3rd+ Episodes, 16 to 17 Therapy Visits	C1F1S2	1.4200
22113	3rd+ Episodes, 18 to 19 Therapy Visits	C1F1S3	1.5876
22121	3rd+ Episodes, 14 to 15 Therapy Visits	C1F2S1	1.2523
22122	3rd+ Episodes, 16 to 17 Therapy Visits	C1F2S2	1.4359
22123	3rd+ Episodes, 18 to 19 Therapy Visits	C1F2S3	1.6195
22131	3rd+ Episodes, 14 to 15 Therapy Visits	C1F3S1	1.3315
22132	3rd+ Episodes, 16 to 17 Therapy Visits	C1F3S2	1.5093
22133	3rd+ Episodes, 18 to 19 Therapy Visits	C1F3S3	1.6870
22211	3rd+ Episodes, 14 to 15 Therapy Visits	C2F1S1	1.3117
22212	3rd+ Episodes, 16 to 17 Therapy Visits	C2F1S2	1.4941
22213	3rd+ Episodes, 18 to 19 Therapy Visits	C2F1S3	1.6765
22221	3rd+ Episodes, 14 to 15 Therapy Visits	C2F2S1	1.3117
22222	3rd+ Episodes, 16 to 17 Therapy Visits	C2F2S2	1.5100
22223	3rd+ Episodes, 18 to 19 Therapy Visits	C2F2S3	1.7083
22231	3rd+ Episodes, 14 to 15 Therapy Visits	C2F3S1	1.3909
22232	3rd+ Episodes, 16 to 17 Therapy Visits	C2F3S2	1.5834
22233	3rd+ Episodes, 18 to 19 Therapy Visits	C2F3S3	1.7759
22311	3rd+ Episodes, 14 to 15 Therapy Visits	C3F1S1	1.5203
22312	3rd+ Episodes, 16 to 17 Therapy Visits	C3F1S2	1.7141
22313	3rd+ Episodes, 18 to 19 Therapy Visits	C3F1S3	1.9079
22321	3rd+ Episodes, 14 to 15 Therapy Visits	C3F2S1	1.5203
22322	3rd+ Episodes, 16 to 17 Therapy Visits	C3F2S2	1.7300
22323	3rd+ Episodes, 18 to 19 Therapy Visits	C3F2S3	1.9398
22331	3rd+ Episodes, 14 to 15 Therapy Visits	C3F3S1	1.5995
22332	3rd+ Episodes, 16 to 17 Therapy Visits	C3F3S2	1.8034
22333	3rd+ Episodes, 18 to 19 Therapy Visits	C3F3S3	2.0073
30111	3rd+ Episodes, 0 to 5 Therapy Visits	C1F1S1	0.4785
30112	3rd+ Episodes, 6 Therapy Visits	C1F1S2	0.6333
30113	3rd+ Episodes, 7 to 9 Therapy Visits	C1F1S3	0.7880
30114	3rd+ Episodes, 10 Therapy Visits	C1F1S4	0.9428
30115	3rd+ Episodes, 11 to 13 Therapy Visits	C1F1S5	1.0976
30121	3rd+ Episodes, 0 to 5 Therapy Visits	C1F2S1	0.5578
30122	3rd+ Episodes, 6 Therapy Visits	C1F2S2	0.6967
30123	3rd+ Episodes, 7 to 9 Therapy Visits	C1F2S3	0.8356
30124	3rd+ Episodes, 10 Therapy Visits	C1F2S4	0.9745
30125	3rd+ Episodes, 11 to 13 Therapy Visits	C1F2S5	1.1134
30131	3rd+ Episodes, 0 to 5 Therapy Visits	C1F3S1	0.6039
30132	3rd+ Episodes, 6 Therapy Visits	C1F3S2	0.7494
30133	3rd+ Episodes, 7 to 9 Therapy Visits	C1F3S3	0.8949
30134	3rd+ Episodes, 10 Therapy Visits	C1F3S4	1.0405
30135	3rd+ Episodes, 11 to 13 Therapy Visits	C1F3S5	1.1860
30211	3rd+ Episodes, 0 to 5 Therapy Visits	C2F1S1	0.4955
30212	3rd+ Episodes, 6 Therapy Visits	C2F1S2	0.6587
30213	3rd+ Episodes, 7 to 9 Therapy Visits	C2F1S3	0.8220
30214	3rd+ Episodes, 10 Therapy Visits	C2F1S4	0.9852
30215	3rd+ Episodes, 11 to 13 Therapy Visits	C2F1S5	1.1485
30221	3rd+ Episodes, 0 to 5 Therapy Visits	C2F2S1	0.5748
30222	3rd+ Episodes, 6 Therapy Visits	C2F2S2	0.7222
30223	3rd+ Episodes, 7 to 9 Therapy Visits	C2F2S3	0.8695
30224	3rd+ Episodes, 10 Therapy Visits	C2F2S4	1.0169
30225	3rd+ Episodes, 11 to 13 Therapy Visits	C2F2S5	1.1643
30231	3rd+ Episodes, 0 to 5 Therapy Visits	C2F3S1	0.6208
30232	3rd+ Episodes, 6 Therapy Visits	C2F3S2	0.7748
30233	3rd+ Episodes, 7 to 9 Therapy Visits	C2F3S3	0.9288

TABLE 6—FINAL CY 2017 CASE-MIX PAYMENT WEIGHTS—Continued

Payment group	Step (episode and/or therapy visit ranges)	Clinical and functional levels (1 = low; 2 = medium; 3 = high)	Final CY 2017 case-mix weights
30234	3rd+ Episodes, 10 Therapy Visits	C2F3S4	1.0829
30235	3rd+ Episodes, 11 to 13 Therapy Visits	C2F3S5	1.2369
30311	3rd+ Episodes, 0 to 5 Therapy Visits	C3F1S1	0.6140
30312	3rd+ Episodes, 6 Therapy Visits	C3F1S2	0.7953
30313	3rd+ Episodes, 7 to 9 Therapy Visits	C3F1S3	0.9765
30314	3rd+ Episodes, 10 Therapy Visits	C3F1S4	1.1578
30315	3rd+ Episodes, 11 to 13 Therapy Visits	C3F1S5	1.3391
30321	3rd+ Episodes, 0 to 5 Therapy Visits	C3F2S1	0.6933
30322	3rd+ Episodes, 6 Therapy Visits	C3F2S2	0.8587
30323	3rd+ Episodes, 7 to 9 Therapy Visits	C3F2S3	1.0241
30324	3rd+ Episodes, 10 Therapy Visits	C3F2S4	1.1895
30325	3rd+ Episodes, 11 to 13 Therapy Visits	C3F2S5	1.3549
30331	3rd+ Episodes, 0 to 5 Therapy Visits	C3F3S1	0.7393
30332	3rd+ Episodes, 6 Therapy Visits	C3F3S2	0.9114
30333	3rd+ Episodes, 7 to 9 Therapy Visits	C3F3S3	1.0834
30334	3rd+ Episodes, 10 Therapy Visits	C3F3S4	1.2554
30335	3rd+ Episodes, 11 to 13 Therapy Visits	C3F3S5	1.4275
40111	All Episodes, 20+ Therapy Visits	C1F1S1	1.7552
40121	All Episodes, 20+ Therapy Visits	C1F2S1	1.8030
40131	All Episodes, 20+ Therapy Visits	C1F3S1	1.8648
40211	All Episodes, 20+ Therapy Visits	C2F1S1	1.8588
40221	All Episodes, 20+ Therapy Visits	C2F2S1	1.9067
40231	All Episodes, 20+ Therapy Visits	C2F3S1	1.9684
40311	All Episodes, 20+ Therapy Visits	C3F1S1	2.1016
40321	All Episodes, 20+ Therapy Visits	C3F2S1	2.1495
40331	All Episodes, 20+ Therapy Visits	C3F3S1	2.2112

To ensure the changes to the HH PPS case-mix weights are implemented in a budget neutral manner, we apply a case-mix budget neutrality factor to the CY 2017 national, standardized 60-day episode payment rate (see section III.C.3. of this final rule). The case-mix budget neutrality factor is calculated as the ratio of total payments when the CY 2017 HH PPS grouper and case-mix weights (developed using CY 2015 claims data) are applied to CY 2015 utilization (claims) data to total payments when the CY 2016 HH PPS grouper and case-mix weights (developed using CY 2014 claims data) are applied to CY 2015 utilization data. Using CY 2015 claims data as of June 30, 2016, we calculated the case-mix budget neutrality factor for CY 2017 to be 1.0214.

The following is a summary of the comments and our responses to comments on the CY 2017 case-mix weights.

Comment: One commenter implied that the recalibration should be based on trends or standards for the type of care Medicare and providers collectively agree are appropriate for Medicare beneficiaries, rather than a single year of data, and that CMS should recognize innovations in the home health industry. Another commenter stated that current home health resource use does not accurately reflect what the resource use should be and Medicare law provides. The commenter stated that under this payment structure, patients with clinically complex and long-term chronic conditions are often either unable to gain access to legally covered care, or they are provided with limited care relative to what their plan of care orders or their OASIS indicates they should receive. One commenter stated that CMS' 2015 decision, to decrease case-mix weights for the third and later episodes of care with 0 to 19 therapy visits due to the CY 2015 recalibration of the case-mix weights (81 FR 43722), is contrary to Medicare coverage law and that a decrease in case-mix weights for later episodes creates broad-based, practical access problems to HHAs for those who qualify for Medicare home health benefit. One commenter suggested that the case-mix weight recalibration can be easily manipulated to cause industry reimbursement to be much less than projected and/or necessary. The commenter stated that CMS eliminated scoring variables from the case-mix system one year, but then added the variables back into the system the subsequent year. The commenter stated that CMS may not be able to identify what patient characteristics may require additional resources and stated that a committee comprised of CMS and industry representatives should be established to oversee the annual changes to the home health case-mix weights.

Response: We note that we did not change the recalibration methodology from previous years. In CY 2015, we proposed and finalized annual recalibration and the methodology to be used for each recalibration. The recalibration determines the points associated with the case-mix variables and the weights associated with the HHRGs based on resource use (estimated using the Bureau of Labor Statistics national hourly wage plus fringe rates for the six home health disciplines and the visit length (reported in 15-minute units) from the home health claim). The points in the model are taken directly from a regression of resource use and reflect the most current, complete utilization data available. Any decreases in the points associated with the case-mix variables or decreases in the case-mix weights reflect fewer resources being furnished in those episodes than what was previously furnished. We update the recalibration weights every year to reflect current utilization data. Variables falling out or coming back into the case-mix system are a direct reflection of the

changes in the services being furnished and reported.

As noted in section III.F. of this final rule, we have conducted research and analyses to potentially revise the HH PPS case-mix methodology. We plan to release a more detailed Technical Report in the future on our research and analyses.

Comment: One commenter expressed concern with the use of 15-minute unit data at uniform levels as proxies for cost in the case-mix weight recalibration. The commenter stated that there are certain fixed costs that do not vary by visit length, including, but not limited to, transportation and administrative costs, and that using a 15 minute time increment as a cost proxy is inaccurate unless it is weighted in relation to the fixed costs incurred regardless of visit length. The commenter stated that using a single weighted 15 minute time unit in the case-mix recalibration results in HHRGs with shorter than average visits having a lower case-mix weight than what is appropriate and HHRGs with longer than average visits having a higher case-mix weight than what is appropriate. The commenter stated that CMS should withdraw the case mix weight recalibration proposal and that any future recalibration based on time units should proceed only if CMS can fairly weight the units to account for costs that are incurred without regard to visit length.

Response: We have used wage weighted 15-minute units as our measure of resource use since the inception of the HH PPS. We did not propose any changes to the methodology or method of estimating resource use in the proposed rule. Weighting the first 15-minute unit to account for fixed costs is not appropriate as payment for the fixed costs of an episode, such as transportation, are already accounted for under the national, standardized 60-day episode payment rate. We will continue to conduct ongoing data analysis to monitor resource use patterns.

Comment: Commenters urged CMS to reconsider the proposed CY 2017 HH PPS case-mix weight adjustments. Commenters stated that the reduced scoring in the clinical and functional dimensions will significantly adversely impact the ability of HHAs to care for certain types of patients and listed the types of patients affected. Commenters stated that the new case-mix weight scoring has removed key conditions from the case mix index: Diabetes as a co-morbid diagnosis, heart disease diagnosis, neurological diagnoses, including their associated functional deficit combination, blood disorder diagnoses, dyspnea as a symptom for which points are attributed, diagnosis combinations, such as the combination of neurological and orthopedic diagnoses with their functional deficits, and reduced points for skin, wound, and ulcer diagnoses. One commenter stated that CMS should ensure access to care for people with these conditions, support high-quality HHAs that care for these populations, and motivate transfer partners, such as hospitals, to seek out HHAs that can care for these populations. The commenter stated that the case-mix weights also reduce payment for clinical and functional domain needs and that their member HHAs which serve patients with complex conditions and high functional needs are disproportionately affected by the changes. Commenters urged CMS to restore justified scoring and weights to ensure that care for patients with these chronic conditions are properly reimbursed.

Another commenter stated that the findings of the home health study required by section 3131(d) of the Affordable Care Act on access to care for vulnerable beneficiaries should be incorporated into the case-mix weights for CY 2017 and that if the current 4-equation case mix model cannot be adapted to account for these beneficiary characteristics, CMS should expedite replacing the current model with one that can more accurately account for variations in patient characteristics and needs.

A commenter stated that these new weights shift payments to HHAs in unpredictable ways related to each individual agency's distribution of patients and expressed concerns that the proposed case-mix weights may cause significant variation in payment depending on an individual HHA's typical case mix. The commenter stated that CMS should produce significantly more detailed impact analyses to assure that the agency specific impacts of these ongoing adjustments to individual case mix weights are not creating unfair impacts on individual agencies that are lost in the aggregate impact analyses. The commenter expressed concerns that the current impact analysis is too broad and masking potential impact issues.

Response: Any changes in the case-mix weights reflect changes in utilization from 2014 (data used for the CY 2016 recalibration) to 2015 (data used for the CY 2017 recalibration). The points table and weights described in the proposed rule are based off of CY 2015 data as of December 31, 2015 and there are changes in the points and weights when using complete 2015 data as of June 30, 2016. Using complete 2015 data, there are 119 variables in the four-equation model versus 110 variables in the CY 2017 proposed rule. In addition, there were fewer variables dropped from the model and more variables with no change in the points when using complete CY 2015 data as of June 30, 2016 than when using 2015 data as of December 31, 2015. A number of the diagnoses that the commenters mentioned now have points associated with the case-mix variables when using complete 2015 data as of June 30, 2016, such as diabetes as a co-morbid diagnosis, heart disease diagnosis, and blood disorder diagnoses. In addition, there were increases in the points for some of the diagnoses mentioned such as ''Other Diagnosis = Skin 1—Traumatic wounds, burns, post-operative complications.'' We encourage commenters to review the updated table of points (Table 3). We note that in 2015, we started the annual recalibration of the case-mix weights. In addition, on October 1, 2015, ICD–10 was implemented. Changes in the point values and case-mix weights may reflect changes due to the transition to ICD–10 as well as changes in the provision of services as a result of the CY 2015 recalibration.

There are five case-mix variables which have had a drop of 4 points from the CY 2016 recalibration (which is based on CY 2014 data) to the CY 2017 recalibration (which is based on CY 2015 data). The total number of visits for episodes with these characteristics decreased from CY 2014 to CY 2015, with decreases ranging from 0.4 to 2.1 visits per episode. Since there are fewer services being provided in CY 2015 than in CY 2014, points associated with these case-mix variables have decreased. It is important to note that we did not propose any changes to the recalibration methodology and we report impact analyses the same way we have done every year, with expenditure effects of policy changes by HHA facility type and area of the country.

In the CY 2017 HH PPS proposed rule, we described our follow-on work to the home health study, providing further information on our research and analyses conducted to potentially revise the HH PPS case-mix methodology to address the home health study findings outlined in the Report to Congress (81 FR 43744 through 43746). In the proposed rule, we stated that we planned to release a more detailed Technical Report in the future on this additional research and analysis conducted on the Home Health Groupings Model (HHGM), an alternative to the current case-mix system. This report will address

vulnerable beneficiaries as identified in the home health study, which include those beneficiaries that have more complex care needs. As noted in section III.F. of this final rule, once the Technical Report is released, we will post a link on our Home Health Agency (HHA) Center Web site at *https://www.cms.gov/center/provider-Type/home-Health-Agency-HHA-Center.html* to receive comments and feedback on the model. While we are not incorporating findings of the section 3131(d) home health study on access to care for vulnerable beneficiaries in the case-mix system for CY 2017, we encourage commenters to provide feedback on our alternate model that may be considered in future rulemaking.

Comment: One commenter stated that CMS has not provided sufficient transparency of the details and methods used to recalibrate the HH PPS case-mix weights in its discussion of the proposed rule and that CMS provides little justification for recalibrating the case-mix weights just one year following the recalibration of case-mix weights in CY 2016 and only four years since the recalibration for the CY 2012 Final Rule. The commenter stated that the proposed recalibration is significant in that their analysis indicates a greater reduction in case weights than the 0.62 percent proposed by CMS as the budget neutrality adjustment. Another commenter requested that CMS describe in detail how the wage index and case-mix weights budget neutrality factors are calculated.

Response: We proposed and finalized annual recalibration to the weights in CY 2015 in order to ensure that the case-mix system reflects current utilization patterns. We use the most current, complete data available at the time of rulemaking. We note that the budget neutrality factor in the proposed rule was based on 2015 claims data as of December 31, 2015. Updating the budget neutrality factor with complete 2015 claims data as of June 30, 2016, data indicated that a budget neutrality factor of 1.0214 is needed. We encourage commenters to review the methodology described in the CY 2015 rule (79 FR 66066) on how the budget neutrality factor is calculated. The method of calculating a budget neutrality factor is similar to the method used in other payment systems.

Final Decision: We are finalizing the recalibrated scores for the case-mix adjustment variables, clinical and functional thresholds, payment regression model, and case-mix weights in Tables 3 through 6. For the final rule, the CY 2017 scores for the case-mix variables, the clinical and functional thresholds, and the case-mix weights were developed using complete CY 2015 claims data as of June 30, 2016. We note that we finalized the recalibration methodology and the proposal to annually recalibrate the HH PPS case-mix weights in the CY 2015 HH PPS final rule (79 FR 66072). No additional proposals were made with regard to the recalibration methodology in the CY 2017 HH PPS proposed rule.

C. CY 2017 Home Health Payment Rate Update

1. CY 2017 Home Health Market Basket Update

Section 1895(b)(3)(B) of the Act requires that the standard prospective payment amounts for CY 2017 be increased by a factor equal to the applicable HH market basket update for those HHAs that submit quality data as required by the Secretary. A detailed description of how we derive the HHA market basket is available in the CY 2013 HH PPS final rule (77 FR 67080–67090). The HH market basket percentage increase for CY 2017 is based on IHS Global Insight Inc.'s (IGI) third quarter 2016 forecast with historical data through the second quarter of 2016. The HH market basket percentage increase for CY 2017 is 2.8 percent.

Section 3401(e) of the Affordable Care Act, adding new section 1895(b)(3)(B)(vi) to the Act, requires that the market basket percentage under the HH PPS (as described in section 1895(b)(3)(B) of the Act) be annually adjusted by changes in economy-wide productivity for CY 2015 and each subsequent calendar year. The statute defines the productivity adjustment, described in section 1886(b)(3)(B)(xi)(II) of the Act, to be equal to the 10-year moving average of change 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, calendar year, cost reporting period, or other annual period) (the ''MFP adjustment''). The Bureau of Labor Statistics (BLS) is the agency that publishes the official measure of private nonfarm business MFP. Please see *http://www.bls.gov/mfp* to obtain the BLS historical published MFP data. The MFP adjustment for CY 2017 (the projection of the 10-year moving average of MFP for the period ending CY 2017) is 0.3 percent. Therefore, the CY 2017 HH market basket percentage of 2.8 percent will be reduced by the MFP adjustment of 0.3 percent. The resulting HH payment update percentage is equal to 2.5 percent, or 2.8 percent less 0.3 percentage point.

Section 1895(b)(3)(B) of the Act requires that the home health update be decreased by 2 percentage points for those HHAs that do not submit quality data as required by the Secretary. For HHAs that do not submit the required quality data for CY 2017, the home health payment update would be 0.5 percent (2.5 percent minus 2 percentage points).

2. CY 2017 Home Health Wage Index

a. Background

Sections 1895(b)(4)(A)(ii) and (b)(4)(C) of the Act require the Secretary to provide appropriate adjustments to the proportion of the payment amount under the HH PPS that account for area wage differences, using adjustment factors that reflect the relative level of wages and wage-related costs applicable to the furnishing of HH services. Since the inception of the HH PPS, we have used inpatient hospital wage data in developing a wage index to be applied to HH payments. We apply the appropriate wage index value to the labor portion of the HH PPS rates based on the site of service for the beneficiary (defined by section 1861(m) of the Act as the beneficiary's place of residence).

We will continue to use the same methodology discussed in the CY 2007 HH PPS final rule (71 FR 65884) to address those geographic areas in which there are no inpatient hospitals, and thus, no hospital wage data on which to base the calculation of the CY 2017 HH PPS wage index. For rural areas that do not have inpatient hospitals, we will use the average wage index from all contiguous CBSAs as a reasonable proxy. For FY 2017, there are no rural geographic areas without hospitals for which we would apply this policy. For rural Puerto Rico, we would not apply this methodology due to the distinct economic circumstances that exist there (for example, due to the close proximity to one another of almost all of Puerto Rico's various urban and non-urban areas, this methodology would produce a wage index for rural Puerto Rico that is higher than that in half of its urban areas). Instead, we would continue to use the most recent wage index previously available for that area. For urban areas without inpatient hospitals, we would use the average wage index of all urban areas within the state as a reasonable proxy for the wage index for that CBSA. For CY 2017, the only urban area without inpatient hospital wage data is Hinesville, GA (CBSA 25980).

b. Updates

Previously, we determined each HHA's labor market area based on

definitions of metropolitan statistical areas (MSAs) issued by the Office of Management and Budget (OMB). In the CY 2006 HH PPS final rule (70 FR 68132), we adopted revised labor market area definitions as discussed in the OMB Bulletin No. 03–04 (June 6, 2003). This bulletin announced revised definitions for MSAs and the creation of micropolitan statistical areas and core-based statistical areas (CBSAs). The bulletin is available online at *www.whitehouse.gov/omb/bulletins/b03-04.html*.

On February 28, 2013, OMB issued Bulletin No. 13–01, announcing revisions to the delineations of MSAs, Micropolitan Statistical Areas, and CBSAs, and guidance on uses of the delineation of these areas. This bulletin is available online at *http://www.whitehouse.gov/sites/default/files/omb/bulletins/2013/b-13-01.pdf*. This bulletin states that it ''provides the delineations of all Metropolitan Statistical Areas, Metropolitan Divisions, Micropolitan Statistical Areas, Combined Statistical Areas, and New England City and Town Areas in the United States and Puerto Rico based on the standards published on June 28, 2010, in the **Federal Register** (75 FR 37246–37252) and Census Bureau data.''

In the CY 2015 HH PPS final rule (79 FR 66085 through 66087), we finalized changes to the HH PPS wage index based on the OMB delineations, as described in OMB Bulletin No. 13–01. In CY 2015, we included a one-year transition to those delineations by using a blended wage index for CY 2015. The CY 2016 HH PPS wage index was fully based on the revised OMB delineations adopted in CY 2015.

The OMB's most recent update to the geographic area delineations was published on July 15, 2015 in OBM bulletin 15–01. This bulletin is available online at *https://www.whitehouse.gov/sites/default/files/omb/bulletins/2015/15-01.pdf*. The revisions to the delineations that affect the HH PPS are changes to CBSA titles and the addition of CBSA 21420, Enid, Oklahoma. CBSA 21420 encompasses Garfield County, Oklahoma.

The CY 2017 wage index is available on the CMS Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/Home-Health-Prospective-Payment-System-Regulations-and-Notices.html*.

3. CY 2017 Annual Payment Update

a. Background

The Medicare HH PPS has been in effect since October 1, 2000. As set forth in the July 3, 2000 final rule (65 FR 41128), the base unit of payment under the Medicare HH PPS is a national, standardized 60-day episode payment rate. As set forth in § 484.220, we adjust the national, standardized 60-day episode payment rate by a case-mix relative weight (as described in section III.B of this final rule) and a wage index value based on the site of service for the beneficiary.

To account for area wage differences, we apply the appropriate wage index value to the labor portion of the HH PPS payment rates. The labor-related share of the HH PPS payment rates continues to be 78.535 percent and the non-labor-related continues to be 21.465 percent, as set out in the CY 2013 HH PPS final rule (77 FR 67068). The following steps are taken to compute the case-mix and wage-adjusted national, standardized 60-day episode payment amount:

(1) Multiply the national, standardized 60-day episode rate by the episode's applicable case-mix weight.

(2) Divide the case-mix adjusted amount into a labor (78.535 percent) and a non-labor portion (21.465 percent).

(3) Multiply the labor portion by the applicable wage index based on the site of service of the beneficiary.

(4) Add the wage-adjusted portion to the non-labor portion, yielding the case-mix and wage adjusted 60-day episode rate, subject to any additional applicable adjustments. In accordance with section 1895(b)(3)(B) of the Act, this document constitutes the annual update of the HH PPS rates. Section 484.225 sets forth the specific annual percentage update methodology. In accordance with § 484.225(i), for a HHA that does not submit HH quality data, as specified by the Secretary, the unadjusted national, standardized 60-day episode rate is equal to the rate for the previous calendar year increased by the applicable HH market basket index amount minus 2 percentage points. Any reduction of the percentage change would apply only to the calendar year involved and would not be considered in computing the prospective payment amount for a subsequent calendar year.

Medicare pays the national, standardized 60-day case-mix and wage-adjusted episode payment on a split percentage payment approach. The split percentage payment approach includes an initial percentage payment and a final percentage payment as set forth in § 484.205(b)(1) and (b)(2). We base the initial percentage payment on the submission of a request for anticipated payment (RAP) and the final percentage payment on the submission of the claim for the episode, as discussed in § 409.43. The claim for the episode that the HHA submits for the final percentage payment determines the total payment amount for the episode and whether we make an applicable adjustment to the episode payment. The end date of the 60-day episode as reported on the claim determines which calendar year rates Medicare would use to pay the claim.

We may adjust the episode payment based on the information submitted on the claim to reflect the following:

- A low-utilization payment adjustment (LUPA) is provided on a per-visit basis as set forth in §§ 484.205(c) and 484.230.
- A partial episode payment (PEP) adjustment as set forth in §§ 484.205(d) and 484.235.
- An outlier payment as set forth in §§ 484.205(e) and 484.240.

b. CY 2017 National, Standardized 60-Day Episode Payment Rate

Section 1895(3)(A)(i) of the Act required that the 60-day episode base rate and other applicable amounts be standardized in a manner that eliminates the effects of variations in relative case mix and area wage adjustments among different home health agencies in a budget neutral manner. To determine the CY 2017 national, standardized 60-day episode payment rate, we will apply a wage index standardization factor, a case-mix budget neutrality factor described in section III.B, a reduction of 0.97 percent to account for nominal case-mix growth from 2012 to 2014 as finalized in the CY 2016 HH PPS final rule (80 FR 68646), the rebasing adjustment described in section II.C, and the HH payment update percentage discussed in section III.C.1 of this final rule.

To calculate the wage index standardization factor, henceforth referred to as the wage index budget neutrality factor, we simulated total payments for non-LUPA episodes using the proposed CY 2017 wage index and compared it to our simulation of total payments for non-LUPA episodes using the CY 2016 wage index. By dividing the total payments for non-LUPA episodes using the proposed CY 2017 wage index by the total payments for non-LUPA episodes using the CY 2016 wage index, we obtain a wage index budget neutrality factor of 0.9996. Therefore, we will apply the wage index budget neutrality factor of 0.9996 in our calculation of the CY 2017 national, standardized 60-day episode rate.

As discussed in section III.B of the final rule, to ensure the changes to the case-mix weights are implemented in a budget neutral manner, we will apply a case-mix weight budget neutrality factor in our calculation of the CY 2017

national, standardized 60-day episode payment rate. The case-mix weight budget neutrality factor is calculated as the ratio of total payments when CY 2017 case-mix weights are applied to CY 2015 utilization (claims) data to total payments when CY 2016 case-mix weights are applied to CY 2015 utilization data. The case-mix budget neutrality factor applied for CY 2017 will be 1.0214 as described in section III.B of this final rule.

Next, as discussed in the CY 2016 HH PPS final rule (80 FR 68646), we will apply a reduction of 0.97 percent to the national, standardized 60-day episode payment rate in CY 2017 to account for nominal case-mix growth between CY 2012 and CY 2014. Then, we will apply the −$80.95 rebasing adjustment finalized in the CY 2014 HH PPS final rule (78 FR 72256), and discussed in section II.C. Lastly, we will update the payment rates by the CY 2017 HH payment update percentage of 2.5 percent as described in section III.C.1 of this final rule. The CY 2017 national, standardized 60-day episode payment rate is calculated in Table 7.

TABLE 7—CY 2017 NATIONAL, STANDARDIZED 60-DAY EPISODE PAYMENT AMOUNT

CY 2016 national, standardized 60-day episode payment	Wage index budget neutrality factor	Case-mix weights budget neutrality factor	Nominal case-mix growth adjustment (1–0.0097)	CY 2017 rebasing adjustment	CY 2017 HH payment update	CY 2017 national, standardized 60-day episode payment
$2,965.12	× 0.9996	× 1.0214	× 0.9903	−$80.95	× 1.025	$2,989.97

The CY 2017 national, standardized 60-day episode payment rate for an HHA that does not submit the required quality data is updated by the CY 2017 HH payment update (2.5 percent) minus 2 percentage points and is shown in Table 8.

TABLE 8—CY 2017 NATIONAL, STANDARDIZED 60-DAY EPISODE PAYMENT AMOUNT FOR HHAS THAT DO NOT SUBMIT THE QUALITY DATA

CY 2016 national, standardized 60-day episode payment	Wage index budget neutrality factor	Case-mix weights budget neutrality factor	Nominal case-mix growth adjustment (1–0.0097)	CY 2017 rebasing adjustment	CY 2017 HH payment update minus 2 percentage points	CY 2017 national, standardized 60-day episode payment
$2,965.12	× 0.9996	× 1.0214	× 0.9903	−$80.95	× 1.005	$2,931.63

c. CY 2017 National Per-Visit Rates

The national per-visit rates are used to pay LUPAs (episodes with four or fewer visits) and are also used to compute imputed costs in outlier calculations. The per-visit rates are paid by type of visit or HH discipline. The six HH disciplines are as follows:

- Home health aide (HH aide);
- Medical Social Services (MSS);
- Occupational therapy (OT);
- Physical therapy (PT);
- Skilled nursing (SN); and
- Speech-language pathology (SLP).

To calculate the CY 2017 national per-visit rates, we start with the CY 2016 national per-visit rates. We then apply a wage index budget neutrality factor, to ensure budget neutrality for LUPA per-visit payments, and then we increase each of the six per-visit rates by the maximum rebasing adjustments described in section II.C. of this rule. We calculate the wage index budget neutrality factor by simulating total payments for LUPA episodes using the CY 2017 wage index and comparing it to simulated total payments for LUPA episodes using the CY 2016 wage index. By dividing the total payments for LUPA episodes using the CY 2017 wage index by the total payments for LUPA episodes using the CY 2016 wage index, we obtain a wage index budget neutrality factor of 1.0000. We will apply the wage index budget neutrality factor of 1.0000 in calculating the CY 2017 national per-visit rates.

The LUPA per-visit rates are not adjusted by the case-mix relative weights. Therefore, there is no case-mix weight budget neutrality factor needed to ensure budget neutrality for LUPA payments. We then apply the rebasing adjustments finalized in the CY 2014 HH PPS final rule (78 FR 72280) to the per-visit rates for each discipline. Finally, the per-visit rates for each discipline are updated by the CY 2017 HH payment update percentage of 2.5 percent. The national per-visit rates are adjusted by the wage index based on the site of service of the beneficiary. The per-visit payments for LUPAs are separate from the LUPA add-on payment amount, which is paid for episodes that occur as the only episode or initial episode in a sequence of adjacent episodes. The CY 2017 national per-visit rates are shown in Tables 9 and 10.

TABLE 9—CY 2017 NATIONAL PER-VISIT PAYMENT AMOUNTS FOR HHAS THAT DO SUBMIT THE REQUIRED QUALITY DATA

HH discipline type	CY 2016 per-visit payment	Wage index budget neutrality factor	CY 2017 rebasing adjustment	CY 2017 HH payment update	CY 2017 per-visit payment
Home Health Aide	$60.87	× 1.0000	+ $1.79	× 1.025	$64.23
Medical Social Services	215.47	× 1.0000	+ 6.34	× 1.025	227.36

TABLE 9—CY 2017 NATIONAL PER-VISIT PAYMENT AMOUNTS FOR HHAS THAT DO SUBMIT THE REQUIRED QUALITY DATA—Continued

HH discipline type	CY 2016 per-visit payment	Wage index budget neutrality factor	CY 2017 rebasing adjustment	CY 2017 HH payment update	CY 2017 per-visit payment
Occupational Therapy	147.95	× 1.0000	+ 4.35	× 1.025	156.11
Physical Therapy	146.95	× 1.0000	+ 4.32	× 1.025	155.05
Skilled Nursing	134.42	× 1.0000	+ 3.96	× 1.025	141.84
Speech-Language Pathology	159.71	× 1.0000	+ 4.70	× 1.025	168.52

The CY 2017 per-visit payment rates for an HHA that does not submit the required quality data are updated by the CY 2017 HH payment update percentage (2.5 percent) minus 2 percentage points and are shown in Table 10.

TABLE 10—CY 2017 NATIONAL PER-VISIT PAYMENT AMOUNTS FOR HHAS THAT DO NOT SUBMIT THE REQUIRED QUALITY DATA

HH Discipline type	CY 2016 per-visit rates	Wage index budget neutrality factor	CY 2017 rebasing adjustment	CY 2017 HH payment update minus 2 percentage points	CY 2017 per-visit rates
Home Health Aide	$60.87	× 1.0000	+ $1.79	× 1.005	$62.97
Medical Social Services	215.47	× 1.0000	+ 6.34	× 1.005	222.92
Occupational Therapy	147.95	× 1.0000	+ 4.35	× 1.005	153.06
Physical Therapy	146.95	× 1.0000	+ 4.32	× 1.005	152.03
Skilled Nursing	134.42	× 1.0000	+ 3.96	× 1.005	139.07
Speech-Language Pathology	159.71	× 1.0000	+ 4.70	× 1.005	165.23

d. Low-Utilization Payment Adjustment (LUPA) Add-On Factors

LUPA episodes that occur as the only episode or as an initial episode in a sequence of adjacent episodes are adjusted by applying an additional amount to the LUPA payment before adjusting for area wage differences. In the CY 2014 HH PPS final rule, we changed the methodology for calculating the LUPA add-on amount by finalizing the use of three LUPA add-on factors: 1.8451 for SN; 1.6700 for PT; and 1.6266 for SLP (78 FR 72306). We multiply the per-visit payment amount for the first SN, PT, or SLP visit in LUPA episodes that occur as the only episode or an initial episode in a sequence of adjacent episodes by the appropriate factor to determine the LUPA add-on payment amount. For example, for LUPA episodes that occur as the only episode or an initial episode in a sequence of adjacent episodes, if the first skilled visit is SN, the payment for that visit would be $261.71 (1.8451 multiplied by $141.84), subject to area wage adjustment.

e. CY 2017 Non-Routine Medical Supply (NRS) Payment Rates

Payments for NRS are computed by multiplying the relative weight for a particular severity level by the NRS conversion factor. To determine the CY 2017 NRS conversion factor, we start with the CY 2016 NRS conversion factor ($52.71) and apply the −2.82 percent rebasing adjustment described in section II.C. of this rule (1 −0.0282 = 0.9718). We then update the conversion factor by the CY 2017 HH payment update percentage (2.5 percent). We do not apply a standardization factor as the NRS payment amount calculated from the conversion factor is not wage or case-mix adjusted when the final claim payment amount is computed. The NRS conversion factor for CY 2017 is shown in Table 11.

TABLE 11—CY 2017 NRS CONVERSION FACTOR FOR HHAS THAT DO SUBMIT THE REQUIRED QUALITY DATA

CY 2016 NRS conversion factor	CY 2017 rebasing adjustment	CY 2017 HH payment update	CY 2017 NRS conversion factor
$52.71	× 0.9718	× 1.025	$52.50

Using the CY 2016 NRS conversion factor, the payment amounts for the six severity levels are shown in Table 12.

TABLE 12—CY 2017 NRS PAYMENT AMOUNTS FOR HHAS THAT DO SUBMIT THE REQUIRED QUALITY DATA

Severity level	Points (scoring)	Relative weight	CY 2017 NRS payment amounts
1	0	0.2698	$14.16

TABLE 12—CY 2017 NRS PAYMENT AMOUNTS FOR HHAS THAT DO SUBMIT THE REQUIRED QUALITY DATA—Continued

Severity level	Points (scoring)	Relative weight	CY 2017 NRS payment amounts
2	1 to 14	0.9742	51.15
3	15 to 27	2.6712	140.24
4	28 to 48	3.9686	208.35
5	49 to 98	6.1198	321.29
6	99+	10.5254	552.58

For HHAs that do not submit the required quality data, we begin with the CY 2016 NRS conversion factor ($52.71) and apply the −2.82 percent rebasing adjustment discussed in section II.C of the proposed rule (1 − 0.0282 = 0.9718). We then update the NRS conversion factor by the CY 2017 HH payment update percentage (2.5 percent) minus 2 percentage points. The CY 2017 NRS conversion factor for HHAs that do not submit quality data is shown in Table 13.

TABLE 13—CY 2017 NRS CONVERSION FACTOR FOR HHAS THAT DO NOT SUBMIT THE REQUIRED QUALITY DATA

CY 2016 NRS conversion factor	CY 2017 rebasing adjustment	CY 2017 HH payment update percentage minus 2 percentage points	CY 2017 NRS conversion factor
$52.71	× 0.9718	× 1.005	$51.48

The payment amounts for the various severity levels based on the updated conversion factor for HHAs that do not submit quality data are calculated in Table 14.

TABLE 14—CY 2017 NRS PAYMENT AMOUNTS FOR HHAS THAT DO NOT SUBMIT THE REQUIRED QUALITY DATA

Severity level	Points (scoring)	Relative weight	CY 2017 NRS payment amounts
1	0	0.2698	$13.89
2	1 to 14	0.9742	50.15
3	15 to 27	2.6712	137.51
4	28 to 48	3.9686	204.30
5	49 to 98	6.1198	315.05
6	99+	10.5254	541.85

f. Rural Add-On

Section 421(a) of the MMA, as amended by section 210 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), requires that the Secretary increase by 3 percent the payment amount otherwise made under section 1895 of the Act, for HH services furnished in rural areas (as defined in section 1886(d)(2)(D) of the Act), for episodes and visits ending on or after April 1, 2010, and before January 1, 2018. Section 421 of the MMA waives budget neutrality related to this provision, as the statute specifically states that the Secretary shall not reduce the standard prospective payment amount (or amounts) under section 1895 of the Act applicable to HH services furnished during a period to offset the increase in payments resulting in the application of this section of the statute.

For CY 2017, home health payment rates for services provided to beneficiaries in areas that are defined as rural under the OMB delineations will be increased by 3 percent as mandated by section 421(a) of the MMA, as amended. The 3 percent rural add-on is applied to the national, standardized 60-day episode payment rate, national per visit rates, and NRS conversion factor when HH services are provided in rural (non-CBSA) areas. Refer to Tables 15 through 18 for these payment rates.

TABLE 15—CY 2017 PAYMENT AMOUNTS FOR 60-DAY EPISODES FOR SERVICES PROVIDED IN A RURAL AREA

For HHAs that DO submit quality data			For HHAs that DO NOT submit quality data		
CY 2017 National, standardized 60-day episode payment rate	Multiply by the 3 percent rural add-on	CY 2017 Rural national, standardized 60-day episode payment rate	CY 2017 National, standardized 60-day episode payment rate	Multiply by the 3 percent rural add-on	CY 2017 Rural national, standardized 60-day episode payment rate
$2,989.97	× 1.03	$3,079.67	$2,931.63	× 1.03	$3,019.58

TABLE 16—CY 2017 PER-VISIT AMOUNTS FOR SERVICES PROVIDED IN A RURAL AREA

	For HHAs that DO submit quality data			For HHAs that DO NOT submit quality data		
HH discipline type	CY 2017 per-visit rate	Multiply by the 3 percent rural add-on	CY 2017 rural per-visit rates	CY 2017 per-visit rate	Multiply by the 3 percent rural add-on	CY 2017 rural per-visit rates
HH Aide	$64.23	× 1.03	$66.16	$62.97	× 1.03	$64.86
MSS	227.36	× 1.03	234.18	222.92	× 1.03	229.61
OT	156.11	× 1.03	160.79	153.06	× 1.03	157.65
PT	155.05	× 1.03	159.70	152.03	× 1.03	156.59
SN	141.84	× 1.03	146.10	139.07	× 1.03	143.24
SLP	168.52	× 1.03	173.58	165.23	× 1.03	170.19

TABLE 17—CY 2017 NRS CONVERSION FACTORS FOR SERVICES PROVIDED IN A RURAL AREA

For HHAs that DO submit quality data			For HHAs that DO NOT submit quality data		
CY 2017 conversion factor	Multiply by the 3 percent rural add-on	CY 2017 rural NRS conversion factor	CY 2017 conversion factor	Multiply by the 3 percent rural add-on	CY 2017 rural NRS conversion factor
$52.50	× 1.03	$54.08	$51.48	× 1.03	$53.02

TABLE 18—CY 2017 NRS PAYMENT AMOUNTS FOR SERVICES PROVIDED IN A RURAL AREA

Severity level	Points (scoring)	For HHAs that DO submit quality data		For HHAs that DO NOT submit quality data	
		Relative weight	CY 2017 NRS payment amounts for rural areas	Relative weight	CY 2017 NRS payment amounts for rural areas
1	0	0.2698	14.59	0.2698	$14.30
2	1 to 14	0.9742	52.68	0.9742	51.65
3	15 to 27	2.6712	144.46	2.6712	141.63
4	28 to 48	3.9686	214.62	3.9686	210.42
5	49 to 98	6.1198	330.96	6.1198	324.47
6	99+	10.5254	569.21	10.5254	558.06

The following is a summary of the comments we received regarding the CY 2017 home health rate update.

Home Health Wage Index

Comment: Several commenters believe that the pre-floor, pre-reclassified hospital wage index is inadequate for adjusting HH costs. The commenters believe that the statute does give CMS the authority to allow HHAs the same reclassification opportunity provided to hospitals and correct some of these inequities. One commenter expressed concern about how the home health wage index is calculated and implemented compared to hospitals within the same CBSA. The commenter believes that the geographic reclassification and rural floor provisions, which are available to hospitals, create inequity for HHAs because CMS does not apply those provisions to the HH wage index. The commenter states that this inequity makes it difficult for HHAs to compete with hospitals in recruiting and retaining nurses and therapists. A few commenters requested that if the rural floor and reclassification provisions that apply to the hospital wage index cannot be applied to the HH wage index, then CMS should develop a HH wage index that is based on home healthcare industry wages.

Response: We continue to believe that the regulations and statutes that govern the HH PPS do not provide a mechanism for allowing HHAs to seek geographic reclassification or to utilize the rural floor provisions that exist for IPPS hospitals. Section 4410(a) of the BBA provides that the area wage index applicable to any hospital that is located in an urban area of a State may not be less than the area wage index applicable to hospitals located in rural areas in that state. This is the rural floor provision

and it is specific to hospitals. The reclassification provision at section 1886(d)(10)(C)(i) of the Act states that the Board shall consider the application of any subsection (d) hospital requesting the Secretary change the hospital's geographic classification. This reclassification provision is only applicable to hospitals as defined in section 1886(d) of the Act.

In addition, we do not believe that using hospital reclassification data would be appropriate as these data are specific to the requesting hospitals and may or may not apply to a given HHA. With regard to implementing a rural floor, we do not believe it would be prudent at this time to adopt such a policy. In Chapter 3 of its March 2013 Report to Congress on Medicare Payment Policy, MedPAC recommended eliminating the rural floor policy from the calculation of the IPPS wage index. On page 65 of the report (available at *http://medpac.gov/documents/reports/mar13_entirereport.pdf)* MedPAC states that in 2007, MedPAC had ''. . . recommended eliminating these special wage index adjustments and adopting a new wage index system to avoid geographic inequities that can occur due to current wage index policies.''

We continue to believe that using the pre-floor, pre-reclassified hospital wage index as the wage adjustment to the labor portion of the HH PPS rates is appropriate and reasonable.

Comment: Several commenters recommend that CMS include wage data from critical access hospitals (CAHs) in calculating the HH wage index in order to make the wage index more reflective of actual local wage practices.

Response: Although the pre-floor, pre-classified hospital wage index does not include data from CAHs, we believe that it reflects the relative level of wages and wage-related costs applicable to providing HH services. As we stated in the August 1, 2003 IPPS final rule (68 FR 45397), the CAHs represent a substantial number of hospitals with significantly different labor costs in many labor market areas where they exist. We further noted that, ''. . . in 89 percent of all labor market areas with hospitals converted to CAH status sometime after 2000, the average hourly wage for CAHs is lower than the average hourly wage for other short-term hospitals in the area.'' In 79 percent of the labor market areas with CAHs the average hourly wage for CAHs is lower than the average hourly wage for other short-term hospitals by 5 percent or greater. These results suggest that the wage data for CAHs, in general, are significantly different from other short-term hospitals and thus may not adequately represent the relative level of wages and wage-related costs applicable to providing HH services.

Comment: A commenter requested that CMS explore a wholesale revision and reform of the HH wage index. Another commenter states that in 2015, CMS indicated that the entire wage index system was under review and that a move to a commuting-based wage index (CBWI) was being considered. The commenter urges CMS to expedite that review and implement a system that not only recognizes variations between localities, but also treats all provider types within a local market equitably.

Response: Our ''Report to Congress: Plan to Reform the Medicare Wage Index'' was submitted by the Secretary on April 11, 2012 and is available on our Wage Index Reform Web page at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Reform.html.* This report states that implementation of a CBWI may require both statutory and regulatory changes. In addition, we believe other intermediate steps for implementation, including the collection of commuting data, may be necessary.

Comment: One commenter believes that the unpredictable year-to-year swings in wage index values are often based on inaccurate or incomplete hospital cost reports. Another commenter requested that CMS describe in detail how the wage index is calculated.

Response: We believe that the hospital cost report data are accurate. We utilize efficient means to ensure and review the accuracy of the hospital cost report data and resulting wage index. The home health wage index is derived from the pre-floor, pre-reclassified wage index which is calculated based on cost report data from hospitals paid under the IPPS. All IPPS hospitals must complete the wage index survey (Worksheet S–3, Parts II and III) as part of their Medicare cost reports. Cost reports will be rejected if Worksheet S–3 is not completed. In addition, our intermediaries perform desk reviews on all hospitals' Worksheet S–3 wage data, and we run edits on the wage data to further ensure the accuracy and validity of the wage data. We believe that our review processes result in an accurate reflection of the applicable wages for the areas given. The processes and procedures describing how the inpatient hospital wage index is developed are discussed in the IPPS rule each year, with the most recent discussion provided in the FY 2017 IPPS final rule (81 FR 56762 through 57345). Any provider type may submit comments on the hospital wage index during the annual IPPS rulemaking cycle.

Comment: A commenter believes that the CMS decision 10 years ago to switch from Metropolitan Statistical Areas (MSAs) to CBSAs for the wage adjustment to the rates has had negative financial ramifications for HHAs in New York City. The commenter stated that unlike past MSA designations, where all of the counties in the New York City designation were from New York State, the 2006 CBSA wage index designation added Bergen, Hudson, and Passaic counties from New Jersey into the New York City CBSA. The commenter also noted that with the CY 2015 final rule, CMS added three more New Jersey counties (Middlesex, Monmouth, and Ocean) to the CBSA used for New York City.

Response: The MSA delineations as well as the CBSA delineations are determined by the OMB. The OMB reviews its Metropolitan Area definitions preceding each decennial census to reflect recent population changes. We believe that the OMB's CBSA designations reflect the most recent available geographic classifications and are a reasonable and appropriate way to define geographic areas for purposes of wage index values. Over 10 years ago, in our CY 2006 HH PPS final rule (70 FR 68132), we finalized the adoption of the revised labor market area definitions as discussed in the OMB Bulletin No. 03–04 (June 6, 2003). In the December 27, 2000 **Federal Register** (65 FR 82228 through 82238), the OMB announced its new standards for defining metropolitan and micropolitan statistical areas. According to that notice, the OMB defines a CBSA, beginning in 2003, as ''a geographic entity associated with at least one core of 10,000 or more population, plus adjacent territory that has a high degree of social and economic integration with the core as measured by commuting ties.'' The general concept of the CBSAs is that of an area containing a recognized population nucleus and adjacent communities that have a high degree of integration with that nucleus. The purpose of the standards is to provide nationally consistent definitions for collecting, tabulating, and publishing federal statistics for a set of geographic areas. CBSAs include adjacent counties that have a minimum of 25 percent commuting to the central counties of the area. This is an increase over the minimum commuting threshold for outlying counties applied in the previous MSA definition of 15 percent.

Based on the OMB's current delineations, as described in the July 15, 2015 OMB Bulletin 15–01, the New Jersey counties of Bergen, Hudson, Middlesex, Monmouth, Ocean, and Passaic belong in the New York-Jersey City-White Plains, NY–NJ (CBSA 35614). In addition, other provider types, such as IPPS hospital, hospice, skilled nursing facility (SNF), inpatient rehabilitation facility (IRF), and the ESRD program, have used CBSAs to define their labor market areas for more than a decade.

Comment: One commenter noted that the wage index for rural Maine continues to be the lowest in New England.

Response: We believe that the wage index values are reflective of the labor costs in each geographic area as they reflect the costs included on the costs reports of hospitals in those specific labor market areas. The wage index values are based on data submitted on the inpatient hospital cost reports. We utilize efficient means to ensure and review the accuracy of the hospital cost report data and resulting wage index. The home health wage index is derived from the pre-floor, pre-reclassified wage index which is calculated based on cost report data from hospitals paid under the IPPS. All IPPS hospitals must complete the wage index survey (Worksheet S–3, Parts II and III) as part of their Medicare cost reports. Cost reports will be rejected if Worksheet S–3 is not completed. In addition, Medicare contractors perform desk reviews on all hospitals' Worksheet S–3 wage data, and we run edits on the wage data to further ensure the accuracy and validity of the wage data. We believe that our review processes result in an accurate reflection of the applicable wages for the areas given. The processes and procedures describing how the inpatient hospital wage index is developed are discussed in the Inpatient Prospective Payment System (IPPS) rule each year, with the most recent discussion provided in the FY 2017 IPPS final rule (81 FR 56761 through 57438). Any provider type may submit comments on the hospital wage index during the annual IPPS rulemaking cycle.

Comment: Several commenters raised concerns around evolving minimum wage standards across the country and recommended that we consider ways to compensate certain geographic areas impacted by increasing minimum wage standards into the HH PPS wage index.

Response: In regard to the rising minimum wage standards, we note that such increases will likely be reflected in future data used to create the hospital wage index to the extent that these changes to state minimum wage standards are reflected in increased wages to hospital staff.

Comment: One commenter stated that rural areas are adversely impacted by the wage index due to increased travel costs due to time and mileage involved in traveling from patient to patient. The commenter recommends that CMS institute a population density adjustment to the wage index.

Response: We do not believe that a population density adjustment is appropriate at this time. Rural HHAs cite the added cost of traveling from one patient to the next patient. However, urban HHAs cite the added costs associated with needed security measures and traffic congestion. The HH wage index values in rural areas are not necessarily lower than the HH wage index values in urban areas. The HH wage index reflects the wages that inpatient hospitals pay in their local geographic areas. In addition, HHAs already receive rural add-on payments for services provided to beneficiaries in rural areas. Section 421(a) of the MMA, as amended by section 210 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10), provides for a payment increase of 3 percent for HH services provided in rural areas for episodes or visits ending on or after April 1, 2010, and before January 1, 2018.

Comment: One commenter urges CMS to adjust the 2017 HH wage index to limit disparity between provider types within a given CBSA to no more than 10 percent.

Response: With regard to issues mentioned about ensuring that the wage index minimizes fluctuations, we note that section 3137(b) of the Affordable Care Act required us to submit a report to the Congress by December 31, 2011 that included a plan to reform the hospital wage index system. This report describes the concept of a Commuting Based Wage Index as a potential replacement to the current Medicare wage index methodology. While this report addresses the goals of broad based Medicare wage index reform, no consensus has been achieved regarding how best to implement a replacement system. These concerns will be taken into consideration while we continue to explore potential wage index reforms. The report that we submitted is available online at *http://www.cms.gov/Medicare/Medicare-Fee-for-ServicePayment/AcuteInpatientPPS/WageIndex-Reform.html*.

Affordable Care Act Rebasing Adjustments

Comment: MedPAC stated that the rebasing reduction will not sufficiently reduce home health payments. MedPAC projected that home health agencies will have Medicare margins of 8.8 percent in 2016, and the rebasing adjustment will not lower payments in 2017 due to the offsetting statutory payment update. MedPAC stated that Medicare has overpaid for home health care since the inception of the HH PPS and more reductions are necessary to stop this pattern from continuing. MedPAC recommended in their March 2016 report that Congress eliminate the payment update for CY 2017 and implement a rebasing reduction in the following 2 years to bring payments closer to costs. MedPAC stated that the decline in utilization since 2010 does not unduly raise concerns about beneficiaries' access to home health care and that the base payment for 2017 will not fall due to rebasing and should not have an impact on access to care. MedPAC recognized that the statute limits CMS' ability to reduce payments but reiterated their recommendation that further reductions are appropriate and would not negatively affect access to care.

Response: As noted by MedPAC, we are constrained to comply with the statutory requirements in our rebasing adjustments. Our rebasing adjustments for CY 2014 through CY 2017 are in accordance with the statute.

Comment: Commenters urged CMS to postpone or stop the implementation of the rebasing reductions. Commenters expressed concerns with the rebasing methodology, impact analysis, and process outlined in the CY 2014 HH PPS proposed and final rules and stated that a more comprehensive study is needed to evaluate the rebasing reductions. Commenters suggested alternatives to rebasing or alternate ways to implement the rebasing reductions.

Response: We thank the commenters for their comments. We did not propose changes to the rebasing adjustments for CY 2014 through CY 2017 finalized in the CY 2014 HH PPS final rule. A majority of the comments received regarding the rebasing adjustments were nearly identical to the comments submitted during the comment period for the CY 2014 HH PPS proposed rule. Therefore, we encourage commenters to review our responses to the comments we received on the rebasing adjustments in the CY 2014 HH PPS final rule (78 FR 72282–72294).

Comment: Commenters were concerned that rebasing adjustments are

based on outdated and incomplete data and do not reflect current or future costs and do not take into account operational and financial challenges providers experience and trends in data. Commenters recommended that CMS perform analysis to determine the need for rebasing and include all costs providers incur. Commenters requested that CMS evaluate the rebasing and case-mix adjustments on ''real-time'' data and work toward that goal going forward. Some commenters also recommended that CMS work in collaboration with the home healthcare community in finding and using current data to make assessments about the impact and appropriateness of payment reductions going forward. Commenters urged CMS to update its analysis to include data from 2015 cost reports to capture costs associated with the implementation of the physician face-to-face encounter requirement and therapy reassessment requirements and the implementation of ICD–10 in projecting profit margins. One commenter stated that the rebasing methodology relies too much on the very poor cost report system. Some commenters stated that the rebasing methodology was too complex and that the public could not understand the approach used.

Response: We note that we proposed and finalized the rebasing adjustments in 2014 using the most current, complete data available at the time of rulemaking. We recommend commenters review the description of the calculation of the adjustments described in the CY 2014 final rule (78 FR 72276 through 72282). We also note that for the CY 2017 HH PPS proposed rule, we analyzed 2014 HHA cost report data and 2014 HHA claims data to determine whether the average cost per episode was higher using 2014 cost report data compared to the 2011 cost report and 2012 claims data used in calculating the rebasing adjustments. Our latest analysis of 2014 cost report and 2014 claims data suggests that an even larger reduction (−5.30 percent) than the reduction described in the CY 2014 HH PPS final rule (−3.45 percent) or the reductions described in the CY 2015 HH PPS final rule and the CY 2016 HH PPS proposed rule (−4.21 and −5.02 percent, respectively) would have been needed in order to align payments with costs (81 FR 43719, 43720). Given that 2012 through 2014 cost data has indicated the need for a larger reduction to the national, standardized 60-day episode payment rate than what was calculated with the 2011 cost data, we question whether the 2015 cost data will show that payments are low relative to the costs associated with providing care during a home health episode of care. However, we plan to continue to monitor costs and payments for any unintended effects of rebasing.

As stated in our responses to comments in the 2014 final rule, we disagree with the commenter's claim that home health agencies have no incentives for ensuring the accuracy of their cost reports and that the cost report data are inaccurate and not representative of the costs that agencies actually incur. Each HH cost report is required to be certified by the Officer or Director of the home health agency as complete and accurate. We also note that any misrepresentation or falsification of any information on the cost report may be punishable by criminal, civil and administrative action, fine and/or imprisonment under federal law. As always, we encourage providers to fill out the Medicare cost reports as accurately as possible.

Comment: Commenters were concerned with the impact of the payment reductions on vulnerable populations and on safety net providers and agencies that serve underserved regions and/or vulnerable beneficiaries. Commenters stated that CMS has not accounted for the effect of the rebasing adjustments on access to care for vulnerable populations and the adjustments will threaten the efficiency of the health care system. The commenter urged CMS to consider the potential impact of payment cuts on the patient population, and mitigate these risks where possible. One commenter urged CMS to more carefully and accurately measure access to home health services and to move beyond the consideration of zip code coverage as a measure of access to care. The commenter provided suggestions for the impact and monitoring analyses. Commenters urged CMS to conduct a more thorough analysis examining the cumulative impact of rebasing, rather than assessing only a one-year impact.

Commenters also expressed concerns that the rebasing reductions put access to home care in jeopardy in various parts of the country. A commenter stated that CMS' approach ignores regional differences in operating margins. Commenters were concerned about the impact of the reductions on margins, citing negative margins. One commenter provided their projection of the percentage of agencies with negative margins in 2017 by agency type and by state. Commenters wanted CMS to remove or adjust the rebasing adjustments and consult with Congress before considering additional reductions, including case-mix reductions, or further rebasing suggested by MedPAC.

Response: The rebasing reductions were finalized in the 2014 HH PPS final rule and the statute required us to implement a 4-year phase-in of the rebasing reductions starting in CY 2014 and in equal increments over the 4-year period. As described in the CY 2016 HH PPS proposed rule, section 3131(a) of the Affordable Care Act required MedPAC to assess, by January 1, 2015, the impact of the mandated rebasing adjustments on quality of and beneficiary access to home health care. As part of this assessment, the statute required MedPAC to consider the impact on care delivered by rural, urban, nonprofit, and for-profit home health agencies. MedPAC's Report to Congress noted that the rebasing adjustments are partially offset by the payment update each year and across all 4 years of the phase in of the rebasing adjustments the cumulative net reduction would equal about 2 percent. MedPAC concluded that, as a result of the payment update offsets to the rebasing adjustments, HHA margins were likely to remain high under the current rebasing policy and quality of care and beneficiary access to care were unlikely to be negatively affected (80 FR 39846). In addition, in their March 2016 report to the Congress, MedPAC recommended that the Congress eliminate the payment update for 2017, and implement a rebasing reduction in the following 2 years to bring payments closer to costs in order to align payments with costs in CY 2017.

As we noted in the CY 2014 HH PPS final rule (78 FR 72291), MedPAC's past reviews of access to home health care found that access generally remained adequate during periods of substantial decline in the number of agencies. MedPAC stated that this is due in part to the low capital requirements for home health care services that allow the industry to react rapidly when the supply of agencies changes or contracts. In addition, in the CY 2017 HH PPS proposed rule, we noted that in CY 2015 there were 2.9 HHAs per 10,000 FFS beneficiaries, which is still markedly higher than the 1.9 HHAs per 10,000 FFS beneficiaries before the implementation of the HH PPS methodology in 2001 (81 FR 43720). Even if some HHAs were to exit the program due to possible payment concerns, the home health market would be expected to remain robust. We plan to continue to monitor for the effects of rebasing as data become available.

In the CY 2017 proposed rule, we also described an alternate case-mix model option, the Home Health Groupings Model (HHGM). If implemented, the Home Health Groupings Model could redistribute payments across the range of home health patients, improve payments for specific vulnerable populations, and help address disincentives to provide services to vulnerable populations. In the proposed rule, we noted that we planned to release a more detailed technical report in the future on this additional research and analysis conducted on the HHGM. Once the technical report is released, we will post a link on our Home Health Agency (HHA) Center Web site at *https://www.cms.gov/center/provider-Type/home-Health-Agency-HHA-Center.html* to receive comments and feedback on the model.

Comment: Commenters stated that CMS' own analysis of 2015 data has shown that the rebasing reductions have had an impact on access to care. Commenters stated that CMS' analysis shows a decrease in the number of home health episodes between 2013 and 2015 and a decrease in the number of Medicare beneficiaries receiving at least one episode of care. Commenters stated that rebasing should be suspended until stakeholders have had an opportunity to conduct a full analysis.

In their comments on the HH PPS proposed rule, MedPAC noted that the decline in the number of episodes continues a trend since 2010, when utilization peaked at 6.8 million episodes. About 70 percent of the decline in volume since the peak has been attributable to lower volume in five states (Florida, Illinois, Louisiana, Tennessee, and Texas). However, even with the recent declines, these five states had levels of per-capita home health utilization greater than double the per-capita rate for the rest of the country.

MedPAC stated that though service volume has declined, policy and economic changes other than Medicare payment policy likely account for a significant portion of this change. The number of hospital discharges, a common source of referrals, has declined since 2009, mitigating the demand for post-acute services. The period has also seen relatively low growth in economy-wide health care spending. In addition, several actions have been taken to curb fraud, waste, and abuse in Medicare home health care. The Department of Justice and other enforcement agencies have launched a number of investigative efforts that have scrutinized Medicare HHAs. The number of agencies declined by 2 percent in 2014, with this decline concentrated in Florida, Michigan, and Texas. These factors likely affected spending and utilization in recent years.

MedPAC stated that this decline follows a period of considerable growth. Home health utilization increased by 67 percent between 2002 and 2010. Given this prior rapid growth, and the reasons for the decline in home health use since 2010, MedPAC believes that the decline in utilization since 2010 does not raise substantive concerns about beneficiaries' access to home health care.

Response: As noted by MedPAC in their comments on the proposed rule, there are various reasons for the decline in home health use since 2010 and policy and economic changes other than Medicare payment policy likely account for a significant portion of this change. We note that we plan to continue to monitor for the effects of rebasing as data become available.

Comment: Some commenters stated that there is an error in CMS's calculation of the proposed CY 2017 national, standardized 60-day episode payment rate that inappropriately inflates the rebasing adjustment. Commenters stated that the Affordable Care Act provision regarding the 4-year phased-in rebasing adjustment strictly limits CMS's authority to impose no more than $80.95 in annual rebasing adjustments from 2014 through 2017. Commenters stated that by subtracting the $80.95 from the rate calculation before adjusting for inflation, CMS has inflated the impact of the rebasing adjustment for CY 2017 from $80.95 to $82.81. Commenters stated that CMS has made this same calculation error for each of the 4 years that the rebasing adjustment has been in place. Commenters stated that compounding the cumulative impact over the 4 years, the proposed CY 2017 national, standardized 60-day episode payment rate is $7.19 less than if CMS had subtracted the rebasing adjustment after adjusting for inflation.

Commenters recommended that CMS correct the calculation methodology, increase the proposed CY 2017 national, standardized 60-day episode payment rate by $7.19, and retroactively adjust the national, standardized 60-day episode payment rates for years 2014 through 2016 to comply with the statutory limitation on the rebasing adjustment.

Response: The last sentence in section 1895(3)(A)(iii)(I) of the Act states that the rebasing adjustment shall be made before the update under subparagraph (B) is applied for the year. Subparagraph (B) describes the home health update percentage. Therefore, the statute requires that the rebasing adjustments be applied before the home health update percentage. The description of the limits is referring to the rebasing adjustments, which must be applied before the home health update percentage. Therefore, no error was made in applying the rebasing adjustment to the national, standardized 60-day episode payment rate before the home health payment percentage and in the CY 2017 national, standardized 60-day episode payment amount or the amounts in CYs 2014 through 2016.

Comment: One commenter stated that instead of the rebasing adjustments, CMS should start the development of a new payment methodology for the therapy component of the HH PPS that accurately bases payment on the severity level of the patient and the necessary resources to treat the condition at the requisite level of intensity.

Response: While a new payment methodology for the therapy component of the HH PPS may redistribute payments for certain patients, the rebasing adjustments are meant to align the national, standardized 60-day episode payment rate, the per-visit LUPA rates, and the NRS conversion factor with the cost of providing care.

Nominal Case-Mix Reduction

Comment: MedPAC stated that they have long held it necessary for CMS to make adjustments to account for nominal case-mix change to prevent additional overpayments. MedPAC stated that the CMS' reduction to account for nominal case-mix growth is consistent with the agency's past findings on trends in case-mix change in the payment system and thus is warranted to ensure the accuracy of payments under the home health PPS. MedPAC stated that a reduction of 0.97 percent should not significantly affect access to care.

Response: We thank MedPAC for their comments.

Comment: Several commenters stated that they wanted CMS to rescind the case-mix reductions for CY 2017 and CY 2018. Some commenters stated that implementation of the nominal case-mix reductions in 2016, 2017, and 2018 violated the limits on payment reductions set out by the Congress and urged CMS to adhere to the statutory limits on home health rate cuts. Commenters expressed concerns with the data and methodology used to develop the proposed case-mix cuts and stated that the annual recalibration should have eliminated any practice of assigning an inaccurate code to increase

reimbursement. Some commenters stated that the nominal case-mix reductions were duplicative of the rebasing reductions. A few commenters stated that the baseline used in calculating the amount of case-mix growth was inappropriate. Commenters stated that the estimate of real case-mix was outdated and needed to be updated. Commenters stated that any analysis of case mix in home care must be put in the context of the current environment and take into account initiatives and trends. Commenters urged CMS to conduct the necessary analyses of 2012 through 2014 nominal case-mix change and share such analyses with stakeholders in the form of a new, evidence-based proposal. Commenters recommended that CMS withdraw the proposed case-mix reductions and consider alternative approaches. Some commenters stated that CMS should implement program integrity measures to control aberrant coding by some providers instead of imposing across-the-board case mix creep adjustments on all providers, and that CMS should not impose adjustments to payments until the completion of rebasing cuts (that is, 2018 or later). Commenters requested that CMS reconsider negative adjustments or spread the adjustments over more years.

Some commenters noted that actual program spending on home health was consistently less than Congressional Budget Office (CBO) estimates and questioned CMS' authority to implement case mix weight adjustments when home health spending was less than these estimates. Commenters stated that there was no increase in aggregate expenditures that warranted the application of this statutory authority, and CMS should withdraw its proposal. One commenter stated that CMS did not perform a detailed analysis of case mix growth for this year's proposed rule.

Response: We thank the commenters for their comments. We finalized the case-mix reductions for CY 2016, CY 2017, and CY 2018 in the CY 2016 HH PPS final rule and did not propose changes to the finalized reduction in the CY 2017 HH PPS proposed rule. The majority of the comments received regarding the payment reductions for nominal case-mix growth were very similar to the comments submitted during the comment period for the CY 2016 HH PPS proposed rule. Therefore, we encourage commenters to review our responses to the comments we received on the payment reductions for nominal case-mix growth in the CY 2016 HH PPS final rule (80 FR 68639–68646). We will continue to monitor real and nominal case-mix growth and may propose additional reductions for nominal case-mix growth, as needed, in the future.

Final Decision: After considering the comments received in response to the CY 2017 HH PPS proposed rule, we are finalizing our proposal to use the pre-floor, pre-reclassified hospital inpatient wage index as the wage adjustment to the labor portion of the HH PPS rates. For CY 2017, the updated wage data are for the hospital cost reporting periods beginning on or after October 1, 2012 and before October 1, 2013 (FY 2013 cost report data). In addition, we are implementing the final year of the rebasing adjustments and the 0.97 percent payment reduction to account for nominal case-mix growth when finalizing the CY 2017 HH PPS payment rates. We note that the rebasing adjustments were finalized in the CY 2014 HH PPS final rule and the payment reductions to account for nominal case-mix growth from 2012 to 2014 were finalized in the CY 2016 HH PPS final rule. No additional adjustments or reductions were proposed in the CY 2017 proposed rule.

D. Payments for High-Cost Outliers Under the HH PPS

1. Background

In the CY 2017 HH PPS proposed rule (81 FR 43737 through 43742), we described the background and current method for determining outlier payments under the HH PPS. Section 1895(b)(5) of the Act allows for the provision of an addition or adjustment to the national, standardized 60-day episode payment amount in the case of episodes that incur unusually high costs due to unusual variations in the type or amount of medically necessary care. Outlier payments are made for episodes whose estimated costs exceed a threshold amount for each Home Health Resource Group (HHRG). Currently, the episode's estimated cost is the sum of the national wage-adjusted per-visit payment amounts for all visits delivered during the episode. The outlier threshold for each case-mix group is the episode payment amount for that group, or the partial episode payment (PEP) adjustment amount for the episode, plus a fixed-dollar loss (FDL) amount that is the same for all case-mix groups.

The outlier payment is defined to be a proportion of the wage-adjusted estimated cost beyond the wage-adjusted threshold. The proportion of additional costs over the outlier threshold amount paid as outlier payments is referred to as the loss-sharing ratio, which is currently 0.80.

As we noted in the CY 2011 HH PPS final rule (75 FR 70397 through 70399), section 3131(b)(1) of the Affordable Care Act amended section 1895(b)(3)(C) of the Act, and required the Secretary to reduce the HH PPS payment rates such that aggregate HH PPS payments were reduced by 5 percent. In addition, section 3131(b)(2) of the Affordable Care Act amended section 1895(b)(5) of the Act by re-designating the existing language as section 1895(b)(5)(A) of the Act, and revising the language to state that the total amount of the additional payments or payment adjustments for outlier episodes may not exceed 2.5 percent of the estimated total HH PPS payments for that year. Section 3131(b)(2)(C) of the Affordable Care Act also added subparagraph (B) which capped outlier payments as a percent of total payments for each HHA at 10 percent. As such, for CY 2011 and subsequent calendar years we target up to 2.5 percent of estimated total payments to be paid as outlier payments, and apply a 10 percent agency-level outlier cap.

2. Changes to the Methodology Used To Estimate Episode Cost

In the CY 2017 HH PPS proposed rule, we described that our analysis of outlier episodes, based on preliminary CY 2015 home health claims data, indicates that there is significant variation in the visit length by discipline for outlier episodes. Those agencies with 10 percent of their total payments as outlier payments are providing shorter, but more frequent skilled nursing visits than agencies with less than 10 percent of their total payments as outlier payments. In addition, we also noted in the proposed rule that outlier payments are predominately driven by the provision of skilled nursing services. As a result of the analysis of CY 2015 home health claims data, we stated that we are concerned that the current methodology for calculating outlier payments may create a financial disincentive for providers to treat medically complex beneficiaries who require longer visits.

The home health environment differs from hospitals and other institutional environments. In the home setting, the patient has a greater role in determining how, when, and if certain interventions are provided. Individual skill, cognitive and functional ability, and financial resources affect the ability of home health patients to safely manage their health care needs, interventions, and medication regimens.[5] Clinically

[5] Ellenbecker, C., Samia, L., Cushman, M., Alster, K. (AHRQ, April, 2008). Patient Safety and Quality in Home Health Care. Patient Safety and Quality: An Evidence-based Handbook for Nurses. Chapter 13.

complex patients generally use more health services, have functional limitations, need more assistance to perform activities of daily living (ADLs), require social support and community resources, and require more complex medical interventions.[6] These complex interventions could include total parenteral nutrition (TPN) therapy and central line catheter care. Higher nursing visit intensity and longer visits are a generally a response to instability of the patient's condition, and/or inability to effectively and safely manage their condition and self-care activities; therefore, more clinically complex, frail, elderly patients generally require more intensive and frequent home health surveillance, increased home health care utilization, and costs.[7] [8]

In addition to the clinical information described above, Mathematica Policy Research published a report in 2010 titled ''Home Health Independence Patients: High Use, but Not Financial Outliers.'' [9] In this report, Mathematica described their analysis of the relationships among the proxy demonstration target group for the Home Health Independence Demonstration, patients who receive outlier payments, and the agencies that serve them. As part of their research, Mathematica examined the degree of overlap between the proxy demonstration target group, who were ill, permanently disabled beneficiaries, and those beneficiaries with episodes of care that received outlier payments. The study found that only a small fraction of proxy demonstration patients had episodes of care that generated outlier payments and that ''differences between the proxy demonstration and outlier patient groups examined in this study suggest that outlier payments are not generally being used to serve the types of severely, permanently disabled beneficiaries that were addressed by the demonstration concept.''

Therefore, we proposed to change the methodology used to calculate outlier payments, using a cost-per-unit approach rather than a cost-per-visit approach. Using this approach, we would convert the national per-visit rates in section III.C.3. into per 15 minute unit rates. Table 19 shows the cost-per-unit payment rates for the calculation of outlier payments, updated with complete CY 2015 home health claims data (as of June 30, 2016). The new per-unit rates by discipline would then be used, along with the visit length data by discipline reported on the home health claim in 15 minute increments (15 minutes = 1 unit), to calculate the estimated cost of an episode to determine whether the claim will receive an outlier payment and the amount of payment for an episode of care. We note that this change in the methodology would be budget neutral as we would still target to pay up to, but no more than, 2.5 percent of total payments as outlier payments in accordance with section 1895(b)(5)(A) of the Act.

TABLE 19—COST-PER-UNIT PAYMENT RATES FOR THE CALCULATION OF OUTLIER PAYMENTS

Visit type	CY 2017 national per-visit payment rates	Average minutes-per-visit	Cost-per-unit (1 unit = 15 minutes)
Home health aide	$64.23	63.0	$15.29
Medical social services	227.36	56.5	60.36
Occupational therapy	156.11	47.1	49.72
Physical therapy	155.05	46.6	49.91
Skilled nursing	141.84	44.8	47.49
Speech-language pathology	168.52	48.1	52.55

In the CY 2017 proposed rule, we stated that we believe that this proposed change to the outlier methodology will result in more accurate outlier payments where the calculated cost per episode accounts for not only the number of visits during an episode of care, but also the length of the visits performed. This, in turn, may address some of the findings from the home health study, where margins were lower for patients with medically complex needs that typically require longer visits, thus potentially creating an incentive to treat less complex patients.

In concert with our proposal to change to a cost-per-unit approach to estimate episode costs and determine whether an outlier episode should receive outlier payments, we proposed to implement a cap on the amount of time per day that would be counted toward the estimation of an episode's costs for outlier calculation purposes. Specifically, we proposed to limit the amount of time per day (summed across the six disciplines of care) to 8 hours or 32 units per day when estimating the cost of an episode for outlier calculation purposes. We noted that we are not limiting the amount of care that can be provided on any given day. We are only limiting the time per day that can be credited towards the estimated cost of an episode when determining if an episode should receive outlier payments and calculating the amount of the outlier payment. For instances when more than 8 hours of care is provided by one discipline of care, the number of units for the line item will be capped at 32 units for the day for outlier calculation purposes. For rare instances when more than one discipline of care is provided and there is more than 8 hours of care provided in one day, the episode cost associated with the care provided during that day will be calculated using a hierarchical method based on the cost per unit per discipline shown in Table 19. The discipline of care with the lowest associated cost per unit will be discounted in the calculation of episode cost in order to cap the estimation of an episode's cost at 8 hours of care per day. For example, if an HHA provided 4.5 hours of skilled nursing and 4.5 hours of home health aide services, all 4.5 hours of skilled nursing would be counted in the

[6] Rich, E., Lipson, D., Libersky, J., Parchman, M. (2012). Coordinating Care for Adults with Complex Care Needs in the Patient-Centered Medical Home: Challenges and Solutions. AHRQ Publication No. 12–0010,

[7] Fried. L., Ferrucci, L., Darer, J., Williamson, J., Anderson, G. (2004). Untangling the Concepts of Disability, Frailty and Comorbidity: Implications for Improved Targeting and Care. Journal of Gerontology. 59(3), 255–263.

[8] Riggs, J., Madigan, E., Fortinsky, R. (2011). Home Health Care Nursing Visit Intensity and Heart Failure Patient Outcomes. Home Health Care Managing Practice. 23(6), 412–420.

[9] Cheh, Valerie and Schurrer, John. Home Health Independence Patients: High Use, but Not Financial Outliers, Report to Centers for Medicare and Medicaid, Mathematical Policy Research. March 31, 2010.

episode's estimated cost and 3.5 hours of home health aide services would be counted in the episode's estimated cost (8 hours − 4.5 hours = 3.5 hours) since home health aide services has a lower cost-per-unit than skilled nursing services.

Out of approximately 6.47 million episodes in our analytic file for 2015, only 17,505 episodes or 0.3 percent of all home health episodes reported instances where over 8 hours of care were provided in a single day (some episodes of which could have resulted from data entry errors). Of those 17,505 episodes, only 8,305 would be considered outlier episodes under the proposed outlier methodology. Therefore, we estimate that approximately 8,300 episodes, out of 6.47 million episodes, would be impacted due to the proposed 8 hour cap.

3. Proposed Fixed Dollar Loss (FDL) Ratio

For a given level of outlier payments, there is a trade-off between the values selected for the FDL ratio and the loss sharing ratio. A high FDL ratio reduces the number of episodes that can receive outlier payments, but makes it possible to select a higher loss-sharing ratio, and therefore, increase outlier payments for qualifying outlier episodes. Alternatively, a lower FDL ratio means that more episodes can qualify for outlier payments, but outlier payments per episode must then be lower. The FDL ratio and the loss-sharing ratio must be selected so that outlier payments do not exceed 2.5 percent of total payments (as required by section 1895(b)(5)(A) of the Act). Historically, we have used a value of 0.80 for the loss-sharing ratio which, we believe, preserves incentives for agencies to provide care efficiently for outlier cases. With a loss sharing ratio of 0.80, Medicare pays 80 percent of the additional estimated costs above the outlier threshold amount. The national, standardized 60-day episode payment amount is multiplied by the FDL ratio. That amount is wage-adjusted to derive the wage-adjusted FDL amount, which is added to the case-mix and wage-adjusted 60-day episode payment amount to determine the outlier threshold amount that costs have to exceed before Medicare would pay 80 percent of the additional estimated costs.

In the CY 2017 HH PPS proposed rule, simulating payments using preliminary CY 2015 claims data (as of December 31, 2015) and the CY 2016 payment rates (80 FR 68649 through 68652), we estimated that outlier payments in CY 2016 would comprise 2.23 percent of total payments. Based on simulations using CY 2015 claims data and the CY 2017 payment rates in section III.C.3 of the CY 2017 HH PPS proposed rule, we stated that we estimate that outlier payments would comprise approximately 2.58 percent of total HH PPS payments in CY 2017 under the current outlier methodology. This 15.7 percent increase is attributable to the increase in the national per-visit amounts through the rebasing adjustments and the decrease in the national, standardized 60-day episode payment amount as a result of the rebasing adjustment and the nominal case-mix growth reduction. Given the statutory requirement to target up to, but no more than, 2.5 percent of total payments as outlier payments, we proposed to increase the FDL ratio for CY 2017, as we believe that maintaining an FDL ratio of 0.45 with a loss-sharing ratio of 0.80 is no longer appropriate given the percentage of outlier payments projected for CY 2017. We did not propose a change to the loss-sharing ratio (0.80) as a loss-sharing ratio of 0.80 for the HH PPS would remain consistent with payment for high-cost outliers in other Medicare payment systems (for example, IRF PPS, IPPS, etc.). In the CY 2017 HH PPS proposed rule, we stated that under the current outlier methodology, the FDL ratio would need to be increased from 0.45 to 0.48 to pay up to, but no more than, 2.5 percent of total payments as outlier payments. Under the proposed outlier methodology which would use a cost per unit rather than a cost per visit when calculating episode costs, we estimated that we will pay out 2.74 percent in outlier payments in CY 2017 using an FDL ratio of 0.48 and that the FDL ratio would need to be increased to 0.56 to pay up to, but no more than, 2.5 percent of total payments as outlier payments. Therefore, in addition to the proposal to change the methodology used to calculate outlier payments, we proposed to increase the FDL ratio from 0.45 to 0.56 for CY 2017. In the CY 2017 HH PPS proposed rule, we stated that we would update our estimate of outlier payments as a percent of total HH PPS payments for the final rule. Using complete CY 2015 claims data as of June 30, 2016, we estimate that the FDL ratio would need to increase from 0.45 to 0.55 for CY 2017 in order to pay up to, but no more than, 2.5 percent of total payments as outlier payments.

In the CY 2017 HH PPS proposed rule, we solicited comments on the proposed changes to the outlier payment calculation methodology and the associated changes in the regulations text at § 484.240 as well as the proposed increase to the FDL ratio. The following is a summary of the comments and our responses.

Comment: MedPAC was supportive of the proposed change to the outlier methodology, stating that the proposed policy improves the targeting of outlier funds and is similar to the method CMS uses when constructing the home health case-mix weights. MedPAC stated that the proposed method will better capture the variability in costs among home health agencies, will better align payments with agencies' actual costs, will reduce vulnerabilities, and will reduce incentives for agencies to not sufficiently treat patients who need longer than average visits under the HH PPS. Other commenters appreciated CMS' effort to develop an outlier policy that better aligns payment with cost and addresses disincentives to provide services to complex patients who need longer visits. A number of commenters requested that CMS finalize the proposed change to the outlier methodology.

Response: We thank MedPAC and other commenters for their support. Our analysis shows that changing the outlier methodology using a 15-minute unit approach better aligns payment with the cost of providing care and may help address some of the findings from the home health study and alleviate potential financial disincentives to treat patients with medically complex needs.

Comment: Several commenters requested specific information or instructions on reporting visits and visit length. A few commenters requested more clarity on how the 15-minute units would be calculated and tracked by the agency. Some commenters expressed concerns that the proposed change in the outlier methodology could result in fraudulent calculation of the time necessary to provide the service. Commenters were concerned that some HHAs may artificially inflate the time spent with patients or misreport the units that were actually delivered. A commenter brought up a concern about the reliability of the paper-based reporting. Commenters were concerned that adjusting payment according to visit length may encourage overutilization and encouraged CMS to put into place screens and checks to prevent potential overestimation of time reporting. A few commenters suggested that CMS consider reimbursing partial 15 minute units on a pro-rata basis to increase payment accuracy and avoid a reporting cliff.

Some commenters expressed concerns about whether HHAs have the data to

accurately capture the length of care provided by each of the six disciplines and whether HHAs and their software vendors will have adequate time to incorporate the proposed changes to their Medicare billing systems. A commenter recommended that CMS delay the particular change to the outlier methodology in order to provide HHAs time to work with their software billing vendors to update their systems and make changes to bill outlier payments correctly. A few commenters stated that the change in the methodology may result in additional costs from their electronic health record vendor to capture the cost per unit as well as staff training to document time in and out when in the home. A commenter stated that the extra expense and time resources should be captured in the estimate of the impact of this proposed change.

Response: We did not propose to change the reporting of visits or visit length in the CY 2017 HH PPS proposed rule. The requirement to report visit length in 15 minute units is a statutory requirement that has been in place since the start of the HH PPS. We encourage providers to continue to bill visits and visit length according to previous guidance. Specifically, see Table 20, which will be added to the Medicare Claims Processing Manual, chapter 11 (Pub. 100–04).

TABLE 20—DEFINITION OF THE 15-MINUTE UNITS

Unit	Time
1	<23 minutes.
2	= 23 minutes to <38 minutes.
3	= 38 minutes to <53 minutes.
4	= 53 minutes to <68 minutes.
5	= 68 minutes to <83 minutes.
6	= 83 minutes to <98 minutes.
7	= 98 minutes to <113 minutes.
8	= 113 minutes to <128 minutes.
9	= 128 minutes to <143 minutes.
10	= 143 minutes to <158 minutes.

Since we are not adding or changing reporting requirements, providers should not have an increase in burden due to this policy. Providers are already required to report visit length, in 15 minute increments, by discipline, on home health claims. We do not have minute data to pay partial 15 minute units on a pro-rated basis. Furthermore, we do not have the statutory authority to require HHAs to report visit lengths in timeframes other than in 15-minute increments in accordance with section 1895(c)(2) of the Act. We will monitor for changes in the reporting of visit lengths and may investigate HHAs with suspect billing patterns. As a reminder, any HHA misreporting information on their home health claims will be in violation of the False Claims Act and could be subject to civil penalties and damages and/or criminal prosecution.

Comment: We received a question asking whether the rural add-on will be used in the calculation of the estimated cost of an episode, when applicable, under the proposed outlier policy.

Response: Yes, the rural add-on will apply in this calculation. We will use rural versus non-rural per unit rates the same way we currently use rural versus non-rural per visit rates to calculate the imputed cost.

Comment: A commenter stated that the outlier proposal rewards quantity, but does not take into account quality. One commenter encouraged CMS to focus on the identified ''bad actor'' agencies and not impose potential administrative burdens on compliant providers.

Response: The proposed change in the outlier methodology is not meant to be punitive, but rather is meant to more accurately calculate the cost of an outlier episode of care and thus better align outlier payments with episode cost than the cost per visit approach. As a result of the analysis of CY 2015 home health claims data, we are concerned the current methodology for calculating outlier payments may create a financial disincentive for HHAs to accept and care for medically complex beneficiaries who require longer visits. We believe that this proposed change to the outlier methodology will result in more accurate outlier payments where the calculated cost per episode accounts for not only the number of visits during an episode of care, but also the length of the visits performed. This, in turn, may address some of the findings from the home health study, where margins were lower for patients with medically complex needs that typically require longer visits, thus potentially creating an incentive to treat only or primarily patients with less complex needs.

Comment: One commenter urged CMS to release data to allow for a historical comparison of HH visits vs. HH units of service over multiple years and requested that CMS update the rate per unit computations with every year using the latest data available.

Response: In the proposed rule, we described the average number of visits by discipline type for a Medicare home health 60-day episode of care from CY 2001 to CY 2015 (81FR 43739). While the number of visits by discipline has changed since 2001, visit length has been relatively stable from CY 2001 to CY 2015. From CY 2001 to CY 2015, the average number of 15-minute units reported for physical therapy visits and skilled nursing visits increased by .1 unit or 1.5 minutes, the average number of 15-minute units reported for occupational therapy visits decreased by .1 unit or 1.5 minutes, and the average number of 15-minute units reported for home health aide services decreased by .2 units or 3 minutes. From CY 2001 to CY 2015, the average number of 15-minute units reported for speech-language pathology services and medical social services remained stable. We note that the per-unit rates used to estimate an episode's cost will be updated by the home health update percentage each year. While we do not plan to re-estimate the per-unit rates by discipline using new per-unit data every year, we will monitor the visit length by discipline as more recent data become available. If there are significant changes, we may propose to update the rates.

Comment: One commenter supported the 10-percent cap on outlier payments. Another commenter disagreed with CMS' proposal to maintain the 10-percent cap on outlier payments and instead suggested that CMS include a minimum provider-specific number of percent of episodes that result in LUPAs. Some commenters stated that the shift to a bundled payment system as well as the shift to move care out of institutionalized settings and into home and community-based settings will lead to an influx of patients with more severe conditions being treated by HHAs. Commenters requested that CMS consider this when developing the final policy. Some commenters recommended that CMS conduct a more detailed analysis in the near future on whether the total outlier cap of 2.5 percent is adequate or whether it needs to be increased for future years. Another commenter recommended that CMS pay out more than 2.5 percent in outlier payments.

Response: The 2.5 percent target of outlier payments to total payments and the 10 percent cap on outlier payments at the home health agency level are statutory requirements, as described in section 1895(b)(5) of the Social Security Act. Therefore, we do not have the authority to adjust or eliminate the 10-percent cap or increase the 2.5 percent target amount. In 2015, only about 1 percent of HHAs received 10 percent of their total HH PPS payments as outlier payments, while almost 71 percent of HHAs received less than 1 percent of their total HH PPS payments as outliers. Therefore, the 10 percent agency-level cap does not seem to be significantly impacting a large portion of HHAs.

Comment: Commenters were concerned with the proposal to increase the FDL ratio from 0.45 to 0.56, stating that the increase would reduce the number of episodes that qualify for outlier payment and reduce payments to providers. A commenter implied that the increase in the FDL ratio was solely due to the change in the outlier methodology calculation. The commenter stated that for those HHAs that provide the most outlier care services, Table 26 in the proposed rule (81 FR 43740) shows average minutes per visit jumping from 27.5 to 104.5 to receive outlier payments under the proposed methodology. The commenter stated that this increase drives the fixed dollar loss ratio increase from the current 0.45 to 0.56 in CY 2017, an almost 25 percent increase. Some commenters stated that raising the FDL will cause access issues for certain patients. Another commenter was concerned about the increase in the FDL ratio, stating that CMS has been overly conservative in their outlier projections in the past. The commenter stated that outlier payments have consistently fallen well below the 2.5 percent target the past several years and urged CMS to recalculate the FDL ratio using less conservative projections to ensure outlier payments are closer to the 2.5 percent target amount. A third commenter recommended that CMS retain the current FDL and consider an alternate method to meet the statutory limit placed on outlier payments, such as lowering the outlier payment to total payment cap.

Response: To clarify, Table 26 in the proposed rule (81FR 43740) indicates that for those agencies with 10 percent of their payments as outlier payments, the average minutes per visit under the current methodology is 27.5, while the average number of minutes per visit under the proposed methodology is 104.5. However, as indicated in our response above, only about 1 percent of HHAs received 10 percent of their total HH PPS payments as outlier payments in 2015. The majority of agencies received less than 1 percent of their total HH PPS payments as outlier payments in 2015. As stated in the proposed rule, regardless of the change in the outlier methodology, we would need to raise the FDL in order to target 2.5 percent of total payments as outliers. We project that the percentage of outlier episodes will increase from 2016 to 2017 as a result of the rebasing and nominal case-mix reductions to the national, standardized 60-day episode payment rate as well as increases to the per-visit rates due to the implementation of the fourth and final year of the rebasing adjustments. Since complete CY 2016 or 2017 data are currently not available, we estimate outlier payments for CY 2016 and CY 2017 using 2015 home health utilization data and applying the CY 2016 and CY 2017 payment parameters. Using complete CY 2015 claims data as of June 30, 2016, we estimate that outlier payments will be 2.20 percent of total payments in CY 2016 and that outlier payments will be 2.84 percent of total payments in CY 2017 when applying the CY 2017 payment parameters and the proposed changes to the outlier methodology. Therefore, we are increasing the FDL from 0.45 to 0.55 to target 2.5 percent of payments as outliers, as required by statute. We note that other payment systems with outlier payments, such as the IRF PPS and IPPS, annually re-assess the fixed-loss cost outlier threshold amount. Adjusting the outlier threshold amount in order to target the statutorily required percentage of total payments as outlier payments is standard practice.

Comment: A commenter expressed concerns about the proposed changes to the outlier methodology and urged CMS to withdraw the proposal and retain the current methodology in calculating outlier payments or delay implementation. Another commenter stated that instead of the proposed policy, CMS should keep the existing methodology and add an outlier add-on to pay for individuals with longer than average visits. Several commenters expressed concerns with CMS' proposal to give equal weight to each 15-minute increment of care, stating that there are certain fixed costs that do not vary with visit length. A few commenters stated that the volume of patients who might need longer than average visits is significantly smaller than the volume of patients who need shorter, but more frequent visits for services, such as insulin injections. A commenter also stated that the proposal needs to account for the costs to initiate a visit and that the beginning of the encounter is more resource-intensive than later in the encounter. Commenters stated that short visits would receive substantially less payment for fixed costs that do not vary based on the length of the visit, such as travel time, and the commenters encouraged CMS to refine the proposed policy to give greater weight to the first 15-minute unit of a visit. Commenters also stated that costs outside the actual HH visit, such as but not limited to documentation and back office costs, would not be captured through the proposed approach.

Response: The purpose of the proposed change in the outlier methodology is to more accurately pay for outlier episodes by taking into account both the number of visits and the visit length by discipline when imputing episode cost. We remind commenters that the units of care per discipline will be summed up for each discipline for the entire episode and then multiplied by the cost per unit in order to estimate the estimated episode cost. Therefore, episodes with four 15-minute skilled nursing visits a day for 10 days would receive the same cost estimate as five 2 hour skilled nursing visits in an episode. Episodes with 15-minute visits may still be able to qualify for outlier payments.

We note that payment for the fixed costs of an episode, such as transportation, are already accounted for under the national, standardized 60-day episode payment rate and the national per-visit payment rates. CMS does not track transportation and other administrative costs for each visit or episode. Section 1895(b)(5)(A) of the Social Security Act states that outlier payments are to be made in the case ''of unusual variations in the type or amount of medically necessary care'' and not for unusual variations in fixed costs. Outlier payments are meant to help mitigate the incentive for HHAs to avoid patients that may have episodes of care that result in unusual variations in the type or amount of medically necessary care. Outlier payments serve as a type of ''reinsurance'' whereby, under the HH PPS, Medicare reimburses HHAs 80 percent of their costs for outlier cases once the case exceeds an outlier threshold amount. We have concerns with HHAs that may be developing business models around outlier payments and are trying to make a profit off of these episodes. The goal of this proposal is to more accurately pay for outlier episodes; we noted in the proposed rule that preliminary analysis indicates that a larger percentage of episodes of care for patients with a fragile overall health status will qualify for outlier payments. The outlier system is meant to help address extra costs associated with extra, and potentially unpredictable, medically necessary care. Therefore, using a linear relationship between costs and visit length aligns with the premise of the outlier payment system and with the statute.

Comment: One commenter stated that additional information is needed to accurately assess the financial impact and ensure that CMS is paying outliers accurately. Other commenters were concerned that the outlier proposal may adversely impact access to home health

services or may result in inadequate payment for patients who require multiple short visits per day, such as insulin dependent diabetic patients who are unable to self-inject. Commenters stated that these patients may receive more expensive types of care at other settings or have unnecessary hospitalizations. Another commenter expressed concerns that changing the methodology could negatively impact physical therapy practicing in the home health setting. Commenters wanted to learn more about the types of patients that may not receive outlier payments under the proposed methodology and how this change may impact access to care for certain vulnerable patient groups. Another commenter stated that CMS should use current data to better understand the clinical characteristics of patients who are currently receiving outlier payments. A few commenters stated that the effects of any changes to the outlier methodology should be closely monitored.

Response: The purpose of the proposed change in the outlier methodology is to better align outlier payments with the estimated cost per episode, accounting for not only the number of visits during an episode of care, but also the length of the visits performed. This, in turn, may address some of the findings from the home health study, where margins were lower for patients with medically complex needs that typically require longer visits, thus potentially creating an incentive to treat medically less complex patients. As noted in our response above, episodes with short, frequent visits may also qualify for outlier payments. We estimate that over two-thirds of outlier episodes under the current payment system would continue to receive outlier payments under the proposed outlier methodology. We note that it is difficult to identify with absolute certainty, through administrative data, the visits and episodes for which the sole purpose was to provide insulin injections to insulin-dependent diabetics that cannot self-inject and for which there is no able or willing caregiver that can assist with providing such injections. In 2015, about 358,000 episodes or 6.6 percent of episodes had diabetes as the primary diagnosis and 1,241,000 or 22.9 percent of episodes had diabetes as the secondary diagnosis. Even though almost 30 percent of episodes had a diagnosis of diabetes, we cannot parse out the exact services provided during these episodes, as there were a variety of services that HHAs could have been providing to patients with diabetes. Given the limitations in the data, extensive impact analysis of insulin-dependent diabetics is not possible. However, we plan to monitor for any unintended results of this policy on insulin-dependent diabetics. We reiterate that the goal of the proposed change to the outlier methodology is to more appropriately pay for outlier episodes, not to create incentives to provide care only to a certain population of patients.

Comment: Another commenter urged CMS to provide additional information on the methodology used to calculate episode costs and to provide maximum transparency throughout the development and implementation process. A commenter questioned whether the new methodology would be based on the episode end date or the service date for the outlier.

Response: The outlier methodology will be based on the episode end date. Detailed information on our methodology is available in section III.D.1 and in our responses to comments above.

Comment: Some commenters opposed the proposed 8-hour cap and wanted CMS to remove the cap, stating that it could negatively impact certain patient groups and could create disincentives for agencies to take on sicker patients who would be likely to be outlier patients. Commenters stated that the cap could result in patients receiving care in other settings and increase the overall healthcare expenditures. One commenter stated that outlier payments were already controlled for budget neutrality, and therefore the 8-hour cap was not needed. Another commenter stated that CMS should evaluate the medical complexity of the patients whose episodes may be affected by the 8-hour cap to avoid any unintended access barriers for patients who clinically warrant extra home health care and resources. Commenters also stated that CMS should remove the per-week cap of 28 hours. A commenter stated that capping the hours of care at 28 hours per week, with a review process which would allow up to 35 hours per week of care, was (1) inconsistent with the language in the program manual specifying less than eight hours per day OR less than six days per week; and (2) created an undue burden on providers by requiring additional paperwork in order to provide adequate care to outlier patients. A few commenters stated that CMS should modify the language in the program manual to recognize the importance of treating outlier patients and the need to do so outside of the traditional confines of the pre-existing definition of part-time and intermittent services. Another commenter urged CMS to carefully consider eliminating the per day and per week caps for certain vulnerable patient groups.

Response: Where a patient is eligible for coverage of home health services, Medicare covers part-time or intermittent home health aide services and skilled nursing services, subject to statutory limits. Section 1861(m)(7)(B) of the Act states that the term ''part–time or intermittent services'' means skilled nursing and home health aide services furnished any number of days per week as long as they are furnished (combined) less than 8 hours each day and 28 or fewer hours each week (or, subject to review on a case-by-case basis as to the need for care, less than 8 hours each day and 35 or fewer hours per week).'' Therefore, the weekly cap on the amount of skilled nursing and home health aide services combined is a statutory limit, not an additional regulatory requirement. As stated in the proposed rule, outlier payments are predominately driven by the provision of skilled nursing services. The 8-hour daily cap on services aligns with the statute, which requires that skilled nursing and home health aide services be furnished less than 8 hours each day.

As noted earlier, out of approximately 6.47 million episodes in our analytic file for 2015, only 17,505 episodes or 0.3 percent of all home health episodes reported instances where over 8 hours of care were provided in a single day (which also could have resulted from data entry errors, as we currently do not use visit length for payment). Of those 17,505 episodes, only 8,305 would be classified as outlier episodes under the proposed outlier methodology. Therefore, we estimate that only 8,300 episodes or so, out of 6.47 million episodes, would be impacted due to the proposed 8 hour cap and we do not expect a significant impact on patients and providers. We plan to monitor for any unintended results of this policy as data become available.

Comment: One commenter stated that the current outlier policy should be eliminated until CMS and the industry have had time to develop a more reasonable outlier provision. The commenter also stated that cost of medical supplies should be included in the imputed cost for episodes.

Response: We will take this comment into consideration given the history of fraud and abuse associated with outlier payments. We note that there is a separate system that covers NRS costs and payments range from $14.16 to $552.58. We will take into consideration the comment about combining NRS

costs with episode costs. However, we note that in the 2014 HH PPS proposed rule, we stated that during our analysis of NRS costs and payments, we found that a significant number of providers listed charges for NRS on the home health claim, but those same providers did not list any NRS costs on their cost reports. Specifically, out of 6,252 cost reports from FY 2011, 1,756 cost reports (28.1 percent) reported NRS charges in their claims, but listed $0 NRS costs on their cost reports. Given the findings from a sample of cost report audits performed and our analysis of NRS payments and costs, we are exploring possible additional edits to the cost report and quality checks at the time of submission to improve future cost reporting accuracy (78 FR 40290). We encourage providers to provide accurate data on the cost report so NRS cost information can be used in the future.

Final Decision: After consideration of all public comments, we are finalizing the proposed changes to the outlier methodology as proposed, as well as the proposed increase to the FDL ratio and the corresponding proposed changes in the regulations text at § 484.240. The methodology to calculate outlier payments will change for CY 2017 to use a cost-per-unit approach as outlined above. The FDL will be set at 0.55 for CY 2017 based on analysis of complete CY 2015 data (as of June 30, 2016).

E. Payment Policies for Negative Pressure Wound Therapy (NPWT) Using a Disposable Device

1. Background

Negative pressure wound therapy (NPWT) is a medical procedure in which a vacuum dressing is used to enhance and promote healing in acute, chronic, and burn wounds. The therapy involves using a sealed wound dressing attached to a pump to create a negative pressure environment in the wound. NPWT can be utilized for varying lengths of time, as indicated by the severity of the wound, from a few days of use up to a span of several months.

In addition to the conventional NPWT systems classified as durable medical equipment (DME), NPWT can also be performed using a disposable device. A disposable NPWT device is a single-use integrated system that consists of a non-manual vacuum pump, a receptacle for collecting exudate, and dressings for the purposes of wound therapy. These disposable systems consist of a small pump, which eliminates the need for a bulky canister. Unlike conventional NPWT systems classified as DME, disposable NPWT devices have a preset continuous negative pressure, there is no intermittent setting, they are pocket-sized and easily transportable, and they are generally battery-operated with disposable batteries.[10]

Section 1895 of the Act requires that the HH PPS includes payment for all covered home health services. Section 1861(m) of the Act defines what items and services are considered to be ''home health services'' when furnished to a Medicare beneficiary under a home health plan of care when provided in the beneficiary's place of residence. Those services include:

- Part-time or intermittent nursing care
- Physical or occupational therapy or speech-language pathology services
- Medical social services
- Part-time or intermittent services of a home health aide
- Medical supplies
- A covered osteoporosis drug
- Durable medical equipment (DME)

The unit of payment under the HH PPS is a national, standardized 60-day episode payment amount with applicable adjustments. The national, standardized 60-day episode payment amount includes costs for the home health services outlined above per section 1861(m) of the Act, except for DME and a covered osteoporosis drug. Section 1814(k) of the Act specifically excludes DME from the national, standardized 60-day episode rate and consolidated billing requirements. DME continues to be paid outside of the HH PPS. The cost of the covered osteoporosis drug (injectable calcitonin), which is covered where a woman is postmenopausal and has a bone fracture, is also not included in the national, standardized 60-day episode payment amount, but must be billed by the HHA while a patient is under a home health plan of care since the law requires consolidated billing of osteoporosis drugs. The osteoporosis drug itself continues to be paid on a reasonable cost basis.

As described above, medical supplies are included in the definition of ''home health services'' and the cost of such supplies is included in the national, standardized 60-day episode payment amount. Medical supplies are items that, due to their therapeutic or diagnostic characteristics, are essential in enabling HHA personnel to conduct home visits or to carry out effectively the care the physician has ordered for the treatment or diagnosis of the patient's illness or injury, as described in section 50.4.1 of Chapter 7 of the Medicare Benefit Policy Manual.[11] Supplies are classified into two categories, specifically:

- Routine: Supplies used in small quantities for patients during the usual course of most home visits; or
- Non-routine: Supplies needed to treat a patient's specific illness or injury in accordance with the physician's plan of care and meet further conditions.

Both routine and non-routine medical supplies are reimbursed on an episodic basis for every Medicare home health patient regardless of whether the patient requires medical supplies during the episode. The law requires that all medical supplies (routine and non-routine) be provided by the HHA while the patient is under a home health plan of care. A disposable NPWT device would be considered a non-routine supply for home health.

As required under sections 1814(a)(2)(C) and 1835(a)(2)(A) of the Act, for home health services to be covered, the patient must receive such services under a plan of care established and periodically reviewed by a physician. As described in § 484.18 of the Medicare Conditions of Participation (CoPs), the plan of care that is developed in consultation with the agency staff, is to cover all pertinent diagnoses, including the types of services and equipment required for the treatment of those diagnoses as well as any other appropriate items, including DME. Consolidated billing requirements ensure that only the HHA can bill for home health services, with the exception of DME and therapy services provided by physicians, when a patient is under a home health plan of care. The types of service most affected by the consolidated billing edits tend to be non-routine supplies and outpatient therapies, since these services are routinely billed by providers other than HHAs, or are delivered by HHAs to patients not under home health plans of care.

As provided under section 1834(k)(5) of the Act, a therapy code list was created based on a uniform coding system (that is, the Healthcare Common Procedure Coding System or HCPCS) to identify and track these outpatient therapy services paid under the Medicare Physician Fee Schedule (MPFS). The list of therapy codes, along with their respective designation, can be found on the CMS Web site, specifically at *https://www.cms.gov/Medicare/*

[10] Dumville JC, Land L, Evans D, Peinemann F. Negative pressure wound therapy for treating leg ulcers. Cochrane Database of Systematic Reviews 2015, Issue 7. Art. No.: CD011354. DOI: 10.1002/14651858.CD011354.pub2.

[11] *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c07.pdf.*

Billing/TherapyServices/AnnualTherapyUpdate.html.

Two of the designations that are used for therapy services are: ''always therapy'' and ''sometimes therapy.'' An ''always therapy'' service must be performed by a qualified therapist under a certified therapy plan of care, and a ''sometimes therapy'' service may be performed by a physician or a non-physician practitioner outside of a certified therapy plan of care. CPT® codes 97607 and 97608 are categorized as a ''sometimes'' therapy, which may be performed by either a physician or a non-physician practitioner outside of a certified therapy plan of care, as described in section 200.9 of Chapter 4 of the Medicare Claims Processing Manual.[12] CPT® codes 97607 and 97608 are subject to the HHA consolidated billing requirements, given that these two codes are considered ''sometimes'' therapy codes and the service can be performed by a therapist or non-physician practitioner and given that these two codes include disposable NPWT devices, which are considered a non-routine supply.

2. The Consolidated Appropriations Act, 2016

As described in the proposed rule, a disposable NPWT device is currently considered a non-routine supply and thus payment for the disposable NPWT device is included in the episodic reimbursement amount. However, the Consolidated Appropriations Act, 2016 (Pub. L 114–113) amends both section 1834 of the Act (42 U.S.C. 1395m) and section 1861(m)(5) of the Act (42 U.S.C. 1395x(m)(5)), requiring a separate payment to a HHA for an applicable disposable device when furnished on or after January 1, 2017, to an individual who receives home health services for which payment is made under the Medicare home health benefit. Section 1834(s)(2) of the Act defines an applicable device as a disposable NPWT device that is an integrated system comprised of a non-manual vacuum pump, a receptacle for collecting exudate, and dressings for the purposes of wound therapy used in lieu of a conventional NPWT DME system. As required by 1834(s)(3) of the Act, the separate payment amount for a disposable NPWT device is to be set equal to the amount of the payment that would be made under the Medicare Hospital Outpatient Prospective Payment System (OPPS) using the Level I HCPCS code, otherwise referred to as Current Procedural Terminology (CPT® 4) codes, for which the description for a professional service includes the furnishing of such a device.

Under the OPPS, CPT® codes 97607 and 97608 (APC 5052—Level 2 Skin Procedures), include furnishing the service as well as the disposable NPWT device. These codes are defined as follows:

- HCPCS 97607—Negative pressure wound therapy, (for example, 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.
- HCPCS 97608—Negative pressure wound therapy, (for example, 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.

3. Payment Policies for NPWT Using a Disposable Device

For the purposes of paying for NPWT using a disposable device for a patient under a Medicare home health plan of care and for which payment is otherwise made under section 1895(b) of the Act, CMS proposed that for instances where the sole purpose for an HHA visit is to furnish NPWT using a disposable device, Medicare will not pay for the visit under the HH PPS. Instead, we proposed that since furnishing NPWT using a disposable device for an individual who receives home health services and for which payment is made under the Medicare home health benefit (that is, a patient under a home health plan of care) is to be paid separately based on the OPPS amount, which includes payment for both the device as well as furnishing the service, the HHA must bill these visits separately under type of bill (TOB) 34x (used for some patients not under a HH plan of care, Part B medical and other health services, and osteoporosis injections) along with the appropriate HCPCS code (97607 or 97608). Visits performed solely for the purposes of furnishing NPWT using disposable device would not be reported on the HH PPS claim (TOB 32x).

If NPWT using a disposable device is performed during the course of an otherwise covered HHA visit (for example, while also furnishing a catheter change), we proposed that the HHA must not include the time spent furnishing NPWT in their visit charge or in the length of time reported for the visit on the HH PPS claim (TOB 32x). Providing NPWT using a disposable device for a patient under a home health plan of care will be separately paid based on the OPPS amount relating to payment for covered OPD services. In this situation, the HHA bills for NPWT performed using an integrated, disposable device under TOB 34x along with the appropriate HCPCS code (97607 or 97608). Additionally, this same visit should also be reported on the HH PPS claim (TOB 32x), but only the time spent furnishing the services unrelated to the provision of NPWT using an integrated, disposable device.

As noted in section III.E.1, since these two CPT® codes (97607 and 97608) are considered ''sometimes'' therapy codes, we proposed that NPWT using a disposable device for patients under a home health plan of care can be performed, in accordance with state law, by a registered nurse, physical therapist, or occupational therapist and the visits would be reported on the type of bill 34x using revenue codes 0559, 042x, 043x. The descriptions for CPT® codes 97607 and 97608 include performing a wound assessment, therefore in the proposed rule we stated that it would only be appropriate for these visits to be performed by a registered nurse, physical therapist, or occupational therapist as defined in § 484.4 of the Medicare Conditions of Participation (CoPs).

As outlined in the proposed rule, since the payment amount for both 97607 and 97608 would be set equal to the amount of the payment that would be made under the OPPS, the payment amount would also be subject to the area wage adjustment policies in place under the OPPS in a given year. Please see Medicare Hospital OPPS Web page for Addenda A and B at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Addendum-A-and-Addendum-B-Updates.html.* These addenda are a ''snapshot'' of HCPCS codes and their status indicators, APC groups, and OPPS payment rates that are in effect at the beginning of each quarter. Section 504(b)(1) of the Consolidated Appropriations Act, 2016 (Pub. L 114–113) also amends section 1833(a)(1) of the Act, which requires that furnishing NPWT using a disposable device be subject to beneficiary coinsurance in the amount of 20 percent. The amount paid to the HHA by Medicare would be equal to 80 percent of the lesser of the actual charge

[12] *https://www.cms.gov/regulations-and-guidance/guidance/manuals/internet-only-manuals-ioms-items/cms018912.html.*

or the payment amount as determined by the OPPS for the year.

In the CY 2017 HH PPS proposed rule, we also noted that in order for a beneficiary to receive NPWT using a disposable device under the home health benefit, the beneficiary must also qualify for the home health benefit in accordance with the existing eligibility requirements (81 FR 43744). To be eligible for Medicare home health services, as set out in sections 1814(a) and 1835(a) of the Act, a physician must certify that the Medicare beneficiary (patient) meets the following criteria:

- Is confined to the home
- Needs skilled nursing care on an intermittent basis or physical therapy or speech-language pathology; or have a continuing need for occupational therapy
- Is under the care of a physician
- Receive services under a plan of care established and reviewed by a physician; and
- Has had a face-to-face encounter related to the primary reason for home health care with a physician or allowed Non-Physician Practitioner (NPP) within a required timeframe.

As set forth in §§ 409.32 and 409.44, to be considered a skilled service, the service must be so inherently complex that it can be safely and effectively performed only by, or under the supervision of, professional or technical personnel. Additionally, care is deemed as ''reasonable and necessary'' based on information reflected in the home health plan of care, the initial and comprehensive assessments as required by § 484.55, and/or the medical record of the individual patient. Coverage for NPWT using a disposable device will be determined based upon a doctor's order as well as patient preference, taking into account the unique medical condition of the patient. Research has shown that patients prefer wound dressing materials that afford the quickest wound healing, pain reduction, maximum exudate absorption to minimize drainage and odor, and they indicated some willingness to pay out of pocket costs.[13] Treatment decisions as to whether to use a disposable NPWT system versus a conventional NPWT DME system is determined by the characteristics of the wound, as well as patient goals and preferences discussed with the ordering physician to best achieve wound healing and reduction. We solicited public comment on all aspects of the proposed payment policies for furnishing NPWT using a disposable device as articulated in this section as well as the corresponding proposed changes to the regulations at § 409.50 in section VII of the proposed rule.

The following is a summary of the comments we received regarding the proposal for the payment of NPWT using a disposable device.

Comment: Many commenters expressed support of the proposed payment policies for the provision of NPWT using a disposable device.

Response: We appreciate the positive feedback from the provider community as well as other stakeholders.

Comment: Many commenters expressed confusion regarding how to bill for wound care visits that would not include the replacement of a disposable NPWT device and encouraged CMS to provide clarification as to how these wound care visits should be billed. In addition, several commenters requested guidance from CMS on how to track time and services related to NPWT using a disposable device in order to ensure they are complying with billing requirements.

Response: We appreciate commenters' interest in wanting to appropriately track and bill for NPWT using a disposable device. We proposed that, where the sole purpose of a home health visit is to ''furnish NPWT using a disposable device,'' we would not pay for the visit under the HH PPS. Rather, those services would be reported on a TOB 34x and paid for separately outside the HH PPS. Where NPWT is furnished using a disposable device, and other services that are unrelated to the NPWT are also furnished, the NPWT services would be billed and paid for separately outside the HH PPS (using TOB 34x), and the services unrelated to NPWT would be billed and paid for under the HH PPS (using TOB 32x).

We hoped our explanation—that, when NPWT is furnished using a disposable device, both the device and the services associated with furnishing the device are paid for separately based on the OPPS amount (81 FR 43643)—would convey that a new device had to be furnished in order for the service to be separately paid outside the HH PPS. However, based on commenters' questions about which services HHAs must bill using bill types 34x and 32x, we believe we need to be clearer about what we meant by ''furnish NPWT using a disposable device'' in the proposed rule. We are clarifying here that, when a HHA ''furnishes NPWT using a disposable device,'' the HHA is furnishing a new disposable NPWT device. This means the HHA provider is either initially applying an entirely new disposable NPWT device, or removing a disposable NPWT device and replacing it with an entirely new one. In both cases, all the services associated with NPWT—for example, conducting a wound assessment, changing dressings, and providing instructions for ongoing care—must be reported on TOB 34x with the corresponding CPT® code (that is, CPT code 97607 or 97608); they may not be reported on the home health claim (TOB 32x). The reimbursement for all of these services is included in the OPPS reimbursement amount for those two CPT® codes. Any follow-up visits for wound assessment, wound management, and dressing changes where a new disposable NPWT device is not applied must be included on the home health claim (TOB 32x).

We are codifying this definition of ''furnishing negative pressure wound therapy (NPWT) using a disposable device'' in our regulations at § 484.202. This is a technical amendment that reflects the substance of our proposal without changes.

In the interest of providing clarification on potential billing scenarios for HHAs furnishing NPWT using a disposable device, we are providing some examples below:

• *Example #1:*

On Monday, a nurse assesses the patient's condition, assesses the wound, and applies a new disposable NPWT device. The nurse also provides wound care education to the patient and family. On the following Monday, the nurse returns, assesses the wound, and replaces the device that was applied the week before with an entirely new disposable NPWT device. In this scenario, the billing procedures are as follows:

++ For each visit, all the services provided by the nurse were associated with furnishing NPWT using a disposable device because the nurse applied a new disposable NPWT device during each visit. The nurse did not provide any services other than furnishing NPWT using a disposable device. Therefore, all the nursing services for both visits should be reported on TOB 34x with CPT® code 97607 or 97608. None of the services should be reported on TOB 32x.

• *Example #2:*

On Monday, a nurse assesses the wound, applies a new disposable NPWT device, and provides wound care education to the patient and family. The nurse returns on Thursday for wound assessment and replaces the fluid management system (or dressing) for the existing disposable NPWT, but does not replace the entire device. The nurse

[13] Corbett Lisa Q. and Ennis William J., What Do Patients Want? Patient Preferences in Wound Care. Advances in Wound Care. August 2014, 3(8): 537–543. doi:10.1089/wound.2013.0458.

returns the following Monday, assesses the patient's condition and the wound, and replaces the device that had been applied on the previous Monday with a new disposable NPWT device. In this scenario, the billing procedures are as follows:

++ For both Monday visits, all the services provided by the nurse were associated with furnishing NPWT using a disposable device. The nurse did not provide any services that were not associated with furnishing NPWT using a disposable device. Therefore, all the nursing services for both Monday visits should be reported on TOB 34x with CPT® code 97607 or 97608. None of the services should be reported on TOB 32x.

++ For the Thursday visit, the nurse checked the wound, but did not apply a new disposable NPWT device, so even though the nurse provided care related to the wound, those services would not be considered furnishing NPWT using a disposable device. Therefore, the services should be reported on bill type 32x and no services should be reported on bill type 34x.

• *Example #3:*

• On Monday, the nurse applies a new disposable NPWT device. On Thursday, the nurse returns for a scheduled visit to change the beneficiary's indwelling catheter. While there, the nurse assesses the wound and applies a new fluid management system (or dressing) for the existing disposable NPWT device, but does not replace the device entirely. In this scenario, the billing procedures are as follows:

++ For the Monday visit, all the nursing services were associated with furnishing NPWT using a disposable device. The nurse did not provide any services that were not associated with furnishing NPWT using a disposable device. Therefore, the HHA should report the nursing visit on TOB 34x with CPT® code 97607 or 97608; the visit should not be reported on a 32x claim.

++ For the Thursday visit, while the nursing services included wound assessment and application of a component of the disposable NPWT device, the nurse did not furnish a new disposable NPWT device. Therefore, the nurse did not furnish NPWT using a disposable device, so the HHA should report all the nursing services for the visit, including the catheter change and the wound care, on TOB 32x.

• *Example #4:*

On Monday, the nurse applies a new disposable NPWT device, and provides instructions for ongoing wound care. During this same visit, per the HH plan of care, the nurse changes the indwelling catheter and provides troubleshooting information and teaching regarding its maintenance. In this scenario, the billing procedures are as follows:

++ The visit included applying a new disposable NPWT device as well as services unrelated to that NPWT service, which means the HHA will submit both a TOB 34x and a TOB 32x.

++ For furnishing NPWT using a disposable device, that is, the application of the new disposable NPWT device and the time spent instructing the beneficiary about ongoing wound care, the HHA would bill using a TOB 34x with CPT® code 97607 or 97608.

++ For services not associated with furnishing NPWT using a disposable device, that is, for the replacement of the indwelling catheter and instructions about troubleshooting and maintenance, the HHA would bill under TOB 32x.

Comment: Several commenters suggested that CMS' payment proposal for furnishing NPWT using a disposable device was not consistent with the intent of section 504 of the Consolidated Appropriations Act, 2016 (Pub. L. 114–113), which they believe is to facilitate the use of less expensive disposable devices in place of more costly DME equipment for wound therapy. Commenters maintained that the payment amount required by the statute is only for the disposable NPWT device and does not incorporate the services associated with the device. They stated that, because the statute refers to a separate payment for the NPWT device, the payment amount is meant to be a payment over and above the home health payment for providing the service. Commenters asserted that, by not allowing the reporting of a home health visit associated with the application of a disposable NPWT device, we would be encouraging providers to continue to provide conventional DME equipment for NPWT rather than NPWT using a disposable device, which effectively limits treatment choices and ignores patient preferences, and is therefore inconsistent with the intent of the statute.

Response: Section 1834(s)(3) of the Act, as added by section 504 of the Consolidated Appropriations Act, 2016, specifies that the payment amount for an applicable disposable device must be equal to the amount of payment that would be made under the hospital outpatient PPS for the HCPCS code ''for which the description for a professional service includes the furnishing of such device.'' The OPPS payment amounts associated with CPT® codes 97607 and 97608 include both the device cost and the related services for furnishing the device (including topical application(s), wound assessment, and instruction(s) for ongoing care). Therefore, the payments we will make for furnishing NPWT with a disposable device beginning CY 2017 will include amounts for both the device and the associated services, which we believe is consistent with the statute. We do not believe our policy will necessarily encourage or discourage the continued use of DME as a treatment option.

We are codifying this policy in our regulations at § 484.205(b), where we state that the separate payment described here is not included in the episode payment. This is a technical amendment that reflects our proposed policy without any change.

Comment: Several commenters requested more details regarding the definition of ''non-manual vacuum pump,'' as that term is used in section 1834(s)(2)(A) of the Act. Commenters also questioned if there are any disposable negative pressure wound therapy pumps that would not qualify for the separate payment.

Response: Section 1834(s)(2) of the Act defines ''an applicable disposable device'' as ''a disposable device that, as determined by the Secretary, is—(A) a disposable negative pressure wound therapy device that is an integrated system comprised of a non-manual vacuum pump, a receptacle for collecting exudate, and dressings for the purposes of wound therapy; and (B) a substitute for, and used in lieu of, a negative pressure wound therapy durable medical equipment item that is an integrated system of a negative pressure vacuum pump, a separate exudate collection canister, and dressings that would otherwise be covered for individuals for such wound therapy.'' We interpret the term ''non-manual'' in the definition to mean, not powered by hand, but rather, powered automatically, mechanically, or electronically. Additionally, a disposable NPWT device is one that stimulates tissue growth and does not simply collect wound exudate (for example,. a Jackson-Pratt drain), and is used in lieu of a DME NPWT system.

We recognize that there are various disposable NPWT devices, and the decision to select one of these systems is usually determined by wound characteristics, indications for use, and in collaboration between the patient's physician and the patient to achieve desired outcomes. If the NPWT disposable device meets the statutory definition, as articulated in section 1834(s)(2) of the Act, then it would be eligible for the separate payment for

furnishing NPWT using a disposable device. Conversely, if a disposable NPWT device does not conform to the definition outlined in the Consolidated Appropriations Act, 2016, then it would not be considered an ''applicable disposable device.''

Comment: Several commenters requested clarification on coverage for those patients who qualify for the Medicare home health benefit, but only receive services from a HHA for CPT® code 97607 or 97608 on a 34x claim. One commenter noted that some HHAs believe the proposed policies for furnishing NPWT using a disposable device will prevent them from billing for other skilled visits related to wound care that occur more frequently than once every seven days when the disposable NPWT device is scheduled to be replaced, and they requested clarification.

Response: When a home health beneficiary receives *only* services related to furnishing NPWT using a disposable device, the HHA will submit only a TOB 34x. Although a HHA may not submit a TOB 32x, the beneficiary of those services is still recognized as a Medicare-covered home health patient. This instruction applies when the *only* home health service being provided in a visit is the furnishing of NPWT using a disposable device, that is, the initial application or replacement of the disposable NPWT device in its entirety. This policy will not prevent HHAs from billing for other skilled visits related to wound care that occur when a new device is not being applied or a device is being entirely replaced.

Clinical practice guidelines for disposable NPWT devices recommend topical dressing changes at least one time per week in between those visits where a new disposable NPWT device is applied or replaced in its entirety.[14] Therefore, if clinical practice guidelines are followed, there will be skilled nursing visits pertaining to wound management, other than for applying a disposable NPWT device in its entirety, and those services would be billed for on the HH PPS claim (TOB 32x), when medically reasonable and necessary.

Comment: One commenter questioned how claims will be billed where the only skilled service is billed on a 34x claim but dependent services are also provided.

Response: To ensure appropriate payment for dependent services (for example, home health aide visits, medical social services) dictated by the beneficiary's plan of care, we will permit TOB 32x home health claims to be used to bill dependent services when the only skilled service (furnishing NPWT using a disposable device) is billed on a 34x claim, as the commenter described. Specifically, we will permit those TOB 32x home health claims, as long as both (1) the patient qualified for home health on the basis of intermittent skilled nursing care that consisted of furnishing NPWT using a disposable device, and (2) condition code 54 (effective July 1, 2016) is used. This code indicates that, (1) the HHA provided no skilled services via the TOB 32x during the billing period (that is, the patient ceased to receive the skilled service that qualifies the patient for the home health benefit—skilled nursing (SN), physical therapy (PT), speech-language pathology services (SLP), or a continued need for occupational therapy after such time that the need for SN, PT or SLP, via the TOB 32x ceased), but that, (2) the HHA has documentation on file of an allowable circumstance for the provision of non-skilled services. The official instructions regarding use of condition code 54 can be found on the CMS Web site at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R3553CP.pdf*.

Comment: Several commenters stated that the OPPS payment amounts for CPT® codes 97607 and 97608 do not capture the administrative costs of a home health care plan, and requested clarification on how the HHA will be paid for these costs.

Response: Section 1834(s) of the Act stipulates that payment for a disposable NPWT device must be equal to the amount of the payment that would be made under the OPPS amount for the HCPCS code for which the description for a professional service includes the furnishing of such device. While that payment amount will cover the costs of the device and related services, we understand the commenters are asking how the administrative costs of home health care that are not built into the OPPS payment amounts for CPT® codes 97607 and 97608 will be paid for. We expect that payment for furnishing NPWT using a disposable device will almost always be made in addition to a HH episode payment, which already includes reimbursement for overhead and administrative costs. These administrative costs are reported on HHA cost reports in accordance with § 484.210, which states that one factor in the calculation of the national, standardized 60-day episode payment is ''Medicare cost data on the most recent audited cost report data available.''

Per the home health Conditions of Participation (CoPs) at § 484.18, a Medicare beneficiary receiving services from a Medicare-certified HHA must be under the care of a physician and the services provided must be in accordance with the home health plan of care. A plan of care developed for a patient should cover all pertinent diagnoses, including mental status, types of services and equipment required, frequency of visits, prognosis, rehabilitation potential, functional limitations, activities permitted, nutritional requirements, medications and treatments, any safety measures to protect against injury, instructions for timely discharge or referral, and any other appropriate items. Therefore, even when a beneficiary requires NPWT furnished using a disposable device, for which payment will be made outside the HH PPS, the beneficiary will also be provided the services and supplies specified in the HH plan of care, and those other services will be paid a HH episode payment under the HH PPS. Additionally, if the HH PPS claim (32x) includes 4 or fewer visits, the national per-visit payment rates paid account for administrative costs, and if the episode is the only episode or the first episode in a sequence of adjacent episodes separated by no more than a 60-day gap, the episode would be eligible for an add-on payment that accounts for the ''front-loading'' of costs incurred in an episode of care (72 FR 49848 and 49849). Therefore, we believe the existing payment policy approach for LUPA episodes represents appropriate payment for episodes that include the furnishing of NPWT using a disposable device as the LUPA payment, and any eligible LUPA add-on, take into account the administrative costs.

Comment: A few commenters inquired as to the low-utilization payment adjustment (LUPA) payment policy as it relates to visits reported on both a 32x and 34x type of bill. Specifically commenters requested clarification on a scenario in which the total number of home health visits provided is more than four, but four or fewer of those visits are billed on a 32x claim, with the remaining visits billed on a 34x claim. Commenters wanted to know whether or not the HHA would receive a LUPA payment or LUPA add-on payment.

Response: If a HHA provides four or fewer visits on the HH PPS claim (32x), the HHA will be paid a standardized per visit payment instead of a 60-day episode payment. This payment adjustment is referred to as a low-

[14] Sandoz H., (2014). Negative pressure wound therapy: clinical utility. Chronic Wound Care Management and Research. Volume 2. 71–79 doi.org/10.2147/CWCMR.S48885.

utilization payment adjustment, or LUPA. For the purposes of determining whether an episode receives the full episode payment amount or a LUPA, only visits on the 32x HH claim will be counted. Visits that are submitted via 34x claims will not count as a visit for purposes of determining whether a HHA receives a full episode payment or a LUPA. Services reported on 34x claims are for certain medical and other health services which are paid from the Part B that are paid outside the HH episode payment. Just as services reported on TOB 34x are not reimbursed under the HH 60-day episode payment, they are also not reimbursed as part of a LUPA.

As indicated in the comment response above, if a LUPA episode is the first episode in a sequence of adjacent episodes or is the only episode of care the beneficiary received, Medicare makes an additional payment called a LUPA add-on payment. Similar to the policy regarding LUPAs, visits for furnishing NPWT using a disposable device will not count as visits for purposes of the LUPA add-on payment. The LUPA add-on payment will still be made for any 32x claim that includes four or fewer visits that is considered the first episode in a sequence of adjacent episodes or is the only episode of care, regardless of whether additional visits are reported for disposable NPWT devices on the TOB 34x.

Comment: Several commenters stated that the implementation of the proposed policies for NPWT using a disposable device would pose a tremendous administrative and operational burden, citing that the policy would necessitate systems changes as well as changes to billing practices. Several commenters noted that they are concerned that the proposed billing approach is overly complicated and will result in both provider and beneficiary confusion.

Response: In accordance with section 1833(a)(1)(AA) of the Act, the Medicare payment amount for furnishing NPWT using a disposable device will be 80 percent of the lesser of the actual charge or the amount equal to the established OPPS amount, and we are requiring HHAs to submit claims for those services on a TOB 34x. We understand some commenters are concerned about the systems and billing changes they may have to make to implement this new policy, but we note that certain services provided under a home health plan of care, but for which reimbursement is not covered under the HH PPS, are currently billed utilizing the TOB 34x (for example, osteoporosis injections and vaccine administration). In addition, certain services provided that are *not* under a home health plan of care are also billed by HHAs on the 34x (for example, diabetes self-management training, smoking and tobacco-use cessation counseling services, bone mass measurements, etc.). Therefore, HHAs should already have familiarity with the procedures for billing as well as the systems requirements necessary for submitting the 34x claim type. However, we recognize the concerns about the education of providers, beneficiaries, and other stakeholders with regard to this new payment policy. We will utilize existing outreach and educational mechanisms such as Open Door Forums, Medicare Learning Network articles, and other products with the goal of educating stakeholders regarding this new payment policy for disposable NPWT devices.

Comment: A few commenters suggested that CMS allow HHAs additional time to make the necessary internal system changes by extending the implementation deadline to July 1, 2017 or another future date. Commenters noted that the postponement would allow time for implementation and appropriate enforcement of the policy.

Response: We acknowledge that some commenters would like additional time to prepare their systems, but section 1834(s)(1) of the Act specifies that the separate payment requirement for applicable disposable devices applies to such devices furnished on or after January 1, 2017.

Comment: Some commenters suggested that requiring separate billing for disposable NPWT devices represents a shift in the benefit away from holistic, interdisciplinary home health care towards a more fragmented benefit.

Response: We appreciate the concern regarding the provision of comprehensive care for home health beneficiaries. HH clinicians should continue to conduct home visits in a comprehensive, holistic manner. The HH plan of care is meant to meet the clinical, psychosocial, and daily living needs of the patient, and should remain focused on the appropriate care. However, accurate accounting of services provided is also an integral part of the provision of home health care through the Medicare benefit. In order for us to provide accurate payment, there must be proper accounting of the services provided by Medicare providers. Therefore, adherence to billing procedures and requirements, including the accurate accounting of services and interventions, is expected in conjunction with the provision of care.

Comment: A few commenters requested clarification regarding which practitioners are permitted to provide NPWT using a disposable device, specifically wanting to know whether licensed practical nurses (LPNs) may do so.

Response: Because specific services can be provided by either a therapist or a non-therapist, CMS created the designation ''sometimes therapy.'' When a code is designated as ''sometimes therapy,'' it may be performed by a qualified therapist (for example, physical therapist or occupational therapist) under a certified therapy plan of care or by another qualified clinician. As we discuss in the proposed rule (81 FR 43743 and 43744), because CPT® codes 97607 and 97608 are considered ''sometimes therapy'' codes (as described in section 200.9 of Chapter 4 of the Medicare Claims Processing Manual),[15] furnishing NPWT using a disposable device for patients under a home health plan of care can be performed by either a physician or a non-physician practitioner, consistent with other CMS guidance. In the proposed rule, we specifically stated that ''sometimes'' therapy can be performed, in accordance with State law, by a registered nurse, physical therapist, or occupational therapist (81 FR 43743). While we believe that the complex nature of furnishing disposable NPWT would best be performed by a registered nurse, physical therapist, or occupational therapist, we recognize that LPNs often provide skilled services, including wound care, to HH beneficiaries in accordance with State law and per agency policies. Per Chapter 7 of CMS's Benefit Policy Manual; section 40.1.2.8, wound care, which would include furnishing NPWT using a disposable device, is considered to be a skilled nursing service, for which the skills of a licensed nurse are usually reasonable and necessary. Skilled nursing services are those provided by skilled, licensed nursing professionals, which includes both LPNs and RNs. Therefore, LPNs also may furnish NPWT using a disposable device in accordance with State law and agency policies.

Comment: One commenter requested clarification regarding the application of the OPPS wage index to the payment amount for a disposable NPWT device.

Response: Since the payment amount for both CPT® codes 97607 and 97608 will be set equal to the amount of the payment that would be made under the

[15] *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c04.pdf.*

OPPS, the payment amount would also be subject to the area wage adjustment policies in place under the OPPS in a given year. We note that the wage index that will apply to this payment will be equal to the current OPPS wage index; for example, for CY 2017 payments for disposable NPWT devices, the CY 2017 OPPS wage index will apply.

Comment: A few commenters urged CMS to provide guidance on how this new disposable NPWT device policy will affect clinical documentation requirements in the medical record.

Response: There are no additional documentation requirements for the provision of NPWT using a disposable device. All existing policies and guidelines will still apply. HHAs may also follow their own internal policies and procedures for documenting clinical information in the patient's medical record beyond those required by regulation.

Final Decision: After consideration of all public comments, we are finalizing our proposal as proposed including the corresponding proposed changes to the regulations at § 409.50. A separate payment will be made to a HHA for furnishing NPWT using a disposable device to an individual who receives home health services for which payment is made under the Medicare home health benefit, for services furnished beginning January 1, 2017. The payment amount for furnishing NPWT using a disposable device under a HH plan of care will be equal to the lesser of the actual charges or the OPPS payment amount for CPT® codes 97607 and 97608, and must be billed via the 34x TOB. HHAs may not bill for furnishing NPWT using a disposable device on a TOB 32x. Payment for HH visits related to wound care, but not requiring the furnishing of an entirely new disposable NPWT device, will still be covered by the HH PPS episode payment and must be billed using TOB 32x. Where a home health visit is exclusively for the purpose of furnishing NPWT using a disposable device, the HHA will submit only a TOB 34x. Where, however, the home health visit includes the provision of other home health services in addition to, and separate from, furnishing NPWT using a disposable device, the HHA will submit both a TOB 32x and TOB 34x—the TOB 32x for other home health services and the TOB 34x for furnishing NPWT using a disposable device. Physical therapists, occupational therapists, registered nurses, and licensed practical nurses are permitted to provide NPWT using a disposable device under a home health plan of care.

Additionally, we are making a technical amendment to the language at 42 CFR 409.50 to update the language regarding beneficiary coinsurance liability for DME and applicable disposable devices. We proposed to amend § 409.50 to account for the coinsurance liability of the beneficiary for applicable disposable devices as ''20 percent of the customary (as reasonable) charge for the services.'' In this final rule, consistent with section 1833(a)(1)(AA) of the Act, we are revising that language to specify that the coinsurance liability for an applicable disposable device is 20 percent of the payment amount for furnishing NPWT using a disposable device (as that term is defined in § 484.202). The changes to § 409.50 are found in section VIII. of this final rule.

And, as part of this final rule, we are clarifying that furnishing NPWT using a disposable device means the HHA is furnishing a new disposable NPWT device, that is, the HHA provider is either initially applying an entirely new disposable NPWT device or removing a disposable NPWT device and replacing it with an entirely new one. As such, we are amending § 484.202 to include the definition of ''furnishing NPWT using a disposable device.'' We are also codifying our final policy, in § 484.205(b), that separate payment is made for furnishing NPWT using a disposable device, which is not included in the episode payment. We did not propose to amend the regulations at § 484.202 or § 484.205, but we believe it is appropriate to include the new policy in the regulation text. The specific changes we are making in the regulations simply codify the final policies we described in the proposed rule and do not reflect any additional substantive changes.

F. Update on Subsequent Research and Analysis Related to Section 3131(d) of the Affordable Care Act

Section 3131(d) of the Patient Protection and Affordable Care Act (Pub. L. 111–148), as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152), (collectively referred to as ''The Affordable Care Act''), directed the Secretary of Health and Human Services (the Secretary) to conduct a study on HHA costs involved with providing ongoing access to care to low-income Medicare beneficiaries or beneficiaries in medically underserved areas and in treating beneficiaries with high levels of severity of illness and to submit a Report to Congress on the study's findings and recommendations. As part of the study, the Affordable Care Act stated that we may also analyze methods to potentially revise the home health prospective payment system (HH PPS). In the CY 2016 HH PPS proposed rule (80 FR 39840), we summarized the Report to Congress on the home health study, required by section 3131(d) of the Affordable Care Act, and provided information on the initial research and analysis conducted to potentially revise the HH PPS case-mix methodology to address the home health study findings outlined in the Report to Congress. In the CY 2017 HH PPS proposed rule (81 FR 43744), we provided an update on additional research and analysis conducted on the Home Health Groupings Model (HHGM), one of the model options referenced in the CY 2016 HH PPS proposed rule (80 FR 39866).

The premise of the HHGM starts with a clinical foundation where home health episodes are grouped by the principal diagnosis based on the expected primary home health interventions that would be required during the episode of care for that diagnosis. In addition to the clinical groupings, the HHGM incorporates other information from the OASIS and claims data to further group home health episodes for payment, including timing of the episode, referral source, functional/cognitive level, and comorbidity adjustment.

While we did not solicit comments on the HHGM in the proposed rule, we received nine comments on the HHGM model. Commenters were generally supportive of the model, but stated that more detailed information is needed before they could provide any substantive comments. As stated in the proposed rule, we will be releasing a Technical Report which will provide more detail as to the research and the analysis conducted on the HHGM. Once the Technical Report is released, we will post a link on our Home Health Agency (HHA) Center Web site at *https://www.cms.gov/center/provider-Type/home-Health-Agency-HHA-Center.html* to receive additional comments and feedback on the model.

G. Update on Future Plans to Group HH PPS Claims Centrally During Claims Processing

Medicare makes payment under the HH PPS on the basis of a national, standardized 60-day episode payment amount that is adjusted for case-mix and geographic wage variations. The national, standardized 60-day episode payment amount includes services from the six HH disciplines (skilled nursing, HH aide, physical therapy, speech-language pathology, occupational therapy, and medical social services)

and non-routine medical supplies. To adjust for case-mix, the HH PPS uses a 153-category case-mix classification to assign patients to a home health resource group (HHRG). Clinical needs, functional status, and service utilization are computed from responses to selected data elements in the Outcome & Assessment Information Set (OASIS) instrument. On Medicare claims, the HHRGs are represented as HIPPS codes. HHAs enter data collected from their patients' OASIS assessments into a free data collection software tool (JHAVEN) provided by CMS. For Medicare patients, the data collection software invokes HH PPS Grouper software to assign a HIPPS code to the patient's OASIS assessment. The HHA includes the HIPPS code assigned by HH PPS Grouper software on the Medicare HH PPS claim, ultimately enabling our claims processing system to reimburse the HHA for services provided to patients receiving Medicare home health services.

We recently implemented a process where we match the claim and the OASIS assessment in order to validate the HIPPS code on the Medicare claim. In addition, we have conducted an analysis and prototype testing of a java-based grouper with our Fiscal Intermediary Shared System (FISS) maintenance contractor. We believe that making additional enhancements to the claim and OASIS matching process would enable us to collect all of the other necessary information to assign a HIPPS code within the claims processing system. Adopting such a process would improve payment accuracy by improving the accuracy of HIPPS codes on claims and decrease costs and burden to HHAs.

In the CY 2017 HH PPS proposed rule, we solicited public comments on grouping HH PPS claims centrally with the claims processing system (81 FR 43746. If we group HH PPS claims centrally within the claims processing system, the HHA would no longer have to maintain a separate process outside of our claims processing system, thus reducing the costs and burden to HHAs associated with the updates of the grouper software as well as the ongoing agency costs associated with embedding the HH PPS Grouper within JHAVEN. Finally, this enhancement will also address current payment vulnerabilities associated with the potential for misreporting HIPPS codes on the claim.

The following is a summary of the comments we received regarding our future plans to group HH PPS claims centrally during claims processing.

Comment: Several commenters supported CMS' proposal to implement centralized grouping of HH PPS claims. These commenters believed that centrally grouping HH claims should simplify and improve the accuracy of HIPPS code assignment and OASIS matching. The commenters would welcome a process that they expect will improve payment accuracy, decrease costs, and reduce administrative burden on providers. One commenter also noted that this proposal would decrease the potential that legitimate claims will be incorrectly identified as fraudulent.

Response: We appreciate the commenters support and agree that grouping claims centrally within the claims processing system will reduce errors associated with reporting incorrect HIPPS codes and OASIS matching. In addition, we also expect that grouping claims centrally will reduce HHA costs and administrative burden. We also believe that it will lead to a more streamlined, efficient claims processing system and improved payment accuracy.

Comment: Several commenters requested that CMS still continue to provide the grouper software and/or algorithm in order for providers to be able to calculate the HIPPS codes so that they can determine the expected reimbursement amount for each claim. The commenters further stated that the ability to value their account receivables is an important business function and necessary for financial reporting purposes.

Response: We understand the importance of HHAs being able to value their account receivables as part of their business processes and planning and we will consider this recommendation as we continue to explore options for grouping HH PPS claims centrally during claims processing.

Comment: One commenter requested that CMS develop an effective and timely communication process to provide the HIPPS codes resulting from the new grouper/claims process.

Response: The HIPPS codes will not change as a result of grouping claims centrally within the claims processing system. We will provide HHAs and other interested parties with sufficient notice and updates regarding our future plans via future rulemaking, our HHA Center page located at *https://www.cms.gov/Center/Provider-Type/Home-Health-Agency-HHA-Center.html*, and our home health, hospice and DME open door forums.

Comment: One commenter requested that CMS provide agencies the ability to review and correct their data submissions similar to what occurs now. If OASIS data corrections cause the assigned HIPPS code to change, the HHA should be able to cancel and resubmit the Request for Anticipated Payment (RAP).

Response: If an OASIS correction results in a new HIPPS code, HHAs would still be able to cancel the RAP and resubmit. A new HIPPS code will be generated within the claims processing system once the new RAP is submitted.

We appreciate the positive feedback and thoughtful comments that we have received regarding this proposal. We continue to believe that this process will increase payment accuracy and will reduce costs and burden to HHAs. We will continue to explore options for grouping HH PPS claims centrally during claims processing.

IV. Provisions of the Home Health Value-Based Purchasing (HHVBP) Model and Analysis of and Responses to Comments

A. Background

As authorized by section 1115A of the Act and finalized in the CY 2016 HH PPS final rule, we implemented the HHVBP Model to begin on January 1, 2016. The HHVBP Model has an overall purpose of improving the quality and delivery of home health care services to Medicare beneficiaries. The specific goals of the Model are to: (1) Provide incentives for better quality care with greater efficiency; (2) study new potential quality and efficiency measures for appropriateness in the home health setting; and, (3) enhance the current public reporting process.

Using the randomized selection methodology finalized in the CY 2016 HH PPS final rule, nine states were selected for inclusion in the HHVBP Model, representing each geographic area across the nation. All Medicare-certified HHAs that provide services in Arizona, Florida, Iowa, Maryland, Massachusetts, Nebraska, North Carolina, Tennessee, and Washington (competing HHAs), are required to compete in the Model. Requiring all Medicare-certified HHAs in the selected states to participate in the Model ensures that: (1) There is no selection bias; (2) participating HHAs are representative of HHAs nationally; and, (3) there is sufficient participation to generate meaningful results.

As finalized in the CY 2016 HH PPS final rule, the HHVBP Model will utilize the waiver authority under section 1115A(d)(1) of the Act to adjust Medicare payment rates under section 1895(b) of the Act beginning in CY 2018 based on performance on applicable measures. Payment adjustments will be increased incrementally over the course

of the HHVBP Model in the following manner: (1) A maximum payment adjustment of 3 percent (upward or downward) in CY 2018; (2) a maximum payment adjustment of 5 percent (upward or downward) in CY 2019; (3) a maximum payment adjustment of 6 percent (upward or downward) in CY 2020; (4) a maximum payment adjustment of 7 percent (upward or downward) in CY 2021; and, (5) a maximum payment adjustment of 8 percent (upward or downward) in CY 2022. Payment adjustments will be based on each HHA's Total Performance Score (TPS) in a given performance year (PY) on (1) a set of measures already reported via OASIS and HHCAHPS for all patients serviced by the HHA and select claims data elements, and (2) three New Measures where points are achieved for reporting data.

B. Smaller- and Larger-Volume Cohorts

As finalized in the CY 2016 HH PPS final rule, the HHVBP Model compares a competing HHA's performance on quality measures against the performance of other competing HHAs within the same state and size cohort. Within each of the nine selected states, each competing HHA is grouped into either the smaller-volume cohort or the larger-volume cohort, as defined in § 484.305. The larger-volume cohort is defined as the group of competing HHAs within the boundaries of selected states that are participating in HHCAHPS in accordance with § 484.250 and the smaller-volume cohort is defined as the group of competing HHAs within the boundaries of selected states that are exempt from participation in HHCAHPS in accordance with § 484.250 (80 FR 68664). An HHA can be exempt from the HHCAHPS reporting requirements for a calendar year period if it has less than 60 eligible unique HHCAHPS patients annually as specified in § 484.250. In the CY 2016 HH PPS final rule, we finalized that when there are too few HHAs in the smaller-volume cohort in each state (such as when there are only one or two HHAs competing within a smaller volume cohort in a given state) to compete in a fair manner, the HHAs would be included in the larger-volume cohort for purposes of calculating the TPS and payment adjustment percentage without being measured on HHCAHPS (80 FR 68664). As discussed in more detail below, we proposed, and are finalizing, the following changes to this methodology: (1) Calculation of the benchmarks and achievement thresholds at the state level rather than the state and size level and (2) a required minimum of 8 HHAs in a cohort.

1. Proposal To Eliminate Smaller- and Larger-Volume Cohorts Solely for Purposes of Setting Performance Benchmarks and Thresholds

In the CY 2016 HH PPS final rule (80 FR 68681–68682), we finalized a scoring methodology for determining achievement points for each measure under which HHAs will receive points along an achievement range, which is a scale between the achievement threshold and a benchmark. The achievement thresholds are calculated as the median of all HHAs' performance on the specified quality measure during the baseline period and the benchmark is calculated as the mean of the top decile of all HHAs' performance on the specified quality measure during the baseline period.

We previously finalized that under the HHVBP Model, we would calculate both the achievement threshold and the benchmark separately for each selected state and for HHA cohort size. Under this methodology, benchmarks and achievement thresholds were calculated for both the larger-volume cohort and for the smaller-volume cohort of HHAs in each state, based on a baseline period running from January 1, 2015 through December 31, 2015. In the CY 2016 HH PPS final rule, we also finalized that, in determining improvement points for each measure, HHAs would receive points along an improvement range, which we defined as a scale indicating the change between an HHA's performance during the performance period and the HHA's performance in the baseline period divided by the difference between the benchmark and the HHAs performance in the baseline year period. We finalized that both the benchmarks and the achievement thresholds would be calculated separately for each state and for HHA cohort size.

We finalized the above policies based on extensive analyses of the 2013–2014 OASIS, claims, and HHCAHPS archived data. We believed that these data were sufficient to predict the effect of cohort use for benchmarking and threshold purposes because they have been used for several years in other CMS quality initiatives such as Home Health Quality Reporting Program.

Since the publication of the CY 2016 HH PPS final rule, we have continued to evaluate the calculation of the OASIS benchmarks and achievement thresholds using 2015 data that was not available when we did the analyses included in the CY 2016 HH PPS final rule. We calculated the benchmarks and achievement thresholds for each OASIS measure for the smaller- and larger-volume cohorts and state-wide for each of the nine states using these data. Our review of the benchmarks and achievement thresholds for each of the cohorts and states indicates that the benchmark values for the smaller-volume cohorts varied considerably more from state-to-state than the benchmark values for the larger-volume cohorts. Some inter-state variation in the benchmarks and achievement thresholds for each of the measures was expected due to different state regulatory environments. However, the overall variation in these values was more than we expected, given the previous analyses. For example, with respect to the Improvement in Bed Transferring measure, we discovered that variation in the benchmark values between the smaller-volume cohorts was nearly three times greater than the variation in the benchmark values for the larger-volume cohorts or the statewide benchmarks. We also discovered that this large variation affected most of the measures. We were concerned that this high variation was not the result of expected differences, like state regulatory policy, but was instead the result of (1) the cohort being so small that there were not enough HHAs in the cohort to calculate the values using the finalized methodology (mean of the top decile); or (2) the cohort being large enough to calculate the values using the finalized methodology, but there were not enough HHAs in the cohort to generate reliable values.

We are including here Tables 21, 22, and 23, which were included as Tables 28, 29 and 30 in the proposed rule (81 FR 43748–43749), to help illustrate this issue below. Each of the three tables include the 10 benchmarks for the OASIS measures that were calculated for the Model using the 2015 QIES roll-up file data for each state. We did not include the claims measures and the HHCAHPS measures in this example because when the proposed rule was in development we did not have all of the 2015 data available. These three tables demonstrate the relationship between the size of the cohort and degree of variation of the different benchmark values among the states. Table 21, Table 22 and Table 23 represent the OASIS measure benchmarks for the smaller-volume cohorts, larger-volume cohorts and the state level (which includes HHAs from both smaller- and larger-volume cohorts), respectively.

For example, the differences in benchmark values for Iowa and Nebraska (two of the four states that

have smaller-volume cohorts) for the Improvement in Bed Transferring measure are: 13.1 (72.7 for Iowa and 85.8 for Nebraska) for the smaller-volume cohort (Table 21); 4.1 (78.1 for Iowa to 82.2 for Nebraska) for the larger-volume cohort (Table 22); and 5.5 (77.6 for Iowa to 83.1 for Nebraska) for the state level cohort (Table 23). We believe that the higher range for the smaller-volume cohorts in these states is a result of the smaller number of HHAs in these cohorts.

TABLE 21—SMALLER-VOLUME COHORT BENCHMARKS

Oasis-based measures	State								
	AZ	FL	IA	MA	MD	NC	NE	TN	WA
Discharged to Community	77.0	88.8	73.6	82.0	.....	75.1	81.1	79.4	.....
Drug Education on All Medications Provided to Patient/ Caregiver during all Episodes of Care	100.0	100.0	100.0	100.0	.....	98.5	100.0	100.0	.....
Improvement in Ambulation- Locomotion	90.6	90.5	72.7	75.6	.....	60.1	84.0	85.2	.....
Improvement in Bathing	82.0	91.2	79.5	71.8	.....	72.1	77.4	81.5	.....
Improvement in Bed Transferring	68.8	80.4	72.7	74.1	.....	55.1	85.8	79.0	.....
Improvement in Dyspnea	84.2	90.4	81.3	62.6	.....	62.5	80.3	93.7	.....
Improvement in Management of Oral Medications	63.0	74.0	58.4	62.0	.....	62.8	65.8	58.9	.....
Improvement in Pain Interfering with Activity	83.2	97.3	82.6	82.3	.....	58.5	78.2	69.0	.....
Influenza Immunization Received for Current Flu Season	73.4	89.8	90.8	83.8	.....	89.2	83.6	88.9	.....
Pneumococcal Polysaccharide Vaccine Ever Received	95.8	91.5	95.8	95.3	.....	83.6	97.0	100.0	.....

TABLE 22—LARGER-VOLUME COHORT BENCHMARKS

Oasis-based measures	State								
	AZ	FL	IA	MA	MD	NC	NE	TN	WA
Discharged to Community	82.1	85.6	78.3	81.2	81.1	78.2	80.3	81.0	83.1
Drug Education on All Medications Provided to Patient/ Caregiver during all Episodes of Care	99.8	100.0	99.9	100.0	99.9	99.7	99.9	99.8	99.7
Improvement in Ambulation- Locomotion	76.4	92.4	76.7	76.1	76.5	75.2	80.8	77.2	70.8
Improvement in Bathing	84.2	94.2	81.9	81.0	81.0	78.9	86.6	83.5	77.7
Improvement in Bed Transferring	76.4	85.4	78.1	80.2	77.5	74.5	82.2	76.8	73.5
Improvement in Dyspnea	85.9	90.5	81.3	82.2	85.1	85.5	80.7	84.2	80.7
Improvement in Management of Oral Medications	69.4	80.5	68.1	73.2	71.7	63.9	68.1	72.2	64.0
Improvement in Pain Interfering with Activity	88.6	96.7	81.0	89.5	84.4	81.5	86.0	81.7	75.5
Influenza Immunization Received for Current Flu Season	88.0	93.3	88.1	90.1	87.9	88.0	95.2	88.2	87.0
Pneumococcal Polysaccharide Vaccine Ever Received	92.5	93.6	94.4	93.8	92.1	93.4	97.0	92.7	92.7

TABLE 23—STATE LEVEL COHORT BENCHMARKS

Oasis-based measures	State								
	AZ	FL	IA	MA	MD	NC	NE	TN	WA
Discharged to Community	81.8	86.3	77.7	81.9	81.1	78.2	80.5	80.9	83.1
Drug Education on All Medications Provided to Patient/ Caregiver during all Episodes of Care	99.8	100.0	100.0	100.0	99.9	99.7	99.9	99.8	99.7
Improvement in Ambulation- Locomotion	77.5	92.1	76.2	76.3	76.5	75.2	82.9	77.9	70.8
Improvement in Bathing	84.1	93.8	81.8	80.3	81.0	78.9	84.6	83.5	77.7
Improvement in Bed Transferring	75.9	84.8	77.6	80.1	77.5	74.5	83.1	77.3	73.5
Improvement in Dyspnea	85.8	90.5	81.9	81.7	85.1	85.5	81.3	85.8	80.7
Improvement in Management of Oral Medications	69.1	79.6	67.3	72.0	71.7	64.1	68.3	72.2	64.0
Improvement in Pain Interfering with Activity	88.1	96.8	81.5	88.4	84.4	81.5	84.3	81.7	75.5

TABLE 23—STATE LEVEL COHORT BENCHMARKS—Continued

Oasis-based measures	State								
	AZ	FL	IA	MA	MD	NC	NE	TN	WA
Influenza Immunization Received for Current Flu Season	87.6	92.9	88.9	90.1	87.9	88.3	94.4	88.2	87.0
Pneumococcal Polysaccharide Vaccine Ever Received	92.9	93.3	94.8	94.2	92.1	93.4	97.0	93.3	92.7

The three tables are based on the data available during the development of the proposed rule. The results highlight that there is a greater degree of inter-state variation in the benchmark values for the cohorts that have fewer HHAs as compared to the variation in benchmark values for the cohorts that have a greater number of HHAs.

We also performed a similar analysis with the achievement thresholds and compared how the individual benchmarks and achievement thresholds would fluctuate from one year to the next for the smaller-volume cohorts, larger-volume cohorts and the state level cohorts. The results of those analyses were similar.

Based on the analyses described above, we are concerned that if we separate the HHAs into smaller- and larger-volume cohorts by state for purposes of calculating the benchmarks and achievement thresholds, HHAs in the smaller-volume cohorts could be required to meet performance standards greater than the level of performance that HHAs in the larger-volume cohorts would be required to achieve. For this reason, we proposed to calculate the benchmarks and achievement thresholds at the state level rather than at the smaller- and larger-volume cohort level for all Model years, beginning with CY 2016. This change will eliminate the increased variation caused by having few HHAs in the cohort but still takes into account that there will be some inter-state variation in the values due to state regulatory differences. We requested public comments on this proposal.

Comment: Most of the comments we received supported this proposal. Several commenters supported this policy because it would reduce variability in performance standards. Some commenters stated that state level comparison cohorts would provide a more robust benchmark than the state level and size based cohort. Some commenters expressed some concern about the proposed change. One commenter suggested CMS should conduct ongoing research to determine the effectiveness of using state level and size based cohorts. One commenter, MedPAC, recommended that CMS calculate benchmarks and achievement thresholds at a national level because Medicare is a national program and there is the possibility that a state level focus could reward low quality agencies. Finally, one commenter stated that it does not make sense to compare disparate groups of HHAs whether the comparisons are done at the local, state, or national levels or even, as currently exists in the Model, among HHAs with similarly-sized patient cohorts but did not provide specific reasons for their view.

Response: We appreciate commenters' support for our proposal to calculate benchmarks and achievement thresholds at the state level. Calculating the benchmarks and achievement thresholds at the state level, rather than at the state level and size cohort level, will eliminate the increased variation caused by having too few HHAs in a cohort. In addition, calculating the benchmarks and achievement thresholds at the state level, rather than the national level, is consistent with the factors considered in proposing selection at the state level, as discussed in the CY 2016 HH PPS final rule (81 FR 68659), including that HHAs should be competing within the same market and that the Model should align with other CMS programs like Home Health Compare and Home Health Five Star that report by state. Calculating the benchmarks and achievement thresholds at the state level rather than at the national level also allows the Model to take into account the inter-state variation in quality measurement due to different state regulatory environments. We will continue to monitor and research the effectiveness of using state level cohorts.

Comment: We received comments that were outside of the scope of our proposed change to the benchmark and achievement threshold calculations. Several commenters expressed concern that HHAs will not know what benchmarks are needed to avoid penalty until the end of the 2016 performance year, and recommended that CMS establish prospective benchmarks based on historical performance so it is clear to HHAs the level of achievement necessary to avoid penalties. Commenters stated that agencies may not invest in quality improvement activities if the potential financial return is difficult to determine and recommended that CMS set benchmarks at a level where most providers have a reasonable expectation of achieving them. A few commenters supported 2015 as the baseline year, and suggested providing HHAs with mid-course snapshots of their performance against the benchmarks. A commenter was concerned that using improvement scores was not sufficiently beneficiary-focused because what really matters are the agency's actual levels of performance. Several other commenters were concerned that using 'improvement' scores may create inequities in payment and penalties because agencies with equal or better levels of achievement could score lower than agencies with lower achievement but higher improvement scores. Another commenter expressed concern that the limited state selection will not sufficiently represent the entire Medicare population due to the lack of measures relating to stabilization and maintenance. Finally, one commenter stated that improvement scores should only exist for the first 3 years of the Model.

Response: As noted, these comments are outside of the scope of the proposed methodology change in the CY 2017 HH PPS proposed rule; however, we are clarifying here the calculation of the benchmarks and how HHAs are notified of the benchmarks. The methodology for calculating the achievement thresholds and benchmarks was described in the CY 2016 HH PPS final rule (80 FR 68681). The achievement threshold for each measure used in the Model is calculated as the median of all HHAs' performance on the specified quality measure during the baseline period (CY 2015). The benchmark is calculated as the mean of the top decile of all HHAs' performance on the specified quality measure during the baseline period (CY 2015). As noted above, we are finalizing a change to the methodology as described in the CY 2016 HH PPS final

rule to calculate benchmark and achievement thresholds at the state level, rather than at the state and cohort-size level.

The preliminary complete set of benchmarks was based on 2015 data for all measures in the Model, calculated both at the state and cohort-size level, was made available to competing HHAs on HHVBP *Connect.* HHVBP *Connect* was available beginning February 2016 and allows HHAs to attain general information about the Model, including the initial baseline benchmarks and achievement thresholds. The most current baseline achievement thresholds and benchmarks used 2015 quality data from the Model's OASIS measures (12 months), HHCAHPS measures (9 months), and claims measures (9 months). This data was posted in April 2016 on HHVBP *Connect.* The baseline achievement thresholds and benchmarks that was based on 12 months for the HHCAHPS measures and the claims measures were included in the Interim Performance Report posted in July 2016 on the HHVBP Secure Portal. The HHVBP Secure Portal was available in May 2016, which allows HHAs to view their own specific measures and scores. The quarterly Interim Performance Reports also allow HHAs to monitor their performance on the quality measures used to calculate their TPS. The Interim Performance Reports (IPRs) posted to the HHVBP Secure Portal in July 2016 included performance scores for the OASIS-based measures for the first quarter of CY 2016. The next IPRs, which are to be posted to the HHVBP Secure Portal in October 2016, will include performance scores for HHCAHPS measures and claims-based measures for the first quarter of CY 2016 as well as the performance scores for the OASIS-based measures for the second quarter of CY 2016. HHAs' performance on the 17 initial measures of the Model (as finalized in section IV.C of this final rule) for CY 2016 to CY 2020 will be determined using state-level achievement thresholds and benchmarks, and individual HHA baseline values calculated using data from the 2015 baseline year; consistent with the finalized proposal to calculate benchmarks and achievement thresholds at the state-level. Performance scores to be posted on the HHVBP Secure Portal in October 2016 will be calculated using the state-level cohort baseline benchmarks and achievement thresholds. HHAs will receive points if they achieve performance equal to or above the achievement threshold, calculated as the median of 2015 values.

Final Decision: For the reasons stated above and in consideration of the comments received, we are finalizing our proposal to calculate the benchmarks and achievement thresholds at the state-level rather than the smaller- and larger-volume cohort level.

2. The Payment Adjustment Methodology

We finalized in the CY 2016 HH PPS final rule that we would use a linear exchange function (LEF) to translate a competing HHA's TPS into a value-based payment adjustment percentage under the HHVBP Model (80 FR 68686). We also finalized that we would calculate the LEF separately for each smaller-volume cohort and larger-volume cohort. In addition, we finalized that if an HHA does not have a minimum of 20 episodes of care during a performance year to generate a performance score on at least five measures, we would not include the HHA in the LEF and we would not calculate a payment adjustment percentage for that HHA.

Since the publication of the CY 2016 HH PPS final rule, we have continued to evaluate the payment adjustment methodology using the most recent data available. We updated our analysis of the 10 OASIS quality measures and two claims-based measures using the newly available 2014 QIES Roll Up File data, which was not available prior to the issuance of that final rule. We also determined the size of the cohorts using the 2014 Quality Episode File based on OASIS assessments rather than archived quality data sources that were used in the CY 2016 rule, whereby the HHAs reported at least five measures with over 20 episodes of care. Based on this data, we determined that with respect to performance year 2016, there were only three states (AZ, FL, NE) that have more than 10 HHAs in the smaller-volume cohort; one state (IA) that has 8–10 HHAs in the smaller-volume cohort, three states (NC, MA, TN) that have 1–3 HHAs in the smaller-volume cohort; and two states (MD, WA) that have no HHAs in the smaller-volume cohort. In the CY 2016 HH PPS final rule (80 FR 68664), we finalized that when there are too few HHAs in the smaller-volume cohort in each state to compete in a fair manner, the HHAs in that cohort would be included in the larger-volume cohort for purposes of calculating their payment adjustment percentage. The CY 2016 rule further defines too few as when there is only one or two HHAs competing within a smaller-volume cohort in a given state.

We also used the more current data source mentioned above to analyze the effects of outliers on the LEF. As indicated by the payment distributions set forth in Table 37 of the proposed rule, which is also included as Table 37 of this rule, the LEF is designed so that the majority of the payment adjustment values fall closer to the median and only a small percentage of HHAs receive adjustments at the higher and lower ends of the distribution. However, when we looked at the more recent data, we discovered that if there are only three or four HHAs in the cohort, one HHA outlier could skew the payment adjustments and deviate the payment distribution from the intended design of the LEF payment methodology where HHAs should fall close to the median of the payment distribution. For example, if there are only three HHAs in the cohort, we concluded that there is a high likelihood that those HHAs would have payment adjustments of −2.5 percent, −2.0 percent and +4.5 percent when the maximum payment adjustment is 5 percent, none falling close to the mean, with the result that those HHAs would receive payment adjustments at the higher or lower ends of the distribution. As the size of the cohort increases, we determined that this became less of an issue, and that the majority of the HHAs would have payment adjustments that are close to the median. This is illustrated in the payment distribution in Table 38 of this rule. Under the payment distribution for the larger-volume cohorts, 80 percent of the HHAs in AZ, IA, FL and NE would receive a payment adjustment ranging from –2.2 percent to +2.2 percent when the maximum payment adjustment is 5 percent (See state level cohort in Table 38). Arizona is a state that has a smaller-volume cohort with only nine HHAs but its payment distribution is comparable, ranging from –1 percent to +1 percent even with one outlier that is at 5 percent.

In order to determine the minimum number of HHAs that would have to be in a smaller-volume cohort in order to insulate that cohort from the effect of outliers, we analyzed performance results related to the OASIS and claims-based measures, as well as HHCAHPS, using 2013 and 2014 data. We specifically simulated the impact that outliers would have on cohort sizes ranging from four HHAs to twelve HHAs. We found that the LEF was less susceptible to large variation from outlier impacts once the cohort size reached a minimum of eight HHAs. We also found that a minimum of eight

HHAs would allow for four states with smaller-volume cohorts to have 80 percent of their payment adjustments fall between –2.3 percent and + 2.4 percent. As a result of this analysis, we proposed that a smaller-volume cohort have a minimum eight HHAs in order for the HHAs in that cohort to be compared only against each other, and not against the HHAs in the larger-volume cohort. We stated that we believe this proposal would better mitigate the impact of outliers as compared to our current policy, while also enabling us to evaluate the impact of the Model on competition between smaller-volume HHAs.

We also proposed that if a smaller-volume cohort in a state has fewer than eight HHAs, those HHAs would be included in the larger-volume cohort for that state for purposes of calculating the LEF and payment adjustment percentages. We stated that if finalized, this change would apply to the CY 2018 payment adjustments and thereafter. We further stated that we will continue to analyze and review the most current cohort size data as it becomes available.

We requested public comments on this proposal.

Comment: Most of the commenters supported the proposed requirement for a minimum of eight HHAs in any size cohort. One commenter suggested that eight HHAs in a smaller-volume cohort could still be significantly impacted by an outlier. A commenter requested more information about how the minimum of 8 HHAs in the cohort was determined. Another commenter suggested that we use a minimum of 12 HHAs rather than 8 HHAs as the minimum number of HHAs required in the cohort. Another commenter suggested that CMS implement economies of scale between agencies to account for the business advantages that larger HHAs have over smaller ones but did not provide any more specific detail. Finally, one commenter suggested that CMS should compare HHAs nationally by altering qualification requirements so that states with a smaller number of qualified agencies can benchmark against national requirements.

Response: We believe that a minimum of 8 HHAs per cohort represents a figure significant enough to mitigate the effect of outliers. As we discussed in the proposed rule, we analyzed performance results related to OASIS and claim-based measures, as well as HHCAHPS, using 2013 and 2014 data to determine if an HHA in a cohort with a minimum number of HHAs would be at a disadvantage with respect to the impact of outlier HHAs on the payment adjustments, when compared to HHAs in larger size cohorts. With this information, we simulated the impact that outliers would have on cohort sizes ranging from 4 to 12 HHAs. We found that, in contrast to the calculation of the achievement thresholds and the benchmarks, the LEF had lower susceptibility to large variation caused by outliers even with a relatively small number of HHAs in the cohort. By running simulations using the data described above, we found that the distribution of payment adjustments was similar whether the number of HHAs in the cohort was 8, 12 or over 30 HHAs. More specifically, having 8, 12 or over 30 HHAs in the cohort permitted the LEF to distribute payments such that 80 percent of the payment adjustments was between −2.5 percent and + 2.5 percent. Further, we conducted a sensitivity analysis examining the difference in the impact that an outlier HHA would have on a cohort size of 8 HHAs as compared to a cohort size of 12 HHAs. By running simulations of adding an outlier to a cohort with 8 HHAs and a cohort of 12 HHAs, we identified that the difference in impact on the payment adjustment on the non-outlier HHAs in the cohort ranged from 0.1 percent to 0.13 percent. We believe that having a minimum of 8 HHAs in the cohort ensures that there are enough states in the Model with a smaller-volume cohort to analyze the impact on competition at the different cohort size levels, and that this outweighs the marginal difference in the impact of outliers as compared to using a minimum of 12 HHAs.

Although it may be operationally possible to have all the smaller-volume HHAs in the nine states compete against each other in a national pool, having HHAs compete at the state level (that is, all HHAs in a state or a cohort of HHAs in the same state) rather than at the national level enables the Model to address the issue of inter-state variation in quality measurement that could be related to different state regulatory environments. This is especially important when considering that performance incentives could flow from states with lower measure scores to states with higher measures scores because of state regulatory differences rather than the quality of care that HHAs provide.

We will continue to monitor and research the impact of cohort size on different measurements.

Final Decision: For the reasons stated above and in consideration of the comments received, we are finalizing the proposal that there must be a minimum of eight HHAs in any size cohort. Under this final policy, a smaller-volume cohort must have a minimum of eight HHAs in order for the HHAs in that cohort to be compared only against each other, and not against the HHAs in the larger-volume cohort. If a smaller-volume cohort in a state has fewer than eight HHAs, those HHAs will be included in the larger-volume cohort for that state for purposes of calculating the LEF and payment adjustment percentages.

C. Quality Measures

In the CY 2016 HH PPS final rule, we finalized a set of quality measures in Figure 4a: Final PY1 Measures and Figure 4b: Final PY1 New Measures (80 FR 68671 through 68673) for the HHVBP Model to be used in PY1, referred to as the ''starter set''.

The measures were selected for the Model using the following guiding principles: (1) Use a broad measure set that captures the complexity of the services HHAs provide; (2) Incorporate the flexibility for future inclusion of the Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014 measures that cut across post-acute care settings; (3) Develop 'second generation' (of the HHVBP Model) measures of patient outcomes, health and functional status, shared decision making, and patient activation; (4) Include a balance of process, outcome and patient experience measures; (5) Advance the ability to measure cost and value; (6) Add measures for appropriateness or overuse; and (7) Promote infrastructure investments. This set of quality measures encompasses the multiple National Quality Strategy (NQS) domains [16] (80 FR 68668). The NQS domains include six priority areas identified in the CY 2016 HH PPS final rule (80 FR 68668) as the CMS Framework for Quality Measurement Mapping. These areas are: (1) Clinical quality of care, (2) Care coordination, (3) Population & community health, (4) Person- and Caregiver-centered experience and outcomes, (5) Safety, and (6) Efficiency and cost reduction. Figures 4a and 4b (inadvertently referred to as Figures 5 and 6 in the CY 2017 HH PPS proposed rule) of the CY 2016 HH PPS final rule identified 15 outcome measures (five from the HHCAHPS, eight from OASIS, and two from the Chronic Care Warehouse (claims)), and nine process measures (six from OASIS, and three New Measures, which were not previously reported in the home health setting).

[16] 2015 Annual Report to Congress, *http://www.ahrq.gov/workingforquality/reports/annual-reports/nqs2015annlrpt.htm.*

During implementation of the Model, we determined that four of the measures finalized for PY1 require further consideration before inclusion in the HHVBP Model measure set as described below. Specifically, we proposed to remove the following measures, as described in Figure 4a of the CY 2016 HH PPS final rule, from the set of applicable measures: (1) Care Management: Types and Sources of Assistance; (2) Prior Functioning ADL/IADL; (3) Influenza Vaccine Data Collection Period: Does this episode of care include any dates on or between October 1 and March 31?; and (4) Reason Pneumococcal Vaccine Not Received. We proposed to remove these four measures, for the reasons discussed below, beginning with the CY 2016 Performance Year (PY1) calculations, and stated that we believe this will not cause substantial change in the first annual payment adjustment that will occur in CY 2018, as each measure is equally weighted and will not be represented in the calculations. As discussed later in this section, we are finalizing the proposed revisions to the measure set, as set forth in Table 31 of the proposed rule and Table 24 of this final rule, which will be applicable to each performance year subject to any changes made through future rulemaking.

We proposed to remove the ''Care Management: Types and Sources of Assistance'' measure because (1) a numerator and denominator for the measure were not made available in the CY 2016 HH PPS final rule; and (2) the potential OASIS items that could be utilized in the development of the measure were not fully specified in the CY 2016 HH PPS final rule. We stated that we want to further consider the appropriate numerator and denominator for the OASIS data source before proposing the inclusion of this measure in the HHVBP Model.

We proposed to remove the ''Prior Functioning ADL/IADL'' measure because (1) the NQF endorsed measure (NQF0430) included in the 2016 HH PPS final rule does not apply to home health agencies; and (2) the NQF endorsed measure (NQF0430) refers to a measure that utilizes the AM–PAC (Activity Measure for Post-Acute Care) tool that is not currently (and has never been) collected by home health agencies.

We proposed to remove the ''Influenza Vaccine Data Collection Period: Does this episode of care include any dates on or between October 1 and March 31?'' measure because this datum element (OASIS item M1041) is used to calculate another HHVBP Model measure ''Influenza Immunization Received for Current Flu Season'' and was not designed as an additional and separate measure of performance.

We proposed to remove the ''Reason Pneumococcal Vaccine Not Received'' measure because (1) these data are reported as an element of the record for clinical decision making and inform agency policy (that is, so that the agency knows what proportion of its patients did not receive the vaccine because it was contraindicated (harmful) for the patient or that the patient chose to not receive the vaccine); and (2) this measure itemizes the reason for the removal of individuals for whom the vaccine is not appropriate, which is already included in the numerator of the ''Pneumococcal Polysaccharide Vaccine Ever Received'' measure also included in the HHVBP Model.

Because the starter set is defined as the quality measures selected for the first year of the Model only, we proposed to revise § 484.315 to refer to ''a set of quality measures'' rather than ''a starter set of quality measures'' and to revise § 484.320(a), (b), (c), and (d) to remove the phrase ''in the starter set''. We also proposed to delete the definition of ''Starter set'' in § 484.305 because that definition would no longer be used in the HHVBP Model regulations following the proposed revisions to §§ 484.315 and 484.320.

The finalized set of applicable measures is presented in Table 24, which excludes the four measures we proposed to remove. For the reasons stated below and in consideration of the comments received, we are finalizing this measure set for PY1 and each subsequent performance year until such time that another set of applicable measures, or changes to this measure set, are proposed and finalized in future rulemaking.

TABLE 24—MEASURE SET FOR THE HHVBP MODEL [17]

NQS Domains	Measure title	Measure type	Identifier	Data source	Numerator	Denominator
Clinical Quality of Care	Improvement in Ambulation-Locomotion.	Outcome	NQF0167	OASIS (M1860)	Number of home health episodes of care where the value recorded on the discharge assessment indicates less impairment in ambulation/locomotion at discharge than at the start (or resumption) of care.	Number of home health episodes of care ending with a discharge during the reporting period, other than those covered by generic or measure-specific exclusions.
Clinical Quality of Care	Improvement in Bed Transferring.	Outcome	NQF0175	OASIS (M1850)	Number of home health episodes of care where the value recorded on the discharge assessment indicates less impairment in bed transferring at discharge than at the start (or resumption) of care.	Number of home health episodes of care ending with a discharge during the reporting period, other than those covered by generic or measure-specific exclusions.
Clinical Quality of Care	Improvement in Bathing	Outcome	NQF0174	OASIS (M1830)	Number of home health episodes of care where the value recorded on the discharge assessment indicates less impairment in bathing at discharge than at the start (or resumption) of care.	Number of home health episodes of care ending with a discharge during the reporting period, other than those covered by generic or measure-specific exclusions.

[17] For more detailed information on the proposed measures utilizing OASIS refer to the *OASIS–C1/ICD–9, Changed Items & Data Collection Resources* dated September 3, 2014 available at *www.oasisanswers.com/LiteratureRetrieve.aspx?ID=215074*.

For NQF endorsed measures see The NQF Quality Positioning System available at *http://www.qualityforum.org/QPS*. For non-NQF measures using OASIS see links for data tables related to OASIS measures at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIQualityMeasures.html*. For information on HHCAHPS measures see *https://homehealthcahps.org/SurveyandProtocols/SurveyMaterials.aspx*.

TABLE 24—MEASURE SET FOR THE HHVBP MODEL [17]—Continued

NQS Domains	Measure title	Measure type	Identifier	Data source	Numerator	Denominator
Clinical Quality of Care	Improvement in Dyspnea	Outcome	NA	OASIS (M1400)	Number of home health episodes of care where the discharge assessment indicates less dyspnea at discharge than at start (or resumption) of care.	Number of home health episodes of care ending with a discharge during the reporting period, other than those covered by generic or measure-specific exclusions.
Communication & Care Coordination.	Discharged to Community	Outcome	NA	OASIS (M2420)	Number of home health episodes where the assessment completed at the discharge indicates the patient remained in the community after discharge.	Number of home health episodes of care ending with discharge or transfer to inpatient facility during the reporting period, other than those covered by generic or measure-specific exclusions.
Efficiency & Cost Reduction	Acute Care Hospitalization: Unplanned Hospitalization during first 60 days of Home Health.	Outcome	NQF0171	CCW (Claims)	Number of home health stays for patients who have a Medicare claim for an unplanned admission to an acute care hospital in the 60 days following the start of the home health stay.	Number of home health stays that begin during the 12-month observation period. A home health stay is a sequence of home health payment episodes separated from other home health payment episodes by at least 60 days.
Efficiency & Cost Reduction	Emergency Department Use without Hospitalization.	Outcome	NQF0173	CCW (Claims)	Number of home health stays for patients who have a Medicare claim for outpatient emergency department use and no claims for acute care hospitalization in the 60 days following the start of the home health stay.	Number of home health stays that begin during the 12-month observation period. A home health stay is a sequence of home health payment episodes separated from other home health payment episodes by at least 60 days.
Patient Safety	Improvement in Pain Interfering with Activity.	Outcome	NQF0177	OASIS (M1242)	Number of home health episodes of care where the value recorded on the discharge assessment indicates less frequent pain at discharge than at the start (or resumption) of care.	Number of home health episodes of care ending with a discharge during the reporting period, other than those covered by generic or measure-specific exclusions.
Patient Safety	Improvement in Management of Oral Medications.	Outcome	NQF0176	OASIS (M2020)	Number of home health episodes of care where the value recorded on the discharge assessment indicates less impairment in taking oral medications correctly at discharge than at start (or resumption) of care.	Number of home health episodes of care ending with a discharge during the reporting period, other than those covered by generic or measure-specific exclusions.
Population/Community Health	Influenza Immunization Received for Current Flu Season.	Process	NQF0522	OASIS (M1046)	Number of home health episodes during which patients a) received vaccination from the HHA or b) had received vaccination from HHA during earlier episode of care, or c) was determined to have received vaccination from another provider.	Number of home health episodes of care ending with discharge, or transfer to inpatient facility during the reporting period, other than those covered by generic or measure-specific exclusions.
Population/Community Health	Pneumococcal Polysaccharide Vaccine Ever Received.	Process	NQF0525	OASIS (M1051)	Number of home health episodes during which patients were determined to have ever received Pneumococcal Polysaccharide Vaccine (PPV).	Number of home health episodes of care ending with discharge or transfer to inpatient facility during the reporting period, other than those covered by generic or measure-specific exclusions.
Clinical Quality of Care	Drug Education on All Medications Provided to Patient/Caregiver during all Episodes of Care.	Process	NA	OASIS (M2015)	Number of home health episodes of care during which patient/caregiver was instructed on how to monitor the effectiveness of drug therapy, how to recognize potential adverse effects, and how and when to report problems (since the previous OASIS assessment).	Number of home health episodes of care ending with a discharge or transfer to inpatient facility during the reporting period, other than those covered by generic or measure-specific exclusions.
Patient & Caregiver-Centered Experience.	Care of Patients	Outcome		CAHPS	NA	NA.
Patient & Caregiver-Centered Experience.	Communications between Providers and Patients.	Outcome		CAHPS	NA	NA.
Patient & Caregiver-Centered Experience.	Specific Care Issues	Outcome		CAHPS	NA	NA.
Patient & Caregiver-Centered Experience.	Overall rating of home health care.	Outcome		CAHPS	NA	NA.
Patient & Caregiver-Centered Experience.	Willingness to recommend the agency.	Outcome		CAHPS	NA	NA.

TABLE 24—MEASURE SET FOR THE HHVBP MODEL [17]—Continued

NQS Domains	Measure title	Measure type	Identifier	Data source	Numerator	Denominator
Population/Community Health	Influenza Vaccination Coverage for Home Health Care Personnel.	Process	NQF0431 (Used in other care settings, not Home Health).	Reported by HHAs through Web Portal.	Healthcare personnel in the denominator population who during the time from October 1 (or when the vaccine became available) through March 31 of the following year: a) received an influenza vaccination administered at the healthcare facility, or reported in writing or provided documentation that influenza vaccination was received elsewhere: or b) were determined to have a medical contraindication/condition of severe allergic reaction to eggs or to other components of the vaccine or history of Guillain-Barre Syndrome within 6 weeks after a previous influenza vaccination; or c) declined influenza vaccination; or d) persons with unknown vaccination status or who do not otherwise meet any of the definitions of the above-mentioned numerator categories.	Number of healthcare personnel who are working in the healthcare facility for at least 1 working day between October 1 and March 31 of the following year, regardless of clinical responsibility or patient contact.
Population/Community Health	Herpes zoster (Shingles) vaccination: Has the patient ever received the shingles vaccination?	Process	NA	Reported by HHAs through Web Portal.	Total number of Medicare beneficiaries aged 60 years and over who report having ever received zoster vaccine (shingles vaccine).	Total number of Medicare beneficiaries aged 60 years and over receiving services from the HHA.
Communication & Care Coordination.	Advance Care Plan	Process	NQF0326	Reported by HHAs through Web Portal.	Patients who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advanced 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.	All patients aged 65 years and older.

In the CY 2016 HH PPS final rule, we finalized that HHAs will be required to begin reporting data on each of the three New Measures no later than October 7, 2016 for the period July 2016 through September 2016 and quarterly thereafter. In the CY 2017 HH PPS proposed rule, we proposed to require annual, rather than quarterly reporting for one of the three New Measures, ''Influenza Vaccination Coverage for Home Health Personnel,'' with the first annual submission in April 2017 for PY2. Specifically, we proposed to require an annual submission in April for the prior 6-month reporting period of October 1–March 31 to coincide with the flu season. We stated that under this proposal, for PY1, HHAs would report on this measure in October 2016 and January 2017. We further stated that HHAs would report on this measure in April 2017 for PY2 and annually in April thereafter. We stated that we believe changing the reporting and submission periods for this measure from quarterly to annually would avoid the need for HHAs to have to report zeroes in multiple data fields for the two quarters (July through September, and April through June) that fall outside of the parameters of the denominator (October through March).

We did not propose to change the quarterly reporting and submission requirements as set forth in the CY 2016 HH PPS final rule (80 FR 68674–68678) for the other two New Measures, ''Advance Care Planning'', and ''Herpes zoster (Shingles) vaccination: Has the patient ever received the shingles vaccination?''

We also proposed to increase the timeframe for submitting New Measures data from seven calendar days (80 FR 68675 through 68678) to fifteen calendar days following the end of each reporting period to account for weekends and holidays.

We invited public comment on these proposals.

Comment: Most commenters expressed support for the removal of the four identified quality measures. One commenter disputed the accuracy of the rationale for removing the prior functioning measure on the basis that it has never been collected by HHAs, citing use of AM–PAC [activity measure for post-acute care], which is based on NQF0430, and urged reconsideration or further development of a measure that considers function (ADLs and IADLs) as a focus of occupational therapy services to this population.

Response: We appreciate the support regarding the proposed removal of these four measures. In regard to the one comment on the prior functioning measure, we determined that NQF0430 utilizes data from the AM–PAC (Activity Measure for Post-Acute Care), a proprietary tool that is not currently, and has never been collected by CMS or utilized in its home health quality programs. CMS will continue to consider how a prior functioning measure could inform a patient's potential for improving, along with its measure development work on functional status, caregiving, and other clinical indicators, to determine whether future modifications to the measure set would be appropriate. We are finalizing the removal of the following measures: (1) Care Management: Types and Sources of Assistance; (2) Prior Functioning ADL/IADL; (3) Influenza Vaccine Data Collection Period: Does this episode of

care include any dates on or between October 1 and March 31; and (4) Reason Pneumococcal Vaccine Not Received as proposed.

Comment: Another commenter suggested that CMS move quickly to eliminate process measures that weakly correlate with health outcomes, and those that measure basic standards of care on which providers have achieved full performance.

Response: We appreciate the perspective on how process measures may correlate with health outcomes. We believe that the process measures selected for use in this Model, which primarily relate to receiving recommended vaccines, are correlated with positive population health outcomes. Regarding those measures where providers have achieved 'full performance', we are monitoring this and may propose in future rulemaking to remove one or more measures if we conclude that it is no longer appropriate for the Model.

Comment: Multiple commenters expressed support for removing the phrase ''starter set'' in describing the initial quality measures set. One commenter stated that while they had no issues with eliminating the phrase ''starter set'' from the quality measures set, CMS should not imply that it is a static set of measures.

Response: We appreciate the support regarding the proposed deletion of ''starter set'' from §§ 484.305, 484.315, and 484.320. CMS will continue to reexamine and revise the measures as needed to develop a concise set of measures for the HHVBP Model. We are finalizing the deletion of ''starter set'' from §§ 484.305, 484.315, and 484.320 as proposed.

Comment: One commenter urged CMS to align measures included in the HHVBP Model with measures being implemented under the provisions of the IMPACT Act when possible to align HHVBP Model measures with those in the HHQRP.

Response: There is intra-agency collaboration at CMS to ensure that measure selection is aligned among the various CMS post-acute care initiatives. We continue to consider options to effectively align future HHVBP Model measures with other HH measures developed to implement requirements under the IMPACT Act.

Comment: Multiple commenters stated their support to increase the New Measures data submission timeframe from 7 to 15 calendar days. There was no opposition to this change.

Response: We appreciate the support regarding the proposal to increase the New Measures data submission timeframe from 7 to 15 calendar days following the end of each reporting period. For the reasons stated in the proposed rule and in consideration of commenters' support for this modification, we are finalizing the 15-day submission timeframe for the New Measures as proposed.

Comment: We received multiple comments, including from MedPAC that supported changing the reporting requirements for the Influenza Vaccination Coverage for Home Health Personnel New Measure from quarterly to annual, including the suggestion that we not require this information to be reported in January 2017 and instead initiate annual collection in April 2017.

Response: We appreciate the suggestion regarding the revised submission timeframe for this measure and we agree. Because the measure refers to an event (flu vaccination) that usually only on an annual basis, we agree that annual reporting in April for the prior six-month period is appropriate. Given the time frame for release of this final rule, HHAs will already have submitted data on this measure for PY 1 in October 2016. HHAs will not be required to report on this measure in January 2017, as proposed, but will report for PY 2 in April 2017, for the period October 1, 2016 (or when the vaccine became available) through March 31, 2017, and annually in April thereafter, as this timing aligns with the influenza vaccination season.

We are finalizing the annual reporting requirement for the Influenza Vaccination Coverage for Home Health Personnel measure with this modification.

Comment: Several commenters suggested measures, or modifications to measures, to be considered for the HHVBP Model, including (1) pneumococcal vaccine in older adults (NQF#0043); (2) working with and supporting caregiving families; (3) changing the drug education measure from a process to outcome measure (examples: a measure of the HHA efforts regarding health literacy, or caregiver understanding of tasks); and (4) modifying the Acute Care Hospitalization: Unplanned Hospitalization during first 60 Days of Home Health measure.

Response: These comments are outside the scope of our proposed changes to the measure set. In the CY 2016 HH PPS final rule, we delineated the principles for developing and retiring measures (80 FR 68667–68669). We continue to review measure appropriateness in terms of statistical and clinical relevance to patient outcomes and will continue to consider additional applicable measures. We also will continue to seek input from the public on measures for consideration. Suggestions for specific measures that support the guiding principles articulated previously in this section for consideration for inclusion in future HHVBP Model measures sets may be submitted by emailing *HHVBPmeasures@abtassoc.com*. Please include the exact name of the measure(s), the specifications of how the measure is calculated, and the reason(s) why you believe the measure(s) would enhance the HHVBP Model.

Comment: One commenter stated its view that CMS has changed the Model's implementation design, which the commenter described as limiting the performance analysis to traditional Medicare enrollees. The commenter stated that including all patients subject to OASIS, including Medicare Advantage and Medicaid patients, is inconsistent with the CY 2016 HH PPS final rule and inappropriate in a VBP model that only affects traditional Medicare payments, and that Medicare should not penalize or reward HHAs for their performance in other payment programs that are outside of traditional Medicare.

Response: As discussed in the CY 2016 final rule, the majority of the measures finalized for use in the model will use OASIS data currently being reported by CMS–CCNs, to promote consistency and to reduce the data collection burden for providers (80 FR 68668). We explained further that using OASIS (and HHCAHPS) data allows the Model to leverage reporting structures already in place to evaluate performance and identify weaknesses in care delivery. OASIS and HHCAHPS measures are collected for applicable Medicare and Medicaid patients for whom the data is collected. Each of these measures is risk adjusted to take into account wide variation in the data.

OASIS and HHCAHPS performance scores utilize data for patients of HHAs for whom we require completion of these instruments, without separate scoring based on data for Medicare beneficiaries. This is also true of measure rates that are publicly reported on Home Health Compare, as well as the performance scoring under this Model. Consistent with this, the term patient is generally used throughout the section of the CY 2016 HH PPS final rule describing the HHVBP Model applicable measure set.

This is also consistent with our implementation of the Model to date. In December 2015 and January 2016, we

provided webinars to educate the HHAs on the Model design, how the TPS was calculated, how data was collected, as well as the details and use of the quality measures. In July 2016, we posted the Interim Performance Reports for each competing HHA on the HHVBP Secure Portal, reflecting measure performance derived from OASIS and HHCAHPS, as well as claim-based measures. In addition, HHAs are informed when the HHAs log into the HHVBP Secure Portal that the Total Performance Score on a set of measures collected via OASIS and HHCAHPS for all patients serviced by the HHA. We note that we have not received any concerns or recalculation requests relating to the scope of quality measure data used to generate these reports.

Comment: We received several additional comments regarding the measure set that were outside the scope of our proposed changes. Some commenters expressed concern that the performance measures do not reflect the patient population served under the Medicare Home Health benefit as the outcome measures focus on a patient's clinical improvement and do not address patients with chronic illnesses; deteriorating neurological, pulmonary, cardiac, and other conditions; and some with terminal illness. These commenters opined that the value of including stabilization measures in the HHVBP Model is readily apparent as it aligns the Model with the Medicare Home Health benefit. Commenters also expressed concerns that 'improvement' is not always the goal for each patient and that stabilization is a reasonable clinical goal for some. Commenters suggested the addition of stabilization or maintenance measures be considered for the HHVBP Model. However, no specific measures were suggested by commenters. Several commenters cited the *Jimmo* v. *Sebelius* settlement. Many of the commenters objected to the use of improvement measures in the HHVBP Model.

Response: We appreciate the comments on the measures methodology and, as discussed in the CY 2016 HH PPS final rule, acknowledge that skilled care may be necessary to improve a patient's current condition, to maintain the patient's current condition, or to prevent or slow further deterioration of the patient's condition, as was clarified through the manual provisions revised as part of *Jimmo* v. *Sebelius* settlement (80 FR 68669). As further stated in that rule, this settlement agreement pertains only to the clarification of CMS's manual guidance on coverage standards, not payment measures like those at issue here, and expressly does not pertain to or prevent the implementation of new regulations, including new regulations pertaining to the HHVBP Model. We refer readers to the CY 2016 HH PPS final rule (80 FR 68669 through 68670) for additional discussion of our analyses of measure selection, including our analyses of existing measures relating to improvement and stabilization. As discussed in that rule, the HHVBP Model is designed such that any measures determined to be good indicators of quality will be considered for use in the HHVBP Model in future years and may be added through the rulemaking process. We will also continue to seek input from the public on the measure set for the HHVBP Model as discussed previously.

Comment: Two commenters stated that OASIS measures can be manipulated and the HHVBP Model should only use claims-based measures because they are more objective. Another commenter suggested that the claim-based measures be weighted greater than OASIS measures for that same reason. Two commenters suggested that CMS use risk adjustment to account for areas where there is ''lack of access to health care or economic disparities''. One commenter posited that data indicates that the margin of error for a sample size of 20 surveys is large when considering typical performance on HHCAHPS measures, and recommends that a minimum of 100 HHCAHPS surveys be established for inclusion within the HHVBP Model.

Response: Although these comments were outside the scope of our proposed changes, we appreciate the issues raised for possible consideration to improve the HHVBP Model in future rulemaking. We conducted extensive testing and consultation in developing the measure set and considered if socioeconomic status could be risk adjusted. OASIS is continuously reviewed and monitored for accuracy in reporting. More information about OASIS can be found at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/OASIS/Regulations.html.* We will continue to seek input from all stakeholders on the measure set for the HH VBP Model as discussed previously.

Final Decision: For the reasons stated and in consideration of the comments received, we are finalizing the removal of the four measures from the measure set for PY 1 and subsequent performance years, as reflected in Table 24: (1) Care Management: Types and Sources of Assistance; (2) Prior Functioning ADL/IADL; (3) Influenza Vaccine Data Collection Period: Does this episode of care include any dates on or between October 1 and March 31; and (4) Reason Pneumococcal Vaccine Not Received. In addition, we are also finalizing as proposed, the deletion of the reference to starter set in §§ 484.305, 484.315, and 484.320, and the 15-day submission timeframe for New Measures data. We are also finalizing an annual submission of the ''Influenza Vaccination Coverage for Home Health Personnel'' New Measure, with the first annual submission in April 2017 for PY2, for the prior 6-month reporting period of October 1 2016–March 31, 2017 to coincide with the flu season.

D. Appeals Process

In the CY 2016 HH PPS final rule (80 FR 68689), we stated that we intended to propose an appeals mechanism in future rulemaking prior to the application of the first payment adjustments scheduled for CY 2018. In the CY 2017 HH PPS proposed rule, we proposed an appeals process for the HHVBP Model which includes the period to review and request recalculation of both the Interim Performance Reports and the Annual TPS and Payment Adjustment Reports, as finalized in the CY 2016 HH PPS final rule (80 FR 68688–68689) and subject to the modifications we proposed, and a reconsideration request process for the Annual TPS and Payment Adjustment Report only, as described later in this section, which may only occur after an HHA has first submitted a recalculation request for the Annual TPS and Payment Adjustment Report.

As finalized in the CY 2016 HH PPS final rule, HHAs have the opportunity to review their Interim Performance Report following each quarterly posting. The Interim Performance Reports are posted on the HHVBP Secure Portal quarterly, setting forth the HHA's measure scores based on available data to date. The first Interim Performance Reports were posted to the HHVBP Secure Portal in July 2016 and included performance scores for the OASIS-based measures for the first quarter of CY 2016. See Table 25 for data provided in each report. Table 25 is similar to Table 32 included in the proposed rule (81 FR 43754) except that it has been revised to reflect that every report contains 12 months of rolling data including the quarters identified in Table 32 of the proposed rule. The quarterly Interim Performance Reports provide competing HHAs with the opportunity to identify and correct calculation errors and resolve discrepancies, thereby minimizing challenges to the annual performance scores linked to payment adjustment.

Competing HHAs also have the opportunity to review their Annual TPS and Payment Adjustment Report. We will inform each competing HHA of its TPS and payment adjustment percentage in an Annual TPS and Payment Adjustment Report provided prior to the calendar year for which the payment adjustment will be applied. The annual TPS will be calculated based on the calculation of performance measures contained in the Interim Performance Reports that have already been received by the HHAs for the performance year.

We proposed specific timeframes for the submission of recalculation and reconsideration requests to ensure that the final payment adjustment percentage for each competing Medicare-certified HHA can be submitted to the Fiscal Intermediary Shared Systems in time to allow for application of the payment adjustments beginning in January of the following calendar year. We believe HHVBP Model payment adjustments should be timely and that the appeals process should be designed so that determinations on recalculations and reconsiderations can be made in advance of the applicable payment year to reduce burden and uncertainty for competing HHAs.

We proposed adding new § 484.335, titled ''Appeals Process for the Home Health Value-Based Purchasing Model,'' which would codify the recalculation request process finalized in the CY 2016 HH PPS final rule and also the proposed reconsideration request process for the Annual TPS and Payment Adjustment Report. The first level of this appeals process would be the recalculation request process, as finalized in the CY 2016 HH PPS final rule and subject to the modifications described later in this section. We proposed that the reconsideration request process for the Annual TPS and Payment Adjustment Report would complete the appeals process, and would be available only when an HHA has first submitted a recalculation request for the Annual TPS and Payment Adjustment Report under the process finalized in the CY 2016 HH PPS final rule, subject to the modifications described later in this section. We stated that we believe that this proposed appeals process will allow the HHAs to seek timely corrections for errors that may be introduced during the Interim Performance Reports that could affect an HHA's payments.

To inform our proposal for an appeals process under the HHVBP Model, we reviewed the appeals policies for two CMS programs that are similar in their program goals to the HHVBP Model, the Medicare Shared Savings Program and Hospital Value-Based Purchasing Program, as well as the appeals policy for the Comprehensive Care for Joint Replacement Model that is being tested by the Center for Medicare and Medicaid Innovation (Innovation Center).

Under section 1115A(d) of the Act, there is no administrative or judicial review under sections 1869 or 1878 of the Act or otherwise for the following:

- The selection of models for testing or expansion under section 1115A of the Act.
- The selection of organizations, sites or participants to test those models selected.
- The elements, parameters, scope, and duration of such models for testing or dissemination.
- Determinations regarding budget neutrality under section 1115A(b)(3) of the Act.
- The termination or modification of the design and implementation of a model under section 1115A(b)(3)(B) of the Act.
- Decisions about expansion of the duration and scope of a model under section 1115A(c) of the Act, including the determination that a model is not expected to meet criteria described in section 1115A(c)(1) or (2) of the Act.

TABLE 25—HHVBP MODEL PERFORMANCE REPORT DATA SCHEDULE

Report type	Publication date	OASIS-based measures and new measures	Claims- and HHCAHPS-based measures
Interim Performance Scores	January	12 months ending 9/30 of previous PY	12 months ending 6/30 of previous PY.
Interim Performance Scores	April	12 months ending 12/31 of previous PY	12 months ending 9/30 of previous PY.
Interim Performance Scores	July	12 months ending 3/31 of current PY	12 months ending 12/31 of previous PY.
Interim Performance Scores	October	12 months ending 6/30 of current PY	12 months ending 3/31 of current PY.
Annual TPS and Payment Adjustment Percentage.	August	Entire 12 months of previous PY [Jan–Dec].	
Annual TPS and Payment Adjustment Percentage (Final).	December	Entire 12 months of previous PY [Jan–Dec] after all recalculations and reconsideration requests processed.	

1. Recalculation

HHAs may submit recalculation requests for both the Interim Performance Reports and the Annual TPS and Payment Adjustment Report via a form located on the HHVBP Secure Portal that is only accessible to the competing HHAs. The request form would be entered by a person who has legal authority to sign on behalf of the HHA and, as finalized in the CY 2016 HH PPS final rule, must be submitted within 30 calendar days of the posting of each performance report on the model-specific Web site. For the reasons discussed later in this section, we proposed to change this policy to require that recalculation requests for both the Interim Performance Report and the Annual TPS and Payment Adjustment Report be submitted within 15 calendar days of the posting of the Interim Performance Report and the Annual TPS and Payment Adjustment Report on the HHVBP Secure Portal instead of 30 calendar days.

For both the Interim Performance Reports and the Annual TPS and Payment Adjustment Report, requests for recalculation must contain specific information, as set forth in the CY 2016 HH PPS final rule (80 FR 68688). We proposed that requests for reconsideration of the Annual TPS and Payment Adjustment Report must also contain this same information.

- The provider's name, address associated with the services delivered, and CMS Certification Number (CCN);
- The basis for requesting recalculation to include the specific quality measure data that the HHA believes is inaccurate or the calculation the HHA believes is incorrect;
- Contact information for a person at the HHA with whom CMS or its agent can communicate about this request, including name, email address, telephone number, and mailing address

(must include physical address, not just a post office box); and,

• A copy of any supporting documentation the HHA wishes to submit in electronic form via the model-specific Web page.

Following receipt of a request for recalculation of an Interim Performance Report or the Annual TPS and Payment Adjustment Report, CMS or its agent will:

• Provide an email acknowledgement, using the contact information provided in the recalculation request, to the HHA contact notifying the HHA that the request has been received;

• Review the request to determine validity, and determine whether the recalculation request results in a score change, altering performance measure scores or the HHA's TPS;

• Conduct a review of quality data if recalculation results in a performance score or TPS change, and recalculate the TPS using the corrected performance data if an error is found; and,

• Provide a formal response to the HHA contact, using the contact information provided in the recalculation request, notifying the HHA of the outcome of the review and recalculation process.

We anticipate providing this response as soon as administratively feasible following the submission of the request.

We will not be responsible for providing HHAs with the underlying source data utilized to generate performance measure scores because HHAs have access to this data via the QIES system.

We proposed that recalculation requests for the Interim Performance Reports must be submitted within 15 calendar days of these reports being posted on the HHVBP Secure Portal, rather than 30 calendar days as finalized in the CY 2016 HH PPS final rule. We believe this would allow recalculations of the Interim Performance Reports posted in July to be completed prior to the posting of the Annual TPS and Payment Adjustment Report in August. We proposed that recalculation requests for the TPS or payment adjustment percentage must be submitted within 15 calendar days of the Annual TPS and Payment Adjustment Report being posted on the HHVBP Secure Portal, rather than 30 days as finalized in the CY 2016 HH PPS final rule. We proposed to shorten this timeframe to allow for a second level of appeals, the proposed reconsideration request process, to be completed prior to the generation of the final data files containing the payment adjustment percentage for each competing Medicare-certified HHA and the submission of those data files to the Fiscal Intermediary Share Systems. We contemplated longer timeframes for the submission of both recalculation and reconsideration requests for the Annual TPS and Payment Adjustment Reports, but believe that this would result in appeals not being resolved in advance of the payment adjustments being applied beginning in January for the applicable performance year. We invited comments on this proposed timeframe for recalculation requests, as well as any alternatives.

2. Reconsideration

We proposed that if we determine that the calculation was correct and deny the HHA request for recalculation of the Annual TPS and Payment Adjustment Report, or if the HHA disagrees with the results of a CMS recalculation of such report, the HHA may submit a reconsideration request for the Annual TPS and Payment Adjustment Report. The reconsideration request and supporting documentation would be required to be submitted via the form on the HHVBP Secure Portal within 15 calendar days of CMS' notification to the HHA contact of the outcome of the recalculation request for the Annual TPS and Payment Adjustment Report.

We proposed that an HHA may request reconsideration of the outcome of a recalculation request for its Annual TPS and Payment Adjustment Report only. We believe that the ability to review the Interim Performance Reports and submit recalculation requests on a quarterly basis provides competing HHAs with a mechanism to address potential errors in advance of receiving their annual TPS and payment adjustment percentage. Therefore, we expect that in many cases, the reconsideration request process proposed would result in a mechanical review of the application of the formulas for the TPS and the LEF, which could result in the determination that a formula was not accurately applied. Reconsiderations would be conducted by a CMS official who was not involved with the original recalculation request.

We proposed that an HHA must submit the reconsideration request and supporting documentation via the HHVBP Secure Portal within 15 calendar days of CMS' notification to the HHA contact of the outcome of the recalculation process so that a decision on the reconsideration can be made prior to the generation of the final data files containing the payment adjustment percentage for each competing Medicare-certified HHA and the submission of those data files to the Fiscal Intermediary Share Systems. We believe that this would allow for finalization of the interim performance scores, TPS, and annual payment adjustment percentages in advance of the application of the payment adjustments for the applicable performance year. As noted above, we contemplated longer timeframes for the submission of both recalculation and reconsideration requests, but believe this would result in appeals not being resolved in advance of the payment adjustments being applied beginning in January for the applicable performance year.

We finalized in the CY 2016 HH PPS final rule (80 FR 68688) that the final TPS and payment adjustment percentage would be provided to competing HHAs in a final report no later than 60 calendar days in advance of the payment adjustment taking effect. In the CY 2017 HH PPS proposed rule, we proposed that the final TPS and payment adjustment percentage be provided to competing HHAs in a final report no later than 30 calendar days in advance of the payment adjustment taking effect to account for unforeseen delays that could occur between the time the Annual TPS and Payment Adjustment Reports are posted and the appeals process is completed.

We solicited comments on our proposals related to the appeals process for the HHVBP Model described in this section and the associated proposed regulation text at § 484.335.

Comment: Many commenters supported the proposed reconsideration process, which would allow a HHA to request reconsideration for the outcome of a recalculation request for its Annual TPS and Payment Adjustment Report.

Response: We appreciate the support to add reconsideration as the second level of review in addition to the recalculation process.

Comment: Many commenters supported the proposed changes to the timeline for submitting recalculation requests. One commenter noted that while they understood the need to shorten the timeframe, they encourage CMS to enforce firm timelines by which HHAs will be notified of the decision of their appeal and for CMS to appropriately staff the appeals team to meet these targets. Another commenter suggested that CMS provide educational tools, such as webinars and/or conference calls, to help HHAs determine inaccuracies in their reports so HHAs can make accurate determinations and submit appeals in a timely manner.

Response: We appreciate the comments supporting the proposed

changes to the timeframes for submitting recalculation requests. We expect to provide timely and transparent adjudication of appeals and notifications to the HHAs. We will continue to offer educational tools, such as webinars and conference calls, to help HHAs in reviewing their performance report so that they may submit any appeals in a timely manner.

Comment: A few commenters disagreed with the proposal to shorten the timeframe for recalculation requests from 30 calendar days to 15 calendar days for both the Interim Performance Reports and the Annual TPS and Payment Adjustment Reports. These same commenters did not agree with the 15-calendar day submission timeline for reconsideration requests. Commenters expressed concern that 15 calendar days does not provide a sufficient amount of time for HHAs to review the reports and determine whether an appeal is needed, collect supporting data, and submit their requests. One commenter also requested that CMS commit to a specific release date for each of the Interim Performance Reports, specifically the 1st day of each publication month, and improve functionality and accessibility of the HHVBP Secure Portal in order for agencies to adequately review the Interim Performance Reports within the 15-calendar day timeframe.

One commenter ''cautiously supports'' the proposal to provide each HHA with its payment adjustment percentage no later than 30 calendar days before the payment adjustment is applied to allow extra time for the appeals process to take place. While the commenter supports more time for HHAs to receive their payment adjustment reports so that they can operationalize the payment adjustments, it stated that it understands this balances additional time for the appeals process. Commenters stated that with this additional time they expect a timely and transparent adjudication of appeals and notification to HHAs.

Response: We proposed to shorten the timeframe for recalculations and reconsiderations to accommodate the time needed to generate and submit the final data file to the FISS to meet the January payment adjustment implementation date for each model year. As described in the proposed rule, we believe that HHAs' ability to review their quarterly Interim Performance Reports and submit recalculation requests provides HHAs with a mechanism to address potential errors in advance of receiving the Annual TPS and Payment Adjustment Report and we expect that in many cases, the reconsideration requests would result in a mechanical review of the application of the formulas for the TPS and LEF. We therefore believe that 15 calendar days is a sufficient amount of time to determine whether an appeal is needed, collect supporting data, and submit a recalculation request following the posting of the Annual TPS and Payment Adjustment Reports. We do not provide dates for the release of the Interim Performance Reports or the Annual TPS and Payment Adjustment Reports because the availability of data varies. We expect to provide timely and transparent adjudication of appeals and notifications to the HHAs and are always looking for ways to improve the functionality and accessibility of the HHVBP Secure Portal.

Comment: One commenter requested that CMS maintain the decision to release final reports no later than 60 calendar days prior to payment adjustments taking effect so that HHAs have enough time to prepare for the impact of the payment adjustment.

Response: We proposed that the final TPS and payment adjustment percentage be provided to competing HHAs in a final report no later than 30 calendar days in advance of the payment adjustment taking effect to account for unforeseen delays that could occur between the time the Annual TPS and Payment Adjustment Reports are posted and the appeals process is completed. We believe that this revised timeframe would provide sufficient notice to HHAs of their payment adjustment in advance of the payment adjustment being applied while at the same time allowing for the proposed second level of appeals. CMS aims to provide the final TPS and payment adjustment percentage to HHAs as far in advance of the payment year as possible following the resolution of the reconsideration process.

Comment: One commenter requested that we clarify whether a successful appeal that changes the performance scores for a particular HHA correspondingly changes the performance rankings of the HHAs in that cohort and whether it would affect their payment adjustments. The commenter also questioned how HHAs will be notified, as well as whether there are further appeal rights.

Response: As noted above, we proposed that if we deny an HHA's request for recalculation of the Annual TPS and Payment Adjustment Report, or if the HHA disagrees with the results of a CMS recalculation of such report, the HHA may submit a reconsideration request for the Annual TPS and Payment Adjustment Report. After a determination has been made on any such reconsideration requests, a final payment adjustment report will be posted that reflects any changes to the payment adjustments as a result of the reconsideration decisions, both for those HHAs that requested the reconsiderations and all other HHAs, and a system generated notification will go to each HHA. If the TPS score or payment adjustment is recalculated for an HHA as a result of that HHA's reconsideration request, the payment adjustments will have to be recalculated for all HHAs in the same cohort. Figure 9 of the CY 2016 HH PPS final rule (80 FR 68688) provides an illustration of how the LEF is calculated. Columns C1–C5 of Figure 9 demonstrate that the LEF coefficient is dependent on the TPS and volume of service for each HHA in the cohort. As a result, if an HHA's reconsideration request results in a change to that HHA's TPS, all other HHAs in the same cohort may experience a minimal change to their respective payment adjustment. We would expect the change to the other HHAs' payment adjustments to be minimal because the magnitude of change would be divided among all the other HHAs in the cohort. We are finalizing in this rule the process for an HHA to request recalculation or reconsideration, following a decision on that HHA's request for recalculation, if the HHA has concerns that its TPS or payment adjustment is miscalculated. There is no further appeal process under the HHVBP model following a decision on the reconsideration request.

Final Decision: For the reasons stated and in consideration of the comments received, we are finalizing the appeals process as proposed and the associated regulation text at § 484.335, titled ''Appeals Process for the Home Health Value-Based Purchasing Model'', with a modification to § 484.335(a)(3)(iv) to correct an erroneous reference to ''reconsideration'' to ''recalculation'' and modifications to § 484.335(b)(1) for clarity and internal consistency. That is, we are finalizing the reconsideration process; the requirement that recalculation requests be submitted within 15 calendar days of the Interim Performance Report or the Annual TPS and Payment Adjustment Report being posted on the HHVBP Secure Portal; the requirement that reconsideration requests be submitted within 15 days of being notified of the results of the recalculation request; and that the final TPS and payment adjustment percentage is provided to competing HHAs in a final report no later than 30 calendar days in advance of the payment adjustment taking effect.

E. Discussion of the Public Display of Total Performance Scores

In the CY 2016 HH PPS final rule (80 FR 68658), we stated that one of the three goals of the HHVBP Model is to enhance current public reporting processes. Annual publicly-available performance reports would be a means of developing greater transparency of Medicare data on quality and aligning the competitive forces within the market to deliver care based on value over volume. The public reports would inform home health industry stakeholders (consumers, physicians, hospitals), as well as all competing HHAs delivering care to Medicare beneficiaries within selected state boundaries, on their level of quality relative to both their peers and their own past performance. These public reports would provide home health industry stakeholders, including providers and suppliers that refer their patients to HHAs, an opportunity to confirm that those beneficiaries are being provided the best possible quality of care available.

We received support via public comments to publicly report the HHVBP Model performance data because they would inform industry stakeholders of quality improvements. These commenters noted several areas of value in performance data. Specifically, commenters suggested that public reports would permit providers to direct patients to a source of information about higher-performing HHAs based on quality reports. Commenters offered that to the extent possible, accurate comparable data will encourage HHAs to improve care delivery and patient outcomes, while better predicting and managing quality performance and payment updates. Although competing HHAs have direct technical support and other tools to encourage best practices, we believe public reporting of their Total Performance Score will encourage providers and patients to utilize this information when selecting a HHA to provide quality care.

We have employed a variety of means to ensure that we maintain transparency while developing and implementing the HHVBP Model. This same care is being taken as we plan public reporting in collaboration with other CMS components that use many of the same quality measures. We continue to engage and inform stakeholders about various aspects of the HHVBP Model through CMS Open Door Forums, webinars, updates to the HHVBP Model Innovation Center Web page (*https://innovation.cms.gov/initiatives/home-health-value-based-purchasing-model*), a dedicated help desk, and a web-based forum where regularly frequently asked questions are published. We have held several webinars since December 2015 to educate competing HHAs. Topics of the webinars ranged from an overview of the HHVBP Model to specific content areas addressed in the CY 2016 HH PPS final rule. The primary purpose of the focused attention provided to the competing HHAs through the HHVBP learning systems and webinars is to facilitate direct communication, sharing of information, and collaboration.

Section 1895(b)(3)(B)(v) of the Act requires HHAs to submit patient-level quality of care data using the Outcome and Information Assessment Set (OASIS) and the Home Health Consumer Assessment of Health Care Providers and Systems (HHCAHPS). Section 1895(b)(3)(B)(v)(III) of the Act states that this quality data is to be made available to the public. Thus, HHAs have been required to collect OASIS data since 1999 and report HHCAHPS data since 2012.

We are considering various public reporting platforms for the HHVBP Model including Home Health Compare (HHC) and the Innovation Center Web page as a vehicle for maintaining information in a centralized location and making information available over the Internet. We believe the public reporting of competing HHAs' performance scores under the HHVBP Model supports our continuing efforts to empower consumers by providing more information to help them make health care decisions, while also encouraging providers to strive for higher levels of quality. As the public reporting mechanism for the HHVBP Model is being developed, we are considering which Model data elements will be meaningful to stakeholders and may inform the selection of HHAs for care.

We are considering public reporting for the HHVBP Model, beginning no earlier than CY 2019, to allow analysis of at least eight quarters of performance data for the Model and the opportunity to compare how those results align with other publicly reported quality data. We are encouraged by the previous stakeholder comments and support for public reporting that could assist patients, physicians, discharge planners, and other referral sources to choose higher-performing HHAs.

Comment: One commenter suggested that CMS not consider public display until after the Model was evaluated and a decision would be made as to whether or not to scale the Model nationally. The commenter stated that it was not appropriate to report outcomes for some HHAs when only those in the nine designated states could be reported, and not all agencies in the United States, potentially putting the reported agencies at a disadvantage. One commenter favored the public display of the TPS, but urged CMS to: (1) Employ a transparent process and involve stakeholders in deciding what is reported; (2) provide a review period with a process for review and appeal before reporting; and (3) provide a clear explanation of what the TPS does and does not say to ensure appropriate consumer understanding and decision making. Finally, several commenters suggested that CMS post the information on the Innovation Center Web site, and not on the HHC Web site. The commenters suggested that posting this information on the Innovation Center Web site would clearly separate the information from national public reporting of all HHAs and be less likely to confuse consumers from non-participating states.

Response: We support providing the public with information to make an informed decision when choosing a Medicare-certified HHA. Similar to current reporting mechanisms for providing information on home health performance, including Home Health Compare and the Home Health Quality Reporting Program (HHQRP), the HHVBP Model's public display would provide all stakeholders in the selected states with additional information as they identify the home health services that best meet their needs. As we expect stakeholders to access publicly reported information for the state in which they are interested in finding services, we would not expect those stakeholders in non-participating states to utilize this information. We do not believe public display of information regarding performance in the Model would create a disadvantage for participating HHAs in their own states because all HHAs in a selected state must participate.

Current CMS public information Web sites, such as Hospital Compare and Nursing Home Compare, help consumers and others choose among providers based on the quality of care and services. We intend to continue to provide opportunities for stakeholder input as we develop a mechanism for public reporting under the HHVBP Model. We appreciate the commenters' concern about avoiding confusion with other public reporting by HHAs. We believe it is also important to make the information available where it is most likely to be accessed by a variety of stakeholders. We are considering an approach that balances access and reduces the likelihood for confusion by perhaps providing a link from the Home

Health Compare Web site (a site with high visibility that is frequently used by consumers of home health services) to the Innovation Center Web site, where stakeholders in the selected states or others may access it.

We appreciate the comments and will continue to gather information from the public as we consider mechanisms for public reporting under the HHVBP Model.

V. Updates to the Home Health Care Quality Reporting Program (HH QRP) and Analysis of and Responses to Comments

A. Background and Statutory Authority

Section 1895(b)(3)(B)(v)(II) of the Act requires that for 2007 and subsequent years, each HHA submit to the Secretary in a form and manner, and at a time, specified by the Secretary, such data that the Secretary determines are appropriate for the measurement of health care quality. To the extent that an HHA does not submit data in accordance with this clause, the Secretary is directed to reduce the home health market basket percentage increase applicable to the HHA for such year by 2 percentage points. As provided at section 1895(b)(3)(B)(vi) of the Act, depending on the market basket percentage for a particular year, the 2 percentage point reduction under section 1895(b)(3)(B)(v)(I) of the Act may result in this percentage increase, after application of the productivity adjustment under section 1895(b)(3)(B)(vi)(I) of the Act, being less than 0.0 percent for a year, and may result in payment rates under the Home Health PPS for a year being less than payment rates for the preceding year.

The Improving Medicare Post-Acute Care Transformation Act of 2014 (the IMPACT Act) imposed new data reporting requirements for certain post-acute care (PAC) providers, including HHAs. For more information on the statutory background of the IMPACT Act, please refer to the CY 2016 HH PPS final rule (80 FR 68690 through 68692).

In that final rule, we established our approach for identifying cross-setting measures and processes for the adoption of measures including the application and purpose of the Measures Application Partnership (MAP) and the notice and comment rulemaking process. More information on the IMPACT Act is also available at *https://www.govtrack.us/congress/bills/113/hr4994*.

In the CY 2016 HH PPS final rule (80 FR 68692), we also discussed the reporting of OASIS data as it relates to the implementation of ICD–10 on October 1, 2015. We submitted a new request for approval to OMB for the OASIS–C1/ICD–10 version under the Paperwork Reduction Act (PRA) process, including a new OMB control number (80 FR 15796). The new information collection request for OASIS–C1/ICD–10 version was approved under OMB control number 0938–1279 with a current expiration date of May 31, 2018. To satisfy requirements in the IMPACT Act that HHAs submit standardized patient assessment data in accordance with section 1899B(b) and to create consistency in the lookback period across selected OASIS items, we have created a modified version of the OASIS, OASIS–C2. We have submitted request for approval to OMB for the OASIS–C2 version under the PRA process (81 FR 18855); also see *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html*. The OASIS–C2 version will replace the OASIS–C1/ICD–10 and will be effective for data collected with an assessment completion date (M0090) on and after January 1, 2017. Information regarding the OASIS–C1/ICD–10 and C2 can be located on the OASIS Data Sets Web page at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/OASIS-Data-Sets.html*.

B. General Considerations Used for the Selection of Quality Measures for the HH QRP

We refer readers to the CY 2016 HH PPS final rule (80 FR 68695 through 68698) for a detailed discussion of the considerations we apply in measure selection for the Home Health Quality Reporting Program (HH QRP), such as alignment with the CMS Quality Strategy,[18] which incorporates the three broad aims of the National Quality Strategy.[19] Overall, we strive to promote high quality and efficiency in the delivery of health care to the beneficiaries we serve. Performance improvement leading to the highest quality health care requires continuous evaluation to identify and address performance gaps and reduce the unintended consequences that may arise in treating a large, vulnerable, and aging population. Quality reporting programs (QRPs), coupled with public reporting of quality information are critical to the advancement of health care quality improvement efforts. Valid, reliable, and relevant quality measures are fundamental to the effectiveness of our QRPs. Therefore, selection of quality measures is a priority for us in all of our QRPs.

We proposed to adopt for the HH QRP one measure that we are specifying under section 1899B(c)(1)(C) of the Act to meet the Medication Reconciliation domain: (1) Drug Regimen Review Conducted with Follow-Up for Identified Issues-Post-Acute Care Home Health Quality Reporting Program (Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC HH QRP). Further, we proposed to adopt for the HH QRP three measures to meet the ''Resource Use and other Measures'' domains required by section 1899B(d)(1) of the Act: (1) Total Estimated Medicare Spending per Beneficiary—Post Acute Care Home Health Quality Reporting Program (MSPB–PAC HH QRP); (2) Discharge to Community-Post Acute Care Home Health Quality Reporting Program (Discharge to Community-PAC HH QRP); and (3) Potentially Preventable 30-Day Post-Discharge Readmission Measure for Post-Acute Care Home Health Quality Reporting Program (Potentially Preventable 30-Day Post-Discharge Readmission Measure for HH QRP).

In our selection and specification of measures, we employ a transparent process in which we seek input from stakeholders and national experts and engage in a process that allows for pre-rulemaking input on each measure, as required by section 1890A of the Act. To meet this requirement, we provided the following opportunities for stakeholder input: Our measure development contractor convened technical expert panels (TEPs) that included stakeholder experts and patient representatives on July 29, 2015, for the Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC HH QRP; on August 25, 2015, September 25, 2015, and October 5, 2015, for the Discharge to Community-PAC HH QRP; on August 12–13, 2015, and October 14, 2015, for the Potentially Preventable 30-Day Post-Discharge Readmission Measure for HH QRP; and on October 29–30, 2015, for the MSPB–PAC HH QRP measures. In addition, we released draft quality measure specifications for public comment on the Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC HH QRP from September 18, 2015 to October 6, 2015, for the Discharge to Community-PAC HH QRP from November 9, 2015 to December 8, 2015, for the Potentially

[18] *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/CMS-Quality-Strategy.html.*

[19] *http://www.ahrq.gov/workingforquality/nqs/nqs2011annlrpt.htm.*

Preventable 30-Day Post-Discharge Readmission Measure for HH QRP from November 2, 2015 to December 1, 2015, and for the MSPB–PAC HH QRP measures from January 13, 2016 to February 5, 2016. Further, we opened a public mailbox, *PACQualityInitiative@cms.hhs.gov*, for the submission of public comments. This PAC mailbox is accessible on our post-acute care quality initiatives Web site, on the IMPACT Act of 2014 Data Standardization & Cross Setting Measures Web page at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-of-2014-Data-Standardization-and-Cross-Setting-MeasuresMeasures.html*.

Additionally, we sought public input from the MAP Post-Acute Care, Long-Term Care Workgroup during the annual public meeting held December 14–15, 2015. The MAP is composed of multi-stakeholder groups convened by the NQF, our current contractor under section 1890(a) of the Act, tasked to provide input on the selection of quality and efficiency measures described in section 1890(b)(7)(B) of the Act. The MAP reviewed each measure proposed in this rule for use in the HH QRP. For more information on the MAP, we refer readers to the CY 2016 HH PPS final rule (80 FR 68692 through 68694). Further, for more information on the MAP's recommendations, we refer readers to the MAP 2015–2016 Considerations for Implementing Measures in Federal Programs public report at *http://www.qualityforum.org/Publications/2016/02/MAP_2016_Considerations_for_Implementing_Measures_in_Federal_Programs_-_PAC-LTC.aspx*.

For measures that do not have NQF endorsement, or which are not fully supported by the MAP for use in the HH QRP, we proposed measures for the HH QRP for the purposes of satisfying the measure domains required under the IMPACT Act measures that most closely align with the national priorities identified in the National Quality Strategy (*http://www.ahrq.gov/workingforquality/*) and with respect to which the MAP supports the measure concept. Further, we discuss below the importance and high-priority status of these proposed measures in the HH setting.

The following is a summary of the comments we received for general consideration regarding our proposals for the HH QRP.

Comment: One commenter supported the criteria that measures selected for the HH QRP be valid, reliable, and relevant, but noted that these criteria did not address the fact that maintaining function through skilled care was a valid goal for home health.

Response: We appreciate the commenter's support regarding the criteria that measures selected for the HH QRP be valid, reliable, and relevant and confirm that maintenance of function is a valid goal for some home health patients.

Comment: We received several comments regarding NQF endorsement of the measures. Several commenters expressed concern about the lack of NQF endorsement for measures. In addition, several commenters recommended that CMS delay implementing the proposed measures until NQF has completed its review and has endorsed the measures. Several commenters noted the NQF MAP committee did not endorse the proposed measures. Additionally, commenters recommended NQF endorsement prior to finalization of use in public reporting. A number of commenters recommended that CMS test new measures for reliability and validity prior to implementation, and encouraged CMS to analyze data to ensure comparability across post-acute care settings. Commenters also requested that testing results be made available to stakeholders.

Response: We acknowledge the commenters' recommendation to delay implementation of the measures until they are NQF-endorsed. While we appreciate the importance of consensus endorsement and intend to seek such endorsement, we must balance the need to address gaps in quality and adhere to statutorily-required timelines as in the case of the quality and resource use measures proposed in order to meet the requirements of the IMPACT Act. We consider and propose appropriate measures that have been endorsed by the NQF whenever possible. We recognize the importance of consensus endorsement and, where possible in light of the statutory deadlines imposed by the IMPACT Act, have adopted measures for the HH QRP that are endorsed by the NQF. However, when this is not feasible because there is no NQF-endorsed measure, we utilize our statutory authority that allows the Secretary to specify a measure for the HH QRP that is not NQF-endorsed where, as in the case for the proposed measures, we have not been able to identify other measures that are endorsed or adopted by a consensus organization.

For measures that do not have NQF endorsement, or which are not fully supported by the MAP for use in the HH QRP, we proposed for the HH QRP for the purposes of satisfying the measure domains required under the IMPACT Act, measures that closely align with the national priorities identified in the National Quality Strategy (*http://www.ahrq.gov/workingforquality/*) and for which the MAP supports the measure concept. Further discussion as to the importance and high-priority status of these proposed measures in the HH setting is included under each quality measure in this final rule. To the extent that we have adopted measures under our exception authority, we intend to seek NQF-endorsement of those measures and will do so as soon as is feasible. Regardless of whether the measures are or are not NQF-endorsed at the time we adopt them, they have all been tested for reliability and/or validity and we believe that the results of that testing support our conclusion that they are sufficiently reliable and valid to warrant their adoption in the HH QRP. The results of our reliability and validity testing for these measures may be found in the Measure Specifications for Measures Proposed in CY 2017 HH QRP Final Rule, posted on the CMS HH QRP Web page at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIQualityMeasures.html*. In regard to additional measure development, testing, and measure refinement, we will continue to test, monitor and validate these measures as part of measure maintenance.

Comment: We received many comments regarding risk-adjusting measure results by socioeconomic status (SES) or sociodemographic status (SDS). A few commenters, including MedPAC, did not support risk-adjustment of measures by SES or SDS status. MedPAC stated that risk adjustment can hide disparities in care and suggested that risk-adjustment reduces pressure on providers to improve quality of care for low-income Medicare beneficiaries. MedPAC supported peer provider group comparisons with providers of similar low-income beneficiary populations. The majority of commenters supported the use of SES or SDS for risk adjustment to account for varying acuity levels of patients in different settings of care, as well as other differences in patient characteristics that could affect health outcomes. The commenters noted in particular the many factors outside the control of home health providers, including access to food and primary care, income, informal caregivers and the condition of a patient's home that should be considered. These

commenters expressed concern that lack of risk-adjustment for these factors may compromise credibility, provide disincentives to serve certain patients and make it difficult to validly compare providers across PAC settings. A few commenters suggested that CMS could take advantage of the National Quality Forum's sociodemographic adjustment trial period.

Response: We appreciate the considerations and suggestions conveyed in relation to the measures and the importance in balancing appropriate risk adjustment along with ensuring access to high quality care. We note that in the measures that are risk adjusted, we do take into account characteristics associated with medical complexity, as well as factors such as age where appropriate to do so. With regard to the incorporation of additional factors including patient characteristics, such as cognitive impairment and function, we have and will continue to take such factors into account, which would include further testing as part of our ongoing measure development monitoring activities. With regard to the suggestions pertaining to the incorporation of socioeconomic factors as risk-adjustors for the measures, NQF is currently undertaking a 2-year trial period in which new measures and measures undergoing maintenance review will be assessed to determine if risk-adjusting for sociodemographic factors is appropriate. This trial entails temporarily allowing inclusion of sociodemographic factors in the risk-adjustment approach for some performance measures. At the conclusion of the trial, NQF will issue recommendations on future permanent inclusion of sociodemographic factors. During the trial, measure developers are encouraged to submit information such as analyses and interpretations, as well as performance scores with and without sociodemographic factors in the risk adjustment model. Several measures developed or maintained by CMS have been brought to NQF since the beginning of the trial. CMS, in compliance with NQF's guidance, has tested sociodemographic factors in the measures' risk models and made recommendations about whether or not to include these factors in the endorsed measures. We intend to continue engaging in the NQF process as we consider the appropriateness of adjusting for sociodemographic factors in our outcome measures.

Furthermore, the HHS Office of the Assistant Secretary for Planning and Evaluation (ASPE) is conducting research to examine the impact of sociodemographic status on quality measures, resource use, and other measures under the Medicare program as directed by the IMPACT Act. We will closely examine the findings of the ASPE reports and related Secretarial recommendations and consider how they apply to our quality programs at such time as they are available. For each of the proposed measures, we applied consistent models where feasible to develop their definitions, other technical specifications and approach to risk-adjustment. We also intend to continue to monitor the reliability and validity of the HHQRP measures, including whether the measures are reliable and valid for cross-setting purposes.

Comment: Two commenters encouraged CMS to give consideration to burden when developing quality measures, and one additionally noted that even measures that rely on existing claims data can pose additional administrative burden, such as time and effort to compile and validate data.

Response: With all new measure development, we are committed to assessing the burden and utility of proposed measures, through Technical Expert Panels, public comment periods and other opportunities for stakeholder input. Of the four measures proposed in the proposed rule, one will be calculated using assessment items already in OASIS instrument and, for that reason, adds no new burden for HHAs. The other three proposed measures are claims-based, and consistent with our general policy for claims-based measures, are calculated using claim files that should have been already compiled and validated by HHAs for other purposes, including reimbursement. Therefore, we do not believe that the adoption of claims-based measures creates a new administrative burden for providers.

Comment: Two commenters expressed support and appreciation for the transparent process employed in developing measures to satisfy the requirements of the IMPACT Act. Other commenters expressed concern over the short timeframe available for stakeholder input into measure development.

Response: We appreciate the support for our transparent process and wish to confirm our commitment to ongoing stakeholder involvement. We appreciate the feedback regarding the timing issues related to IMPACT Act implementation. It is our intent to move forward with IMPACT Act implementation in a manner in which the measure development process continues to be transparent, and includes input and collaboration from experts, the PAC provider community, and the public at large. It is of the utmost importance to us to continue to engage stakeholders, including providers, patients and their families, throughout the measure development lifecycle through their participation in our measure development public comment periods, the pre-rulemaking process, TEPs convened by our measure development contractors, open door forums and other opportunities. With that, we note that with regard to the measure development process we have provided the various opportunities as previous described and we have provided multiple opportunities for stakeholder input on the proposed measures, including soliciting feedback from a TEP, and pre-rulemaking public comment periods. Specifically and in addition to the various opportunities for the stakeholder input previously described, we have also worked to be responsive to stakeholder concerns pertaining to the length of various comment periods, and in response to those concerns, we have extended our public comment periods for measures under development on several occasions. We also encourage feedback through our IMPACT Act PAC Quality Initiative resource and feedback mailbox at *PACQualityInitiative@cms.hhs.gov* or at the SNF QRP resource and feedback mailbox at *SNFQualityQuestions@cms.hhs.gov*. We thank all stakeholders for their thoughtful feedback on and engagement with the measure development and rulemaking process.

Comment: One commenter thanked CMS for clarifying that OASIS assessments are used for Home Health beneficiaries that are in Medicaid, MA, and FFS, and commended CMS for providing education on the changes coming for the HH QRP.

Response: We thank the commenter for their support.

C. Process for Retaining, Removing, and Replacing Previously Adopted Home Health Quality Reporting Program Measures for Subsequent Payment Determinations

Consistent with the policies of other provider QRPs, including the Hospital Inpatient Quality Reporting Program (Hospital IQR) (77 FR 53512 through 53513), the Hospital Outpatient Quality Reporting Program (Hospital OQR) (77 FR 68471), the LTCH QRP (77 FR 53614 through 53615), and the IRF QRP (77 FR 68500 through 68507), we proposed that when we initially adopt a measure for the HH QRP for a payment determination, this measure would be automatically retained for all subsequent payment determinations

unless we proposed to remove or replace the measure, or unless the exception discussed below applied.

We proposed to define the term ''remove'' to mean that the measure is no longer a part of the HH QRP measure set, data on the measure would no longer be collected for purposes of the HH QRP, and the performance data for the measure would no longer be displayed on HH Compare. We also proposed to use the following criteria when considering a quality measure for removal: (1) Measure performance among HHAs is so high and unvarying that meaningful distinctions in improvements in performance can no longer be made; (2) performance or improvement on a measure does not result in better patient outcomes; (3) a measure does not align with current clinical guidelines or practice; (4) a more broadly applicable measure (across settings, populations, or conditions) for the particular topic is available; (5) a measure that is more proximal in time to desired patient outcomes for the particular topic is available; and (6) a measure that is more strongly associated with desired patient outcomes for the particular topic is available. These items would still appear on OASIS for previously established purposes that are non-related to our HH QRP. HHAs would be able to access these reports using the Certification and Survey Provider Enhanced Reports (CASPER) system and could use the information for their own monitoring and quality improvement efforts.

Further, we proposed to define ''replace'' to mean that we would adopt a different quality measure in place of a currently used quality measure, for one or more of the reasons described above. Additionally, we proposed that any such ''removal'' or ''replacement'' would take place through notice and comment rulemaking, unless we determined that a measure was causing concern for patient safety. Specifically, in the case of a HH QRP measure for which there was a reason to believe that the continued collection raised possible safety concerns or would cause other unintended consequences, we proposed to promptly remove the measure and publish the justification for the removal in the **Federal Register** during the next rulemaking cycle. In addition, we would immediately notify HHAs and the public through the usual communication channels, including listening session, memos, email notification, and Web postings. If we removed a measure under these circumstances, we would also not continue to collect data on that measure under our alternative authorities for purposes other than the HH QRP.

We invited public comment on our proposed policy for retaining, removing and replacing previously adopted quality measures, including the criteria we proposed to use when considering whether to remove a quality measure from the HH QRP

Comment: One commenter expressed support for the proposed criteria to remove or replace measures from the HH QRP and no longer display them on HH Compare. Another commenter expressed concern that the criterion ''performance or improvement on a measure does not result in better patient outcomes'' could be interpreted as equating to functional improvement and exclude patients who need skilled care to maintain function. This commenter also requested clarification of the word ''topic'' in the criterion ''a measure that is more proximal in time to desired patient outcomes for the particular topic is available.''

Response: We appreciate the support for our policy for determining when HH QRP measures should be removed or replaced. We wish to clarify that ''improvement'' on a measure means an improved agency performance score and that better patient outcomes can encompass both functional stabilization and improvement. In addition, we wish to clarify that the word ''topic'' in the referenced criterion refers to the measure focus area, such as pain management.

Final Decision: After consideration of the comments received, we are finalizing our proposed policy on the process for retaining, removing, and replacing previously adopted HH QRP measures.

D. Quality Measures That Will Be Removed From the Home Health Quality Initiative, and Quality Measures That Are Proposed for Removal From the HH QRP Beginning With the CY 2018 Payment Determination

In 2015, we undertook a comprehensive reevaluation of all 81 HH quality measures, some of which are used only in the Home Health Quality Initiative (HHQI) and others that are also used in the HH QRP. This review of all the measures was performed in accordance with the guidelines from the CMS Measure Management System (MMS) (*https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/MMS-Blueprint.html*). The goal of this reevaluation was to streamline the measure set, consistent with MMS guidance and in response to stakeholder feedback. This reevaluation included a review of the current scientific basis for each measure, clinical relevance, usability for quality improvement, and evaluation of measure properties, including reportability and variability. Our measure development and maintenance contractor convened a Technical Expert Panel (TEP) on August 21, 2015, to review, and advise on the reevaluation results. The TEP provided feedback on which measures are most useful for patients, caregivers, clinicians, and stakeholders, and on analytics and an environmental scan conducted to inform measure set revisions. Further information about the TEP feedback is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/Health-Quality-Reporting-Program-HHQRP–TEP-.zip*.

As a result of the comprehensive reevaluation described above, we identified 28 HHQI measures that were either ''topped out'' and/or determined to be of limited clinical and quality improvement value by TEP members. Therefore, these measures will no longer be included in the HHQI. A list of these measures, along with our reasons for no longer including them in the HHQI, can be found at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIQualityMeasures.html*.

In addition, based on the results of the comprehensive reevaluation and the TEP input, we proposed to remove 6 process measures from the HH QRP, beginning with the CY 2018 payment determination, because they are ''topped out'' and therefore no longer have sufficient variability to distinguish between providers in public reporting. These 6 measures are different than the 28 measures that will no longer be included within the HHQI. Items used to calculate one or more of these six measures may still appear on the OASIS for previously established purposes that are not related to the HH QRP.

The 6 process measures we proposed to remove from the HH QRP are:

- Pain Assessment Conducted;
- Pain Interventions Implemented during All Episodes of Care;
- Pressure Ulcer Risk Assessment Conducted;
- Pressure Ulcer Prevention in Plan of Care;
- Pressure Ulcer Prevention Implemented during All Episodes of Care; and
- Heart Failure Symptoms Addressed during All Episodes of Care.

The technical analysis that supported our proposal to remove the six process

measures can be found at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIQualityMeasures.html*.

We invited public comment on the above proposal to remove 6 process measures from the HH QRP.

Comment: We received many comments in favor of the removal of 28 measures from the HHQI and the proposed removal of 6 measures from the HH QRP. MedPAC and other commenters supported removal of measures that were ''topped out'' and limited in their ability to distinguish between providers. One commenter suggested CMS review the National Academy of Medicine's recent report to help identify high priority measures for a smaller measure set, while another suggested a dashboard of measures aligned across home health quality initiatives, including star ratings, Home Health Compare and the home health value-based purchasing demonstration. Some commenters recommended that removed measures be replaced by claims-based measures that can be independently verified, outcome measures or measures of patient stabilization. One commenter opposed removal of the Improvement in Grooming, Improvement in Toileting Hygiene, Improvement in Light Meal Preparation, and Improvement in Phone Use measures from the HHQI, citing these as important indicators of safety at home; the commenter also stressed the importance of fall prevention. Another commenter requested that CMS seek additional stakeholder input before removing measures. A few commenters requested that information for removed measures continue to be collected and made available to agencies for quality improvement purposes. One commenter recommended that CMS monitor removed topped out measures to assure that quality does not decrease. One commenter recommended that the measures be removed from the CASPER reporting system as well, while another requested removal from OASIS.

Response: We appreciate the support from MedPAC and other commenters for a more focused measure set. We wish to clarify that the data for the measures no longer included in the HHQI or removed from the HH QRP may still appear on OASIS for previously established purposes that are not related to our HH QRP, and if still collected will be available to home health agencies, via the CASPER on-demand reports, for the purpose of monitoring and improving quality efforts.

Final Decision: After consideration of the comments we received, we are finalizing our proposal to remove 6 process measures from the HH QRP.

E. Process for Adoption of Updates to HH QRP Measures

We believe that it is important to have in place a subregulatory process to incorporate non-substantive updates into the measure specifications so that these measures remain up-to-date. We also recognize that some changes are substantive and might not be appropriate for adoption using a subregulatory process.

Therefore, in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53504 and 53505), we finalized a policy for the Hospital IQR Program under which we use a subregulatory process to make nonsubstantive updates to measures used for that program. For what constitutes substantive versus nonsubstantive changes, we make this determination on a case-by-case basis. Examples of nonsubstantive changes to measures might include: Updated diagnosis or procedure codes, medication updates for categories of medications, broadening of age ranges, and exclusions for a measure. Nonsubstantive changes may also include updates to NQF-endorsed measures based upon changes to guidelines upon which the measures are based. Examples of changes that we might consider to be substantive would be those in which: The changes are so significant that the measure is no longer the same measure, or when a standard of performance assessed by a measure becomes more stringent (for example, changes in acceptable timing of medication, procedure/process, or test administration). Another example of a substantive change might be where the NQF has extended its endorsement of a previously endorsed measure to a new setting, such as extending a measure from the inpatient setting to hospice.

We proposed to implement the same process for adopting updates to measures in the HH QRP, and to apply this process, including our policy for determining on a case-by-case basis whether an update is substantive or nonsubstantive. We believe this process adequately balances our need to incorporate updates to the HH QRP measures in the most expeditious manner possible while preserving the public's ability to comment on updates that do not fundamentally change a measure that it is no longer the same measure that we originally adopted.

We invited public comment on this proposal. We received no comments on this proposal.

Final Decision: We are finalizing our proposed process for adopting updates to HH QRP measures as proposed.

F. Modifications to Guidance Regarding Assessment Data Reporting in the OASIS

We proposed modifications to our coding guidance related to certain pressure ulcer items on the OASIS. In the CY 2016 HH PPS final rule (80 FR 68700), we adopted the NQF #0678 Percent of Residents or Patients with Pressure Ulcers that are New or Worsened (Short Stay) measure for use in the HH QRP for the CY 2018 HH QRP payment determination and subsequent years. Concurrent with the effective date for OASIS–C2 of January 1, 2017, we will use this modified guidance for the reporting of current pressure ulcers. The purpose of this modification is to align with reporting guidance used in other post-acute care settings and with the policies of relevant clinical associations. Chapter 3 of the OASIS–C1/ICD–10 Guidance Manual currently states ''Stage III and IV (full thickness) pressure ulcers heal through a process of contraction, granulation, and epithelialization. They can never be considered 'fully healed' but they can be considered closed when they are fully granulated and the wound surface is covered with new epithelial tissue.'' We utilize professional organizations, such as the National Pressure Ulcer Advisory Panel (NPUAP) to provide clinical insight and expertise related to the use and completion of relevant OASIS items. Based on the currently published position statements and best practices available from the NPUAP,[20] effective January 1, 2017, full-thickness (Stage 3 or 4) pressure ulcers should not be reported on OASIS as unhealed pressure ulcers once complete re-epithelialization has occurred. This represents a change in past guidance, and will allow OASIS data collection to conform to professional clinical guidelines, and align with pressure ulcer reporting practices in other post-acute care settings. In addition to revising guidance related to closed Stage 3 and 4 pressure ulcers, we are changing the reporting instructions when a graft is applied to a pressure ulcer. Current guidance states that when a graft is placed on a pressure ulcer, the wound remains a pressure ulcer and is not concurrently reported as a surgical wound on the OASIS. To align with reporting guidance in other post-acute care settings, effective January 1, 2017, once a graft is applied to a pressure

[20] *http://www.npuap.org/wp-content/uploads/2012/01/Reverse-Staging-Position-Statement.pdf.*

ulcer, the wound will be reported on OASIS as a surgical wound, and no longer be reported as a pressure ulcer.

The following is a summary of the comments we received regarding our proposal for new pressure ulcer guidelines.

Comment: We received two comments addressing the proposal for new pressure ulcer coding guidelines, effective January 1, 2017. One commenter concurred that full thickness (Stage 3 or 4) pressure ulcers should not be reported as unhealed once re-epithelialized, but did not agree that once a graft is applied to a pressure ulcer, the wound should be reported as a surgical wound instead of a pressure ulcer. This commenter suggested that CMS clearly specify which grafts change the classification of a pressure ulcer to a surgical wound. The commenter also suggested that ''urinary diversions'' and ''arterial ulcers exempt from the stasis ulcer category'' be added to the OASIS item set for the purpose of adding case mix points. Another commenter noted the pressure ulcer related guidance and item changes would cause confusion and require extensive re-education and review of every comprehensive assessment, thus resulting in an administrative and clinician burden with risk for error. They added that caring for these ulcers without adequate reimbursement could result in poor patient outcomes and quality measure scores.

Response: We appreciate the comments and suggestions. These proposals were made to allow OASIS data collection to conform to professional clinical guidelines, and align with pressure ulcer reporting practices in other post-acute care settings to support cross-setting quality measurement related to pressure ulcers. Additional guidance and ongoing provider support will be available through the OASIS Q&A Help Desk and the OASIS Q&As, both available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/OASIS/HHAQA.html.* After considering the comments received, we are making the changes to this measure as proposed.

G. HH QRP Quality, Resource Use, and Other Measures for the CY 2018 Payment Determination and Subsequent Years

For the CY 2018 payment determination and subsequent years, in addition to the quality measures we stated that we would retain if our proposed policy on retaining measures is finalized, we proposed to adopt four new measures. These four measures were developed to meet the requirements of the IMPACT Act. These measures are:

- MSPB–PAC HH QRP;
- Discharge to Community–PAC HH QRP;
- Potentially Preventable 30-Day Post-Discharge Readmission Measure for HH QRP; and
- Drug Regimen Review Conducted with Follow-Up for Identified Issues–PAC HH QRP.

For the risk-adjustment of the resource use and other measures, we understand the important role that sociodemographic status plays in the care of patients. However, we continue to have concerns about holding agencies to different standards for the outcomes of their patients of diverse sociodemographic status because we do not want to mask potential disparities or minimize incentives to improve the outcomes of disadvantaged populations. We routinely monitor the impact of sociodemographic status on agencies' results on our measures.

The NQF is currently undertaking a 2-year trial period in which new measures and measures undergoing maintenance review will be assessed to determine if risk-adjusting for sociodemographic factors is appropriate. For 2 years, NQF will conduct a trial of temporarily allowing inclusion of sociodemographic factors in the risk-adjustment approach for some performance measures. At the conclusion of the trial, NQF will issue recommendations on future permanent inclusion of sociodemographic factors. During the trial, measure developers are expected to submit information such as analyses and interpretations, as well as performance scores with and without sociodemographic factors in the risk adjustment model.

Furthermore, ASPE is conducting research to examine the impact of sociodemographic status on quality measures, resource use, and other measures under the Medicare program as directed by the IMPACT Act. We will closely examine the findings of the ASPE reports and related Secretarial recommendations and consider how they apply to our quality programs at such time as they are available.

1. Measure That Addresses the IMPACT Act Domain of Resource Use and Other Measures: MSPB–PAC HH QRP

We proposed an MSPB–PAC HH QRP measure for inclusion in the HH QRP for the CY 2018 payment determination and subsequent years. Section 1899B(d)(1)(A) of the Act requires the Secretary to specify resource use measures, including total estimated Medicare spending per beneficiary, on which PAC providers consisting of SNFs, IRFs, LTCHs, and HHAs are required to submit necessary data specified by the Secretary. Rising Medicare expenditures for post-acute care, as well as wide variation in spending for these services, underlines the importance of measuring resource use for providers rendering these services. Between 2001 and 2013, Medicare PAC spending grew at an average annual rate of 6.1 percent and doubled to $59.4 billion, while payments to inpatient hospitals grew at an annual rate of 1.7 percent over this same period.[21] A study commissioned by the Institute of Medicine found that variation in PAC spending explains 73 percent of variation in total Medicare spending across the United States.[22]

We reviewed the NQF's consensus-endorsed measures and were unable to identify any NQF-endorsed resource use measures for PAC settings. Therefore, we proposed to adopt this MSPB–PAC HH QRP measure under section 1899B(e)(2)(B) of the Act, which allows us to specify a measure under section 1899B of the Act that is not NQF-endorsed if the measure deals with a specified area or medical topic the Secretary has determined to be appropriate for which there is no feasible or practical NQF-endorsed measure, and we have given due consideration to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. Given the current lack of resource use measures for PAC settings, our MSPB–PAC HH QRP measure would provide valuable information to HHAs on their relative Medicare spending in delivering services to approximately 3.5 million Medicare beneficiaries.[23]

The MSPB–PAC HH QRP episode-based measure would provide actionable and transparent information to support HHAs' efforts to promote care coordination and deliver high quality care at a lower cost to Medicare. The MSPB–PAC HH QRP measure holds HHAs accountable for the Medicare payments within an ''episode of care'' (episode), which includes the period during which a patient is directly under the HHA's care, as well as a defined period after the end of the HHA treatment, which may be reflective of and influenced by the services

[21] MedPAC, ''A Data Book: Health Care Spending and the Medicare Program,'' (2015). 114.

[22] Institute of Medicine, ''Variation in Health Care Spending: Target Decision Making, Not Geography,'' (Washington, DC: National Academies 2013). 2.

[23] Figures for 2013. MedPAC, ''Medicare Payment Policy,'' Report to the Congress (2015). xvii–xviii.

furnished by the HHA. MSPB–PAC HH QRP episodes, constructed according to the methodology described below, have high levels of Medicare spending with substantial variation. In FY 2014, Medicare FFS beneficiaries experienced 5,379,410 MSPB–PAC HH QRP episodes triggered by admission to a HHA. The mean payment-standardized, risk-adjusted episode spending for these episodes was $10,348 during that fiscal year. There was substantial variation in the Medicare payments for these MSPB–PAC HH QRP episodes—ranging from approximately $2,480 at the 5th percentile to approximately $31,964 at the 95th percentile. This variation was partially driven by variation in payments occurring following HH treatment.

Evaluating Medicare payments during an episode creates a continuum of accountability between providers and has the potential to improve post-treatment care planning and coordination. While some stakeholders throughout the measure development process supported the MSPB–PAC measures and believe that measuring Medicare spending was critical for improving efficiency, others believed that resource use measures did not reflect quality of care in that they do not take into account patient outcomes or experience beyond those observable in claims data. However, we believe that HHAs involved in the provision of high quality PAC care as well as appropriate discharge planning and post-discharge care coordination will perform well on this measure, because beneficiaries will experience fewer costly adverse events (for example, avoidable hospitalizations, infections, and emergency room usage). Furthermore, it is important that the cost of care be explicitly measured so that, in conjunction with other quality measures, we can publicly report HHAs that are involved in the provision of high quality care at lower cost.

We developed an MSPB–PAC measure for each of the four PAC settings. In addition to this measure, we finalized a LTCH-specific MSPB–PAC measure in the FY 2017 IPPS/LTCH final rule (81 FR 57199 through 57207), an IRF-specific MSPB–PAC measure in the FY 2017 IRF PPS final rule (81 FR 52087 through 52095), and a SNF-specific MSPB–PAC measure in the FY 2017 SNF PPS final rule (81 FR 52014 through 52021). These four setting-specific MSPB–PAC measures are aligned to the greatest extent possible, in terms of episode construction and measure calculation given the differences in the payment systems for each setting, and types of patients served in each setting, to ensure the accuracy of the measures in each PAC setting. The setting-specific measures account for differences between settings and between episode types within the home health setting, in payment policy, the types of data available, and the underlying health characteristics of beneficiaries. Each of the MSPB–PAC measures assess Medicare Part A and Part B spending during an episode, and the numerator and denominator are defined as similarly as possible across the MSPB–PAC measures. In recognition of the differences between home health episode types, the MSPB–PAC HH QRP measure compares episodes triggered by Partial Episode Payment (PEP) and Low-Utilization Payment Adjustment (LUPA) claims only with episodes of the same type, as detailed below. A PEP is a pro-rated adjustment for shortened episodes as a result of patient discharge and readmission to the same provider within the same 60-day home health claim, or patient transfer to another HHA with no common ownership within the same 60-day claim. If a patient is discharged to a hospital, SNF, or IRF, and readmitted to the same HHA within the 60-day claim, a PEP adjustment does not apply. A LUPA adjustment applies where there are four or fewer visits in a home health claim.

The MSPB–PAC measures mirror the general construction of the IPPS hospital MSPB measure, which was adopted for the Hospital IQR Program beginning with the FY 2014 program, and was implemented in the Hospital VBP Program beginning with the FY 2015 program. The measure was endorsed by the NQF on December 6, 2013 (NQF #2158).[24] The hospital MSPB measure evaluates hospitals' Medicare spending relative to the Medicare spending for the national median hospital during a hospital MSPB episode which starts 3 days prior to admission and ends 30-days after discharge. It assesses Medicare Part A and Part B payments for services performed by hospitals and other healthcare providers during a hospital MSPB episode, which comprises the periods immediately prior to, during, and following a patient's hospital inpatient stay.[25] [26] Similarly, the MSPB–PAC measures assess all Medicare Part A and Part B payments for FFS claims with a start date that begins at the episode trigger and continues for the length of the episode window (which, as discussed in this section, is the time period during which Medicare FFS Part A and Part B services are counted towards the MSPB–PAC HH QRP episode). There are differences between the MSPB–PAC measures and the hospital MSPB measure to reflect differences in payment policies and the nature of care provided in each PAC setting. The MSPB–PAC measures exclude a limited set of services determined to be clinically unrelated that are provided to a beneficiary during the episode window while the hospital MSPB measure includes all Part A and Part B services and does not exclude services based on clinical relatedness.[27]

As noted above, the hospital-level MSPB measure includes a period spanning from three days prior to a hospitalization through 30 days post-discharge. MSPB–PAC episodes may begin within 30 days of discharge from an inpatient hospital, as part of a patient's trajectory from an acute to a PAC setting. A home health episode beginning within 30 days of discharge from an inpatient hospital would therefore be included: Once in the hospital's MSPB measure; and once in the HHA's MSPB–PAC measure. Aligning the hospital MSPB and MSPB–PAC measures in this way creates continuous accountability and aligns incentives to improve care planning and coordination across inpatient and PAC settings.

We sought and considered the input of stakeholders throughout the measure development process for the MSPB–PAC measures. We convened a TEP consisting of 12 panelists with combined expertise in all of the PAC settings on October 29 and 30, 2015, in Baltimore, Maryland. A follow-up email survey was sent to TEP members on November 18, 2015, to which 7 responses were received by December 8, 2015. The MSPB–PAC TEP Summary Report is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/Technical-Expert-Panel-on-Medicare-Spending-Per-Beneficiary.pdf*. The measures were also presented to the MAP Post-Acute Care/Long-Term Care (PAC/LTC) Workgroup on December 15, 2015. As the MSPB–PAC measures were under development, there were three voting

[24] QualityNet, ''Measure Methodology Reports: Medicare Spending Per Beneficiary (MSPB) Measure,'' (2015). *http://www.qualitynet.org/dcs/ContentServer?pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228772053996*.

[25] QualityNet, ''Measure Methodology Reports: Medicare Spending Per Beneficiary (MSPB) Measure,'' (2015). *http://www.qualitynet.org/dcs/ContentServer?pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228772053996*

[26] FY 2012 IPPS/LTCH PPS final rule (76 FR 51619).

[27] FY 2012 IPPS/LTCH PPS final rule (76 FR 51620).

options for members: Encourage continued development, do not encourage further consideration, and insufficient information.[28] The MAP PAC/LTC Workgroup voted to ''encourage continued development'' for each of the MSPB–PAC measures.[29] The MAP PAC/LTC Workgroup's vote of ''encourage continued development'' was affirmed by the MAP Coordinating Committee on January 26, 2016.[30] The MAP's concerns about the MSPB–PAC measures, as outlined in its final report, ''MAP 2016 Considerations for Implementing Measures in Federal Programs: Post-Acute Care and Long-Term Care,'' and Spreadsheet of Final Recommendations were taken into consideration during our measure development process and are discussed as part of our responses to public comments we received during the measure development process, described below.[31] [32]

Since the MAP's review and recommendation of continued development, we have continued to refine the risk adjustment model and conduct measure testing for the MSPB–PAC measures. The MSPB–PAC measures are both consistent with the information submitted to the MAP and support the scientific acceptability of these measures for use in quality reporting programs.

In addition, a public comment period, accompanied by draft measures specifications, was originally open from January 13 to 27, 2016 and extended to February 5. A total of 45 comments on the MSPB–PAC measures were received during this 3.5 week period. The comments received also covered each of the MAP's concerns as outlined in their Final Recommendations.[33] The MSPB–PAC Public Comment Summary Report is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/2016_03_24_mspb_pac_public_comment_summary_report.pdf* and the MSPB–PAC Public Comment Supplementary Materials are available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/2016_03_24_mspb_pac_public_comment_summary_report_supplementary_materials.pdf*. These documents contain the public comments (summarized and verbatim), along with our responses including statistical analyses. The MSPB–PAC HH QRP measure, along with the other MSPB–PAC measures, as applicable, will be submitted for NQF endorsement when feasible.

To calculate the MSPB–PAC HH QRP measure for each HHA, we first define the construction of the MSPB–PAC HH QRP episode, including the length of the episode window as well as the services included in the episode. Next, we apply the methodology for the measure calculation. The specifications are discussed further in this section. More detailed specifications for the MSPB–PAC measures, including the MSPB–PAC HH QRP measure in this rule, are available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIQualityMeasures.html*.

a. Episode Construction

We proposed that an MSPB–PAC HH QRP episode would begin at the episode trigger, which is defined as the first day of a patient's home health claim with a HHA. This admitting HHA is the provider for whom the MSPB–PAC HH QRP measure is calculated (that is, the attributed provider). The episode window is the time period during which Medicare FFS Part A and Part B services are counted towards the MSPB–PAC HH QRP episode. Because Medicare FFS claims are already reported to the Medicare program for payment purposes, HHAs will not be required to report any additional data to CMS for calculation of this measure. Thus, there will be no additional data collection burden from the implementation of this measure.

Our MSPB–PAC HH QRP episode construction methodology differentiates between episodes triggered by standard HH claims (for which there is no PEP or LUPA adjustment) and claims for which PEP and LUPA adjustments apply, reflecting the HH PPS payment policy. MSPB–PAC HH Standard, PEP, and LUPA episodes would be compared only with MSPB–PAC HH Standard, PEP, and LUPA episodes, respectively. Differences in episode construction between these three episode types are noted below; they otherwise share the same definition.

We proposed that the episode window would be comprised of a treatment period and an associated services period.

The definition of the treatment period depends on the type of MSPB–PAC HH QRP episode. For MSPB–PAC HH Standard and LUPA QRP episodes, the treatment period begins at the episode trigger (that is, on the first day of the home health claim) and ends after 60 days after the episode trigger. For MSPB–PAC HH PEP QRP episodes, the treatment period begins at the episode trigger (that is, on the first day of the home health claim) and ends at discharge. The treatment period includes those services that are provided directly by the HHA.

The associated services period is the time during which Medicare Part A and Part B services that are not treatment services are counted towards the episode, subject to certain exclusions, such as planned admissions and organ transplants that are clinically unrelated services as discussed in detail below. The definition of the associated services period is the same for each of the MSPB–PAC HH QRP episode types: The associated services period begins at the episode trigger and ends 30 days after the end of the treatment period. The length of the episode window varies between episode types: since the treatment period for the MSPB–PAC HH Standard and LUPA QRP episodes is defined as being 60 days from the episode trigger, the length of the episode window—that is, treatment period plus associated services period—will be a total of 90 days. In contrast, as the treatment period for MSPB–PAC HH PEP QRP episodes is defined as being from the episode trigger to discharge, the length of the episode window will vary depending on the length of time that the patient is under the care of the HHA.

Certain services are excluded from the MSPB–PAC HH QRP episodes because they are clinically unrelated to HHA care, and/or because HHAs may have limited influence over certain Medicare

[28] National Quality Forum, Measure Applications Partnership, ''Process and Approach for MAP Pre-Rulemaking Deliberations, 2015–2016'' (February 2016) *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81693*.

[29] National Quality Forum, Measure Applications Partnership Post-Acute Care/Long-Term Care Workgroup, ''Meeting Transcript—Day 2 of 2'' (December 15, 2015) 104–106 *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81470*.

[30] National Quality Forum, Measure Applications Partnership, ''Meeting Transcript—Day 1 of 2'' (January 26, 2016) 231–232 *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81637*.

[31] National Quality Forum, Measure Applications Partnership, ''MAP 2016 Considerations for Implementing Measures in Federal Programs: Post-Acute Care and Long-Term Care'' Final Report, (February 2016) *http://www.qualityforum.org/Publications/2016/02/MAP_2016_Considerations_for_Implementing_Measures_in_Federal_Programs_-_PAC-LTC.aspx*.

[32] National Quality Forum, Measure Applications Partnership, ''Spreadsheet of MAP 2016 Final Recommendations'' (February 1, 2016) *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81593*.

[33] National Quality Forum, Measure Applications Partnership, ''Spreadsheet of MAP 2016 Final Recommendations'' (February 1, 2016) *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81593*.

services delivered by other providers during the episode window. These limited service-level exclusions are not counted towards a given HHA's Medicare spending to ensure access to care for beneficiaries with certain conditions and complex care needs. Certain services that have been determined by clinicians to be outside of the control of a HHA include: planned hospital admissions; management of certain preexisting chronic conditions (for example, dialysis for end-stage renal disease (ESRD) and enzyme treatments for genetic conditions); treatment for preexisting cancers; organ transplants; and preventive screenings (for example, colonoscopy and mammograms). Exclusion of such services from the MSPB–PAC HH QRP episode ensures that facilities do not appear more expensive due to these services and do not have disincentives to treat patients with certain conditions or complex care needs.

An MSPB–PAC episode may begin during the post-treatment associated services period of an MSPB–PAC HH QRP episode, that is, during the 30 days after the end of the treatment period as defined above for the different MSPB–PAC HH QRP episode types. One possible scenario occurs where a beneficiary leaves the care of the HHA and is then admitted to a SNF within 30 days (that is, during the post-treatment phase of the associated services period

The SNF claim would be included once as an associated service for the attributed provider of the first MSPB–PAC HH QRP episode and once as a treatment service for the attributed provider of the second MSPB–PAC SNF QRP episode. As in the case of overlap between hospital and PAC episodes discussed earlier, this overlap is necessary to ensure continuous accountability between providers throughout a beneficiary's trajectory of care, as both providers share incentives to deliver high quality care at a lower cost to Medicare. Even within the HH setting, one MSPB–PAC HH QRP episode may begin in the post-treatment associated services period of another MSPB–PAC HH QRP episode, that is, during the 30 days after the end of the treatment period. The second HH claim would be included once as an associated service for the attributed HHA of the first MSPB–PAC HH QRP episode and once as a treatment service for the attributed HHA of the second MSPB–PAC HH QRP episode. Again, this ensures that HHAs have the same incentives throughout both MSPB–PAC HH QRP episodes to deliver quality care and engage in patient-focused care planning and coordination. If the second MSPB–PAC HH QRP episode were excluded from the second HHA's MSPB–PAC HH QRP measure, that HHA would not share the same incentives as the first HHA of the first MSPB–PAC HH QRP episode. If a patient transfers from one HHA to another during the standard 60-day home health claim (for example, after 30 days), this first home health claim would be subject to a PEP adjustment in accordance with the HH PPS. This PEP claim would trigger an MSPB–PAC HH PEP QRP episode, and since the treatment period for an MSPB–PAC HH PEP QRP episode ends at discharge, the second MSPB–PAC HH QRP episode (of any type) would begin during the associated services period of the MSPB–PAC HH PEP QRP episode.

The MSPB–PAC HH QRP measure was designed to benchmark the resource use of each attributed provider against what their spending is expected to be as predicted through risk adjustment. As discussed further below, the measure takes the ratio of observed spending to expected spending for each episode and then takes the average of those ratios across all of the attributed provider's episodes. The measure is not a simple sum of all costs across a provider's episodes, thus mitigating concerns about double counting.

b. Measure Calculation

Medicare payments for Part A and Part B claims for services included in MSPB–PAC HH QRP episodes, defined according to the methodology previously discussed are used to calculate the MSPB–PAC HH QRP measure. Measure calculation involves determination of the episode exclusions, the approach for standardizing payments for geographic payment differences, the methodology for risk adjustment of episode spending to account for differences in patient case mix, and the specifications for the measure numerator and denominator. The measure calculation is performed separately for MSPB–PAC HH Standard, PEP, and LUPA QRP episodes to ensure that they are compared only to other MSPB–PAC HH Standard, PEP, and LUPA episodes, respectively. The final MSPB–PAC HH QRP measure is the episode-weighted average of the average scores for each type of episode, as described below.

(1) Exclusion Criteria

In addition to service-level exclusions that remove some payments from individual episodes, we exclude certain episodes in their entirety from the MSPB–PAC HH QRP measure to ensure that the MSPB–PAC HH QRP measure accurately reflects resource use and facilitates fair and meaningful comparisons between HHAs. The episode-level exclusions are as follows:

- Any episode that is triggered by a HH claim outside the 50 states, DC, Puerto Rico, and U.S. territories.
- Any episode where the claim(s) constituting the attributed HHA provider's treatment have a standard allowed amount of zero or where the standard allowed amount cannot be calculated.
- Any episode in which a beneficiary is not enrolled in Medicare FFS for the entirety of a 90-day lookback period (that is, a 90-day period prior to the episode trigger) plus episode window (including where a beneficiary dies), or is enrolled in Part C for any part of the lookback period plus episode window.
- Any episode in which a beneficiary has a primary payer other than Medicare for any part of the 90-day lookback period plus episode window.
- Any episode where the claim(s) constituting the attributed HHA provider's treatment include at least one related condition code indicating that it is not a prospective payment system bill.

(2) Standardization and Risk Adjustment

Section 1899B(d)(2)(C) of the Act requires that the MSPB–PAC measures be adjusted for the factors described under section 1886(o)(2)(B)(ii) of the Act, which include adjustment for factors such as age, sex, race, severity of illness, and other factors that the Secretary determines appropriate. Medicare payments included in the MSPB–PAC HH QRP measure are payment-standardized and risk-adjusted. Payment standardization removes sources of payment variation not directly related to clinical decisions and facilitates comparisons of resource use across geographic areas. We proposed to use the same payment standardization methodology as that used in the NQF-endorsed hospital MSPB measure. This methodology removes geographic payment differences, such as wage index and geographic practice cost index (GPCI), incentive payment adjustments, and other add-on payments that support broader Medicare program goals including indirect graduate medical education (IME) and hospitals serving a disproportionate share of uninsured patients (DSH).[34]

[34] QualityNet, ''CMS Price (Payment) Standardization—Detailed Methods'' (Revised May 2015) *https://qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier4&cid=1228772057350.*

Risk adjustment uses patient claims history to account for case-mix variation and other factors that affect resource use but are beyond the influence of the attributed HHA. As part of the risk adjustment methodology for MSPB–PAC HH QRP episodes, we adjust for demographics (through age brackets) at the time of the episode trigger and using diagnostic information in the recent past, up to the start of the episode. To assist with risk adjustment for MSPB–PAC HH QRP episodes, we create mutually exclusive and exhaustive clinical case mix categories using the most recent institutional claim in the 60 days prior to the start of the MSPB–PAC HH QRP episode. The beneficiaries in these clinical case mix categories have a greater degree of clinical similarity than the overall HH patient population, and allow us to more accurately estimate Medicare spending. Our MSPB–PAC HH QRP model, adapted for the HH setting from the NQF-endorsed hospital MSPB measure, uses a regression framework with a 90-day hierarchical condition category (HCC) lookback period and covariates including the clinical case mix categories, HCC indicators, age brackets, indicators for originally disabled, ESRD enrollment, and long-term care status, and selected interactions of these covariates where sample size and predictive ability make them appropriate. During the public comment period that ran from January 13 to February 5, 2016 discussed above, we sought and considered public comment regarding the treatment of hospice services occurring within the MSPB–PAC HH QRP episode window. Given the comments received, we proposed to include the Medicare spending for hospice services but risk adjust for them, such that MSPB–PAC HH QRP episodes with hospice are compared to a benchmark reflecting other MSPB–PAC HH QRP episodes with hospice. We believe that this provides a balance between the measure's intent of evaluating Medicare spending and ensuring that providers do not have incentives against the appropriate use of hospice services in a patient-centered continuum of care.

As noted previously, we understand the important role that sociodemographic status, beyond age, plays in the care of patients. However, we continue to have concerns about holding providers to different standards for the outcomes of their patients of diverse sociodemographic status because we do not want to mask potential disparities or minimize incentives to improve the outcomes of disadvantaged populations. We will monitor the impact of sociodemographic status on providers' results on our measures.

The NQF is currently undertaking a 2-year trial period in which new measures and measures undergoing maintenance review will be assessed to determine if risk-adjusting for sociodemographic factors is appropriate. For 2 years, NQF will conduct a trial of temporarily allowing inclusion of sociodemographic factors in the risk-adjustment approach for some performance measures. At the conclusion of the trial, NQF will issue recommendations on future permanent inclusion of sociodemographic factors. During the trial, measure developers are expected to submit information such as analyses and interpretations as well as performance scores with and without sociodemographic factors in the risk adjustment model.

Furthermore, ASPE is conducting research to examine the impact of sociodemographic status on quality measures, resource use, and other measures under the Medicare program as required under the IMPACT Act. We will closely examine the findings of the ASPE reports and related Secretarial recommendations and consider how they apply to our quality programs at such time as they are available.

While we conducted analyses on the impact of age by sex on the performance of the MSPB–PAC HH QRP risk-adjustment model and proposed to adjust by age brackets as a demographic factor, we did not propose to adjust the MSPB–PAC HH measure for socioeconomic factors. As this MSPB–PAC HH QRP measure will be submitted to the NQF for consideration of endorsement, we prefer to await the results of this trial and study before deciding whether to risk adjust for socioeconomic and demographic factors. We will monitor the results of the trial, studies, and recommendations. We invited public comment on how socioeconomic and demographic factors should be used in risk adjustment for the MSPB–PAC HH QRP measure.

The comments we received on this topic, with their responses, appear below.

Comment: Several commenters recommended that the risk adjustment model for the MSPB–PAC HH QRP measure include variables for SES/SDS factors. A commenter recommended that a ''fairer'' approach than using SES/SDS factors as risk adjustment variables would be to compare resource use levels that have not been adjusted for SES/SDS factors across peer providers (that is, providers with similar shares of beneficiaries with similar SES characteristics).

Response: We refer readers to section V.G. where we also discuss these topics.

Comment: Several commenters recommended that additional variables be included in risk adjustment to better capture clinical complexity. A few commenters suggested the inclusion of functional status and other patient assessment data. Commenters recommended that additional variables should include obesity, amputations, CVAs (hemiplegia/paresis), and ventilator status. Some commenters recommended that caregiver support be included in the risk adjustment model. One commenter recommended accounting for medical and post-surgical patients. One commenter recommended excluding high-cost and outlier patients, and a few commenters requested data be made available to stakeholders to allow them to evaluate predictors of spending.

Response: We thank the commenters for their suggestions. The risk adjustment model includes HCC indicators to account for amputations, hemiplegia, and paresis. We believe that the other risk adjustment variables adequately adjust for ventilator dependency and obesity through variables for HCCs, clinical case mix categories, and prior inpatient and ICU length of stay. We account for medical and post-surgical patients through clinical case mix categories which distinguish between beneficiaries coming to the HHA from a prior medical or surgical stay. The clinical case mix category for prior inpatient medical stays is further broken down into ICU and non-ICU stays, and the clinical case mix category for prior inpatient surgical stays is further broken down into orthopedic and non-orthopedic stays. We believe that our risk adjustment model and measure calculation accounts for high-cost and outlier patients; further details can be found in the MSPB–PAC Measure Specifications, a link for which has been provided above. Details on the coefficients of the MSPB–PAC risk adjustment models are provided in the MSPB–PAC Public Comment Supplementary Materials, a link for which has been provided above.

We understand the commenter's view of the importance of caregiver support for ensuring a successful outcome. We note that the MSPB–PAC HH QRP measure is based upon claims data, which does not include data on the availability of family or caregiver support. We considered the potential use of information about caregiver support in the risk adjustment model for the MSPB–PAC HH QRP measure.

However, as noted in the MSPB–PAC Public Comment Summary Report, a link for which has been provided above, even where non-claims data on caregiver support are available; there may be inherent subjectivity in determining the availability of such support. More details of the MSPB–PAC HH QRP risk adjustment model are provided in the MSPB–PAC Measure Specifications, and the coefficients for the MSPB–PAC risk adjustment models are included in the MSPB–PAC Public Comment Supplementary Materials; the links for these documents have been provided above.

We recognize the importance of accounting for beneficiaries' functional and cognitive status in the calculation of predicted episode spending. We considered the potential use of functional status information in the risk adjustment models for the MSPB–PAC measures. As with the caregiver support information discussed above, we decided to not include information derived from current setting-specific assessment instruments given that we are migrating towards standardized data as mandated by the IMPACT Act. We will revisit the inclusion of functional status in these measures' risk adjustment models in the future when the standardized functional status data mandated by the IMPACT Act-mandated become available. Once they are available, we will take a gradual and systematic approach in evaluating how they might be incorporated. We intend to implement any changes if appropriate based on testing.

(3) Measure Numerator and Denominator

The MPSB–PAC HH QRP measure is a payment-standardized, risk-adjusted ratio that compares a given HHA's Medicare spending against the Medicare spending of other HHAs within a performance period. Similar to the hospital MSPB measure, the ratio allows for ease of comparison over time as it obviates the need to adjust for inflation or policy changes.

The MSPB–PAC HH QRP measure is calculated as the ratio of the MSPB–PAC Amount for each HHA divided by the episode-weighted median MSPB–PAC Amount across all HHAs. To calculate the MSPB–PAC Amount for each HHA, calculate the average of the ratio of the standardized spending for HH Standard episodes over the expected spending (as predicted in risk adjustment) for HH Standard episodes, the average of the ratio of the standardized spending for HH PEP episodes over the expected spending (as predicted in risk adjustment) for HH PEP episodes, and the average of the ratio of the standardized spending for HH LUPA episodes over the expected spending (as predicted in risk adjustment) for HH LUPA episodes. This quantity is then multiplied by the average episode spending level across all HHAs nationally for Standard, PEP, and LUPA episodes. The denominator for a HHA's MSPB–PAC HH QRP measure is the episode-weighted national median of the MSPB–PAC Amounts across all HHAs. An MSPB–PAC HH QRP measure of less than 1 indicates that a given HHA's Medicare spending is less than that of the national median HHA during a performance period. Mathematically, this is represented in equation (A):

$$(A)\ \ MSPB\text{-}PAC\ HH\ Measure_j = \frac{MSPB\text{-}PAC\ Amount_j}{National\ Median\ MSPB\text{-}PAC\ Amount}$$

$$= \frac{\left(\frac{1}{n_j}\sum_{i\in\{I_j\}}\frac{Y_{ij}}{\widehat{Y_{ij}}}\right)\left(\frac{1}{n}\sum_j\sum_{i\in\{I_j\}}Y_{ij}\right)}{Episode\text{-}Weighted\ Median\ of\ HHA\ Providers'\ MSPB\text{-}PAC\ Amount}$$

Where:

Y_{ij} = attributed standardized spending for episode i and provider j

$\hat{Y}_{ij}$ = expected standardized spending for episode i and provider j, as predicted from risk adjustment

n_j = number of episodes for provider j

n = total number of episodes nationally

$i \in \{I_j\}$ = all episodes i in the set of episodes attributed to provider j.

a. Data Sources

The MSPB–PAC HH QRP resource use measure is an administrative claims-based measure. It uses Medicare Part A and Part B claims from FFS beneficiaries and Medicare eligibility files. The claims are payment standardized to adjust for geographic and other differences, as discussed above.

b. Cohort

The measure cohort includes Medicare FFS beneficiaries with a HH treatment period ending during the data collection period.

c. Reporting and Reliability

We intend to provide initial confidential feedback to providers, prior to public reporting of this measure, based on Medicare FFS claims data from discharges in CY 2016. We intend to publicly report this measure using claims data from discharges in CY 2017. We proposed to use a minimum of 20 episodes for reporting and inclusion in the HH QRP. For the reliability calculation, as described in the measure specifications provided above, we used data from FY 2014. The reliability results support the 20 episode case minimum, and 94.27 percent of HHAs had moderate or high reliability (above 0.4).

The comments we received on this topic, with their responses, appear below.

Comment: Several commenters believed that the MSPB–PAC HH QRP treatment period should end at discharge, rather than 60 days after the episode trigger. A few commenters expressed concern about double-counting services through overlapping MSPB–PAC HH QRP episodes. A commenter recommended collapsing consecutive MSPB–PAC HH QRP episodes into one episode to better account for the treatment of chronically ill patients.

Response: We appreciate the commenters' feedback. The length of the MSPB–PAC HH QRP treatment period is 60 days for standard episodes to reflect that HHAs are paid under the HH PPS at a rate based on a 60-day period as determined by the Home Health Resource Groups (HHRGs), regardless of when the last visit actually takes place. Defining the MSPB–PAC HH QRP treatment period based on the relevant Medicare payment policy aligns with

the definition of the treatment periods for the other MSPB–PAC measures. Allowing an MSPB–PAC HH QRP episode to begin during the post-treatment associated services period of another MSPB–PAC HH QRP episode ensures that HHAs have continuous accountability and aligned incentives throughout a beneficiary's care trajectory. We note that the MSPB–PAC HH QRP measure is not a simple sum of spending across an HHA's episodes, mitigating concerns about double-counting. Instead, the construction of the numerator and denominator is such that the ratio of observed and predicted episode spending are averaged across all of a given providers' episodes. That is, the MSPB–PAC HH QRP measure compares the observed and expected episode spending levels for each of the MSPB–PAC HH QRP episode types (that is, Standard, PEP, and LUPA episodes) to generate the provider score. As noted in the MSPB–PAC Measure Specifications, a link for which has been provided above, patient characteristics and treatment regimens can change significantly during long sequences of consecutive home health claims. Allowing each home health claim to trigger a new episode promotes the accuracy of predicted MSPB–PAC HH QRP episode spending by using the most recent patient information for each claim in the risk adjustment model.

Comment: Several commenters recommended that a geographic-specific (for example, state or regional) median should be used instead of the national median, citing differences in cost, and patient population.

Response: We appreciate the commenters' input. We proposed to use the same payment standardization methodology as that used in the NQF-endorsed hospital MSPB measure to account for variation in Medicare spending. This methodology removes geographic payment differences, such as wage index and geographic practice cost index (GPCI), incentive payment adjustments, and other add-on payments that support broader Medicare program goals, including indirect graduate medical education (IME) and hospitals serving a disproportionate share of uninsured patients (DSH). Given the use of payment standardization, as well as risk adjustment, calculating PAC provider resource use relative to the national median provider of the same type may also be useful in identifying variation in utilization and encouraging providers to reduce this variation, in accordance with the measures' goals of providing actionable, transparent information to providers. We believe that this approach accounts for the differences that the commenters raise while also maintaining consistency with the NQF-endorsed hospital MSPB measure's methodology for addressing regional variation through payment standardization.

Comment: A few commenters, including MedPAC, recommended the use of uniform single MSPB–PAC measure that could be used to compare providers' resource use across settings, but recognized that we do not have a uniform PPS for all the PAC settings currently. In the absence of a single PAC PPS, they recommended a single MSPB–PAC measure for each setting that could be used to compare providers within a setting. In addition, they recommended that under a single measure, the episode definitions, service inclusions/exclusions, and risk adjustment methods should be the same across all PAC settings.

Response: The four separate MSPB–PAC measures reflect the unique characteristics of each PAC setting and the population they serve. The four setting-specific MSPB–PAC measures are defined as consistently as possible across settings given the differences in the payment systems for each setting, and types of patients served in each setting. We have taken into consideration these differences and aligned the specifications, such as episode definition, service inclusions/exclusions and risk adjustment methods for each setting, to the extent possible while ensuring the accuracy of the measures in each PAC setting.

Each of the measures assess Medicare Part A and Part B spending during the episode window which begins upon admission to the provider's care and ends 30 days after the end of the treatment period. The service-level exclusions are harmonized across settings. The definition of the numerator and denominator is the same across settings. However, specifications differ between settings when necessary to ensure that the measures accurately reflect patient care and align with each setting's payment system. For example, LTCHs and IRFs are paid a stay-level payment based on the assigned MS–LTC–DRG and CMG, respectively, while SNFs are paid a daily rate based on the RUG level and HHA providers are reimbursed based on a fixed 60-day period for standard home health claims. While the definition of the episode window as consisting of a treatment period and associated services period is consistent across settings, including a post-discharge period, the duration of the treatment period varies to reflect how providers are paid under the payment policy in each setting, as discussed above. The duration of the associated services period that ends 30 days after the end of the treatment period is consistent between settings. The MSPB–PAC HH QRP measure distinguishes between episodes triggered by standard home health claims (that is, those to which neither a PEP nor LUPA adjustment applies), and claims subject to a PEP or LUPA adjustment to reflect the provisions of the HH PPS.

There are also differences in services included in consolidated billing for each setting: For example, durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) claims are covered by the LTCH, IRF, and SNF PPSs but are not paid through the HH PPS. This affects the way certain first-day service exclusions related to prior institutional care are defined for each measure. Readmissions of the same patient to the same provider within 7 or fewer days are collapsed into one treatment period for the MSPB–PAC SNF, IRF, and LTCH QRP measures but are not in the MSPB–PAC HH QRP measure. This is due to the existence of many long sequences of consecutive home health claims, during which time patient characteristics and care regimens can change significantly, as discussed above.

We recognize that there is considerable overlap in where beneficiaries are treated for similar PAC needs but believe there are some important differences between the care profiles of certain types of beneficiaries that are difficult to capture in a single measure that performs comparisons across settings.

In addition, the risk adjustment models for the MSPB–PAC measures share the same covariates to the greatest extent possible to account for patient case mix; however, certain settings' measures also incorporate additional setting-specific information where available to increase the predictive power of the risk adjustment models. For example, the MSPB–PAC LTCH QRP risk adjustment model uses MS–LTC–DRGs and Major Diagnostic Categories (MDCs) and the MSPB–PAC IRF QRP model includes Rehabilitation Impairment Categories (RICs). The HH and SNF settings do not have analogous variables that directly reflect a patient's clinical profile.

We will continue to work towards a more uniform measure across settings as we gain experience with these measures, including further research and analysis about comparability of resource use measures across settings for clinically similar patients, different

treatment periods and windows, risk adjustment, service exclusions, and other factors.

Comment: A few commenters expressed concern that the MSPB–PAC HH QRP measure will give incentive to HHAs to avoid medically complex beneficiaries, such as those with chronic conditions like end-stage renal disease (ESRD), which would result in unintended consequences.

Response: To mitigate the risk of creating incentives for HHAs to avoid medically complex beneficiaries, who may be at higher risk for poor outcomes and higher costs, we have included factors related to medical complexity in the risk adjustment methodology for the MSPB–PAC HH QRP measure, including an indicator for ESRD. We also exclude certain services from the MSPB–PAC HH QRP measure that are clinically unrelated to HHA care and/or because HHAs may have limited influence over those services delivered by other providers during the episode window, such as dialysis for ESRD.

Comment: Two commenters expressed support for the MSPB–PAC HH QRP measure; one commenter noted that the MSPB–PAC measures are resource use measures that are not a standalone indicator of quality.

Response: As part of the HH QRP, the MSPB–PAC HH QRP measure will be reported with quality measures; we direct readers to section V.H. for a discussion of quality measures. We believe it is important that the cost of care be explicitly measured so that, in conjunction with other quality measures, we can publicly report which HHAs are involved in the provision of high quality care at lower cost.

Comment: One commenter noted that the MSPB–PAC HH QRP measure is complicated and may be difficult for providers to understand.

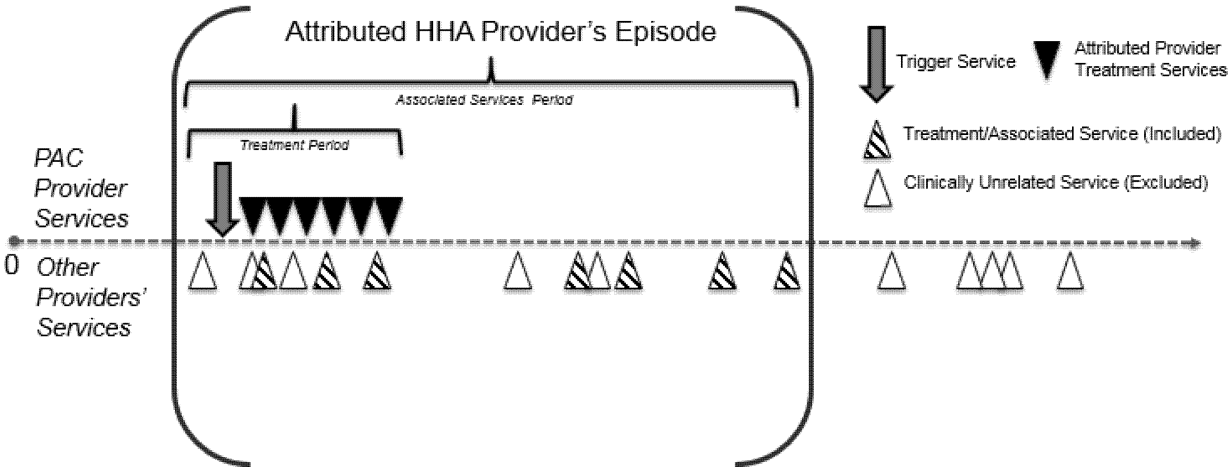
Response: With regard to the concerns regarding the complexity of the measures, we direct readers to the documentation on the MSPB–PAC measures, links for which have been provided above. In particular, the MSPB–PAC Measure Specifications include a high-level summary of the measures and simplified example of the calculation. To further clarify, please see Table 26 and Diagram 1, which further illustrate the MSP–PAC HH QRP measure's construction:

TABLE 26—MSPB–PAC HH QRP EPISODE WINDOWS

Episode type	Treatment period	Associated services period
MSPB–PAC HH Standard ...	• Begins at episode trigger	• Begins at episode trigger.
MSPB–PAC HH LUPA	• Ends 60 days after episode trigger	• Ends 30 days after the end of the treatment period.
MSPB–PAC HH PEP	• Begins at episode trigger	• Begins at episode trigger.
	• Ends at discharge	• Ends 30 days after the end of the treatment period.

This concept of an episode window consisting of a treatment period and associated services period is illustrated below in Figure 1.

FIGURE 1: MSPB-PAC HH QRP Episode Window



Regarding the commenter's concern about how the MSPB–PAC HH QRP measure will be communicated to providers, we refer readers to section V.G. where we also discuss these topics.

Comment: One commenter suggested that descriptive statistics on the measure scores by provider-level characteristics (for example, rural/urban status and bed size) would be useful to evaluate measure design decisions.

Response: Table 27 shows the MSPB–PAC HH provider scores by provider characteristics, calculated using FY 2014 data.

TABLE 27—MSPB–PAC HH SCORES BY PROVIDER CHARACTERISTIC

Provider characteristic	Number of providers	Mean score	Score percentile						
			1st	10th	25th	50th	75th	90th	99th
All Providers	11,829	0.97	0.47	0.75	0.87	0.97	1.06	1.16	1.48
Urban/Rural:									
Urban	9,798	0.96	0.46	0.74	0.86	0.97	1.06	1.16	1.48
Rural	2,025	0.98	0.52	0.80	0.89	0.98	1.06	1.15	1.48
Unknown	6	0.94	0.76	0.76	0.79	0.97	1.06	1.07	1.07
Ownership Type:									
For profit	9,360	0.97	0.46	0.74	0.86	0.97	1.07	1.17	1.48
Non-profit	1,856	0.96	0.54	0.80	0.89	0.96	1.02	1.10	1.47
Government	613	0.97	0.42	0.76	0.87	0.96	1.06	1.19	1.64
Census Division:									
New England	354	0.98	0.37	0.79	0.92	0.99	1.06	1.13	2.08
Middle Atlantic	541	0.96	0.24	0.77	0.90	0.97	1.06	1.14	1.46
East North Central	2,432	0.95	0.43	0.72	0.84	0.95	1.06	1.15	1.54
West North Central	746	0.98	0.42	0.74	0.87	0.97	1.06	1.20	1.64
South Atlantic	2,008	1.02	0.55	0.85	0.93	1.02	1.11	1.20	1.45
East South Central	439	1.03	0.65	0.89	0.97	1.03	1.10	1.17	1.34
West South Central	3,234	0.95	0.51	0.73	0.84	0.95	1.06	1.16	1.45
Mountain	698	0.97	0.46	0.77	0.88	0.97	1.07	1.16	1.63
Pacific	1,330	0.92	0.52	0.74	0.83	0.92	1.00	1.09	1.34
Other	47	0.80	0.56	0.67	0.74	0.79	0.85	0.92	1.06
No. of Episodes:									
0–99	3,395	0.92	0.30	0.60	0.75	0.90	1.06	1.24	1.89
100–249	3,011	0.96	0.65	0.77	0.86	0.96	1.05	1.15	1.34
250–499	2,523	0.98	0.70	0.82	0.89	0.97	1.06	1.14	1.28
500–1000	1,665	1.00	0.75	0.87	0.93	1.00	1.07	1.14	1.29
1000 +	1,235	1.02	0.81	0.91	0.96	1.01	1.08	1.15	1.28

Final Decision

After careful consideration of the public comments, we are finalizing our proposal to adopt the measure, Medicare Spending Per Beneficiary—Post Acute Care for the Home Health Quality Reporting Program, beginning with the CY 2018 HH QRP, as proposed. A link for the MSPB–PAC Measure Specifications has been provided above.

To summarize, we are finalizing the definition of an MSPB–PAC HH QRP episode, beginning from episode trigger. An episode window is comprised of a treatment period beginning at the episode trigger. The treatment periods ends 60 days after the episode trigger for MSPB–PAC HH Standard and LUPA QRP episodes, while the treatment period ends upon discharge for MSPB–PAC HH PEP QRP episodes. The associated services period begins at the episode trigger and ends 30 days after the end of the treatment period for each of the MSPB–PAC HH QRP episodes.

We exclude certain services that are clinically unrelated to HHA care and/or because HHAs may have limited influence over certain Medicare services delivered by other providers during the episode window. We also exclude certain episodes in their entirety from the MSPB–PAC HH QRP measure, such as where a beneficiary is not enrolled in Medicare FFS for the entirety of the lookback period plus episode window.

We are finalizing the inclusion of Medicare payments for Part A and Part B claims for services included in the MSPB–PAC HH QRP episodes to calculate the MSPB–PAC HH QRP measure.

We are finalizing our proposal to risk adjust using covariates including age brackets, HCC indicators, prior inpatient stay length, ICU stay length, clinical case mix categories, indicators for originally disabled, ESRD enrollment, and long-term care status, and hospice claim in episode window. The measure also adjusts for geographic payment differences such as wage index and GPCI, and adjust for Medicare payment differences resulting from IME and DSH.

We calculate the individual providers' MSPB–PAC Amount, which is inclusive of MSPB–PAC HH QRP observed episode spending over the expected episode spending as predicted through risk adjustment. MSPB–PAC HH Standard, PEP, and LUPA QRP episode spending is compared only with MSPB–PAC HH Standard, PEP, and LUPA QRP episode spending, respectively. The final MSPB–PAC HH QRP measure is the episode-weighted average of the average scores for each type of episode.

2. Measure That Addresses the IMPACT Act Domain of Resource Use and Other Measures: Discharge to Community-Post Acute Care Home Health Quality Reporting Program

Section 1899B(d)(1)(B) of the Act requires that no later than the specified application date (which under section 1899B(a)(1)(E)(ii) is October 1, 2016 for SNFs, IRFs and LTCHs and January 1, 2017 for HHAs), the Secretary specify a measure to address the domain of discharge to community. We proposed to adopt the measure, Discharge to Community-PAC HH QRP for the HH QRP, beginning with the CY 2018 payment determination and subsequent years as a Medicare fee-for-service (FFS) claims-based measure to meet this requirement.

This measure assesses successful discharge to the community from a HH setting, with successful discharge to the community including no unplanned hospitalizations and no deaths in the 31 days following discharge from the HH agency setting. Specifically, this measure reports a HHA's risk-standardized rate of Medicare FFS patients who are discharged to the community following a HH episode, do not have an unplanned admission to an acute care hospital or LTCH in the 31 days following discharge to community, and remain alive during the 31 days following discharge to community. The term ''community,'' for this measure, is

defined as home/self-care, without home health services, based on Patient Discharge Status Codes 01 and 81 on the Medicare FFS claim.[35] [36] This measure is specified uniformly across the PAC settings, in terms of the definition of the discharge to community outcome, the approach to risk adjustment, and the measure calculation.

Discharge to a community setting is an important health care outcome for many patients for whom the overall goals of post-acute care include optimizing functional improvement, returning to a previous level of independence, and avoiding institutionalization. Returning to the community is also an important outcome for many patients who are not expected to make functional improvement during their HH episode and for patients who may be expected to decline functionally due to their medical condition. The discharge to community outcome offers a multi-dimensional view of preparation for community life, including the cognitive, physical, and psychosocial elements involved in a discharge to the community.[37] [38]

In addition to being an important outcome from a patient and family perspective, patients discharged to community settings, on average, incur lower costs over the recovery episode, compared with patients discharged to institutional settings.[39] [40] Given the high costs of care in institutional settings, encouraging post-acute providers to prepare patients for discharge to community, when clinically appropriate, may have cost-saving implications for the Medicare program.[41] In addition, providers have discovered that successful discharge to the community was a major driver of their ability to achieve savings, where capitated payments for post-acute care were in place.[42] For patients who require long-term care due to persistent disability, discharge to community could result in lower long-term care costs for Medicaid and for patients' out-of-pocket expenditures.[43]

Analyses conducted for ASPE on PAC episodes, using a 5 percent sample of 2006 Medicare claims, revealed that relatively high average, unadjusted Medicare payments associated with discharge from IRFs, SNFs, LTCHs, or HHAs to institutional settings, as compared with payments associated with discharge from these PAC providers to community settings.[44] Average, unadjusted Medicare payments associated with discharge to community settings ranged from $0 to $4,017 for IRF discharges; $0 to $3,544 for SNF discharges, $0 to $4,706 for LTCH discharges, and $0 to $992 for HHA discharges. In contrast, payments associated with discharge to non-community settings were considerably higher, ranging from $11,847 to $25,364 for IRF discharges, $9,305 to $29,118 for SNF discharges, $12,465 to $18,205 for LTCH discharges, and $7,981 to $35,192 for HHA discharges.[45]

Measuring and comparing agency-level discharge to community rates is expected to help differentiate among agencies with varying performance in this important domain, and to help avoid disparities in care across patient groups. Variation in discharge to community rates has been reported within and across post-acute settings, across a variety of facility-level characteristics such as geographic location (for example, regional location, urban or rural location), ownership (for example, for-profit or nonprofit), freestanding or hospital-based units, and across patient-level characteristics such as race and gender.[46] [47] [48] [49] [50] [51] In the HH Medicare FFS population, using CY 2013 national claims data, we found that approximately 82 percent of episodes ended with a discharge to the community. A multi-center study of 23 LTCHs demonstrated that 28.8 percent of 1,061 patients who were ventilator-dependent on admission were discharged to home.[52] A single-center study revealed that 31 percent of LTCH hemodialysis patients were discharged to home.[53] One study noted that 64 percent of beneficiaries who were discharged from the home health episode did not use any other acute or post-acute services paid by Medicare in the 30 days after discharge[54] and a second study noted that between 58 percent and 63 percent of beneficiates were discharged to home with rates varying by admission site.[55] However, significant numbers of patients were admitted to hospitals (29 percent) and lesser numbers to SNFs (7.6 percent),

[35] Further description of patient discharge status codes can be found, for example, at *https://med.noridianmedicare.com/web/jea/topics/claim-submission/patient-status-codes.*

[36] This definition is not intended to suggest that board and care homes, assisted living facilities, or other settings included in the definition of ''community'' for the purpose of this measure are the most integrated setting for any particular individual or group of individuals under the Americans with Disabilities Act (ADA) and section 504.

[37] El-Solh AA, Saltzman SK, Ramadan FH, Naughton BJ. Validity of an artificial neural network in predicting discharge destination from a post-acute geriatric rehabilitation unit. Archives of physical medicine and rehabilitation. 2000;81(10):1388–1393.

[38] Tanwir S, Montgomery K, Chari V, Nesathurai S. Stroke rehabilitation: availability of a family member as caregiver and discharge destination. *European journal of physical and rehabilitation medicine.* 2014;50(3):355–362.

[39] Dobrez D, Heinemann AW, Deutsch A, Manheim L, Mallinson T. Impact of Medicare's prospective payment system for inpatient rehabilitation facilities on stroke patient outcomes. *American journal of physical medicine & rehabilitation/Association of Academic Physiatrists.* 2010;89(3):198–204.

[40] Gage B, Morley M, Spain P, Ingber M. Examining Post Acute Care Relationships in an Integrated Hospital System Final Report. RTI International;2009.

[41] Newcomer RJ, Ko M, Kang T, Harrington C, Hulett D, Bindman AB. Health Care Expenditures After Initiating Long-term Services and Supports in the Community Versus in a Nursing Facility. Med Care. 2016 Mar;54(3):221–228.

[42] Doran JP, Zabinski SJ. Bundled payment initiatives for Medicare and non-Medicare total joint arthroplasty patients at a community hospital: bundles in the real world. The Journal of arthroplasty. 2015;30(3):353–355.

[43] Newcomer RJ, Ko M, Kang T, Harrington C, Hulett D, Bindman AB. Health Care Expenditures After Initiating Long-term Services and Supports in the Community Versus in a Nursing Facility. Med Care. 2016 Jan 12. Epub ahead of print.

[44] Gage B, Morley M, Spain P, Ingber M. Examining Post Acute Care Relationships in an Integrated Hospital System. Final Report. RTI International;2009.

[45] Ibid.

[46] Reistetter TA, Karmarkar AM, Graham JE, et al. Regional variation in stroke rehabilitation outcomes. Archives of physical medicine and rehabilitation. 2014;95(1):29–38.

[47] El-Solh AA, Saltzman SK, Ramadan FH, Naughton BJ. Validity of an artificial neural network in predicting discharge destination from a post-acute geriatric rehabilitation unit. Archives of physical medicine and rehabilitation. 2000;81(10):1388–1393.

[48] March 2015 Report to the Congress: Medicare Payment Policy. Medicare Payment Advisory Commission;2015.

[49] Bhandari VK, Kushel M, Price L, Schillinger D. Racial disparities in outcomes of inpatient stroke rehabilitation. Archives of physical medicine and rehabilitation. 2005;86(11):2081–2086.

[50] Chang PF, Ostir GV, Kuo YF, Granger CV, Ottenbacher KJ. Ethnic differences in discharge destination among older patients with traumatic brain injury. Archives of physical medicine and rehabilitation. 2008;89(2):231–236.

[51] Berges IM, Kuo YF, Ostir GV, Granger CV, Graham JE, Ottenbacher KJ. Gender and ethnic differences in rehabilitation outcomes after hip-replacement surgery. American journal of physical medicine & rehabilitation/Association of Academic Physiatrists. 2008;87(7):567–572.

[52] Scheinhorn DJ, Hassenpflug MS, Votto JJ, et al. Post-ICU mechanical ventilation at 23 long-term care hospitals: a multicenter outcomes study. Chest. 2007;131(1):85–93.

[53] Thakar CV, Quate-Operacz M, Leonard AC, Eckman MH. Outcomes of hemodialysis patients in a long-term care hospital setting: a single-center study. American journal of kidney diseases: the official journal of the National Kidney Foundation. 2010;55(2):300–306.

[54] Wolff JL, Meadow A, Weiss CO, Boyd CM, Leff B. Medicare home health patients' transitions through acute and post-acute care settings. Medical care. 2008;46(11):1188–1193.

[55] Riggs JS, Madigan EA. Describing Variation in Home Health Care Episodes for Patients with Heart Failure. Home Health Care Management & Practice 2012; 24(3) 146–152.

IRFs (1.5 percent), home health (7.2 percent) or hospice (3.3 percent).[56]

Discharge to community is a desirable health care outcome, as targeted interventions have been shown to successfully increase discharge to community rates in a variety of post-acute settings.[57] [58] [59] [60] [61] Many of these interventions involve discharge planning or specific rehabilitation strategies, such as addressing discharge barriers and improving medical and functional status. [62] [63] [64] [65] [66] The effectiveness of these interventions suggests that improvement in discharge to community rates among post-acute care patients is possible through modifying provider-led processes and interventions.

A TEP convened by our measure development contractor was strongly supportive of the importance of measuring discharge to community outcomes, and implementing the proposed measure, Discharge to Community-PAC HH QRP into the HH QRP. The panel provided input on the technical specifications of this proposed measure, including the feasibility of implementing the measure, as well as the overall measure reliability and validity. A summary of the TEP proceedings is available on the PAC Quality Initiatives Downloads and Videos Web page at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

We also solicited stakeholder feedback on the development of this measure through a public comment period held from November 9, 2015 through December 8, 2015. Several stakeholders and organizations, including the MedPAC, among others, supported this measure for implementation. The public comment summary report for the proposed measure is available on the CMS Web site at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

The NQF-convened MAP met on December 14 and 15, 2015, and provided input on the use of this proposed Discharge to Community-PAC HH QRP measure in the HH QRP. The MAP encouraged continued development of the proposed measure to meet the mandate of the IMPACT Act. The MAP supported the alignment of this proposed measure across PAC settings, using standardized claims data. More information about the MAP's recommendations for this measure is available at *http://www.qualityforum.org/Publications/2016/02/MAP_2016_Considerations_for_Implementing_Measures_in_Federal_Programs_-_PAC-LTC.aspx*.

Since the MAP's review and recommendation of continued development, we have continued to refine the risk adjustment model and conduct measure testing for this measure, as recommended by the MAP. This measure is consistent with the information submitted to the MAP and is scientifically acceptable for current specification in the HH QRP. As discussed with the MAP, we intend to perform additional analyses as the measure steward.

We reviewed the NQF's consensus-endorsed measures and were unable to identify any NQF-endorsed resource use or other measures for post-acute care focused on discharge to the community. In addition, we are unaware of any other post-acute care measures for discharge to community that have been endorsed or adopted by other consensus organizations. Therefore, we proposed the measure, Discharge to Community-PAC HH QRP, under the Secretary's authority to specify non-NQF-endorsed measures under section 1899B(e)(2)(B) of the Act.

We proposed to use data from the Medicare FFS claims and Medicare eligibility files to calculate this measure. We proposed to use data from the ''Patient Discharge Status Code'' on Medicare FFS claims to determine whether a patient was discharged to a community setting for calculation of this measure. In all PAC settings, we tested the accuracy of determining discharge to a community setting using the ''Patient Discharge Status Code'' on the PAC claim by examining whether discharge to community coding based on PAC claim data agreed with discharge to community coding based on PAC assessment data. We found excellent agreement between the two data sources in all PAC settings, ranging from 94.6 percent to 98.8 percent. Specifically, in the HH setting, using 2013 data, we found 97 percent agreement in discharge to community codes when comparing ''Patient Discharge Status Code'' from claims and Discharge Disposition (M2420) and Inpatient Facility (M2410) on the OASIS C discharge assessment, when the claims and OASIS assessment had the same discharge date. We further examined the accuracy of ''Patient Discharge Status Code'' on the PAC claim by assessing how frequently discharges to an acute care hospital were confirmed by follow-up acute care claims. We found that 50 percent of HH claims with acute care discharge status codes were followed by an acute care claim in the 31 days after HH discharge. We believe these data support the use of the ''Patient Discharge Status Code'' for determining discharge to a community setting for this measure. In addition, the proposed measure has high feasibility because all data used for measure calculation are derived from Medicare FFS claims and eligibility files, which are already available to us.

Based on the evidence, we proposed to adopt the measure entitled, ''Discharge to Community–PAC HH QRP'', for the HH QRP for the CY 2018 payment determination and subsequent years. This measure is calculated utilizing 2 years of data as defined below. We proposed a minimum of 20 eligible episodes in a given HHA for public reporting of the measure for that

[56] Ibid.

[57] Kushner DS, Peters KM, Johnson-Greene D. Evaluating Siebens Domain Management Model for Inpatient Rehabilitation to Increase Functional Independence and Discharge Rate to Home in Geriatric Patients. Archives of physical medicine and rehabilitation. 2015;96(7):1310–1318.

[58] Wodchis WP, Teare GF, Naglie G, et al. Skilled nursing facility rehabilitation and discharge to home after stroke. Archives of physical medicine and rehabilitation. 2005;86(3):442–448.

[59] Berkowitz RE, Jones RN, Rieder R, et al. Improving disposition outcomes for patients in a geriatric skilled nursing facility. Journal of the American Geriatrics Society. 2011;59(6):1130–1136.

[60] Kushner DS, Peters KM, Johnson-Greene D. Evaluating use of the Siebens Domain Management Model during inpatient rehabilitation to increase functional independence and discharge rate to home in stroke patients. PM & R: the journal of injury, function, and rehabilitation. 2015;7(4):354–364.

[61] Parker, E., Zimmerman, S., Rodriguez, S., & Lee, T. Exploring best practices in home health care: a review of available evidence on select innovations. Home Health Care Management and Practice, 2014; 26(1): 17–33.

[62] Kushner DS, Peters KM, Johnson-Greene D. Evaluating Siebens Domain Management Model for Inpatient Rehabilitation to Increase Functional Independence and Discharge Rate to Home in Geriatric Patients. Archives of physical medicine and rehabilitation. 2015;96(7):1310–1318.

[63] Wodchis WP, Teare GF, Naglie G, et al. Skilled nursing facility rehabilitation and discharge to home after stroke. Archives of physical medicine and rehabilitation. 2005;86(3):442–448.

[64] Berkowitz RE, Jones RN, Rieder R, et al. Improving disposition outcomes for patients in a geriatric skilled nursing facility. Journal of the American Geriatrics Society. 2011;59(6):1130–1136.

[65] Kushner DS, Peters KM, Johnson-Greene D. Evaluating use of the Siebens Domain Management Model during inpatient rehabilitation to increase functional independence and discharge rate to home in stroke patients. PM & R: the journal of injury, function, and rehabilitation. 2015;7(4):354–364.

[66] Parker, E., Zimmerman, S., Rodriguez, S., & Lee, T. Exploring best practices in home health care: a review of available evidence on select innovations. Home Health Care Management and Practice, 2014; 26(1): 17–33.

HHA. Since Medicare FFS claims data are already reported to the Medicare program for payment purposes, and Medicare eligibility files are also available, HHAs will not be required to report any additional data to CMS for calculation of this measure. The measure denominator is the risk-adjusted expected number of discharges to community. The measure numerator is the risk-adjusted estimate of the number of home health patients who are discharged to the community, do not have an unplanned readmission to an acute care hospital or LTCH in the 31-day post-discharge observation window, and who remain alive during the post-discharge observation window. The measure is risk-adjusted for variables such as age and sex, principal diagnosis, comorbidities, and ESRD status among other variables. For technical information about this proposed measure, including information about the measure calculation, risk adjustment, and denominator exclusions, we refer readers the document titled ''Proposed Measure Specifications for Measures Proposed in the CY 2017 HH QRP proposed rule'', available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIQualityMeasures.html*

We intend to provide initial confidential feedback to home health agencies, prior to the public reporting of this measure, based on Medicare FFS claims data from discharges in CYs 2015 and 2016. We intend to publicly report this measure using claims data from discharges in CYs 2016 and 2017. We plan to submit this measure to the NQF for consideration for endorsement.

We invited public comment on our proposal to adopt the measure, Discharge to Community–PAC HH QRP for the HH QRP. The following is summary of the comments we received.

Comment: Commenters noted the importance of home and community supports such as caregiver availability, willingness, and ability to support the person in the community; availability of an established home, and community supports in determining a beneficiary's ability to be discharged to community and remain in their home or community setting. Several commenters expressed concern that the risk adjustment methodology does not include adjustment for sociodemographic or socioeconomic status. Commenters believed that sociodemographic and socioeconomic factors were strong predictors of return to the community, and since they were outside a provider's control, they should be accounted for in risk adjustment. One commenter noted that the measure does not adjust for regional differences in community-based needs and supports that result from factors such as geographic variance in availability of affordable housing. Another commenter expressed concern that more than half of home health patients do not have an acute care stay within 30 days prior to admission to the HHA, and therefore, may not have the principle diagnosis and comorbidity included in the risk adjustment model.

Response: We understand the importance of home and community supports for ensuring a successful discharge to community outcome. The discharge to community measure is a claims-based measure and currently, there are no standardized data on variables such as living status or family and caregiver supports across the four PAC settings. We appreciate and will consider the commenter's suggestion to account for potential challenges of discharging patients to the community in different geographic areas. With regard to the suggestions pertaining to risk adjustment methodologies pertaining to sociodemographic factors, we refer the readers to section III.D.2.f where we also discuss these topics. For patients for whom index inpatient claims are not available, earlier inpatient claims, as well as physician and other claims, will be used to capture comorbidities and other covariates. These include principal diagnoses, surgical procedures, ESRD or disability as reason for entitlement, dialysis, prior hospitalizations and length of any previous acute hospital stays.

Comment: MedPAC and other commenters expressed concern about relying on discharge coding to determine discharge to community settings. MedPAC and other commenters recommended that we confirm discharge to a community setting with the absence of a subsequent claim to a hospital, IRF, SNF, or LTCH, to ensure that discharge to community rates reflect actual facility performance. Two commenters suggested additional measure testing and development to assess the reliability of patient discharge codes.

Response: We are committed to developing measures based on reliable and valid data. This measure does confirm the absence of hospital or LTCH claims following discharge to a community setting. Unplanned hospital and PAC readmissions following the discharge to community, including those on the day of HHA discharge, are considered an unfavorable outcome. We will consider verifying the absence of IRF and SNF claims following discharge to a community setting, as we continue to refine this measure. Nonetheless, we would like to note that an ASPE report on post-acute care relationships found that, following discharge to community settings from IRFs, LTCHs, or SNFs in a 5 percent Medicare sample, IRFs or SNFs were very infrequently reported as the next site of post-acute care. Because the discharge to community measure is a measure of discharge destination from the PAC setting, we have chosen to use the PAC-reported discharge destination (from the Medicare FFS claims) to determine whether a patient/resident was discharged to the community (based on Discharge Status Codes 01 and 81). We examined accuracy of determining discharge to a community setting using the ''Patient Discharge Status Code'' on the PAC claim by examining agreement with discharge to community as determined using assessment data; we found strong agreement between the two data sources. We found excellent agreement between the two data sources in all PAC settings for the status of ''discharge to the community,'' ranging from 94.6 percent to 98.8 percent. Specifically, in the HH setting, using 2013 data, we found 97 percent agreement in discharge to community codes when comparing ''Patient Discharge Status Code'' from claims and Discharge Disposition (M2420) and Inpatient Facility (M2410) on the OASIS C discharge assessment, when the claims and OASIS assessment had the same discharge date. We further examined accuracy of ''Patient Discharge Status Code'' on the PAC claim by assessing how frequently discharges to an acute care hospital were confirmed by follow-up acute care claims. We found that 50 percent of HH claims with acute care discharge status codes were followed by an acute care claim in the 31 days after HH discharge. We believe these data support the use of the claims ''Patient Discharge Status Code'' for determining discharge to a community setting for this measure. The use of the claims discharge status code to identify discharges to the community was discussed at length with the TEP convened by our measure development contractor. TEP members did not express significant concerns regarding the accuracy of the claims discharge status code in coding community discharges, nor about our use of the discharge status code for defining this quality measure. A summary of the TEP proceedings is available on the PAC Quality Initiatives Downloads and Videos Web site at *https://*

www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.

Comment: One commenter raised concern that the measure does not adjust for factors that are unique to certain specific provider types, such as providers offering dedicated services to patients with certain medical conditions. The commenter noted that providers caring for these populations might encounter greater challenges in discharging patients to the community due to special needs such as affordable and safe housing, mental health and substance abuse counseling, and medication management and supports. Another commenter noted that the measure could incentivize agencies to not treat patients who pose a financial risk, such as those with chronic conditions like end stage renal disease.

Response: We appreciate the commenters' suggestion that the discharge to community measure should adjust for providers primarily caring for specialty populations that may encounter greater challenges with discharge to community settings. Our risk adjustment model accounts for a comprehensive list of diagnoses and comorbidities. We will use the feedback gathered from the comment period to better assess how we can inform further testing of the association between providers primarily caring for specialty populations and discharge to community outcomes as we refine this measure.

Comment: Some commenters expressed concern regarding the use of the Patient Discharge Status Code variable to define community discharges, noting that home health agencies typically do not use code ''81'' and noted that including it in the measure specifications could increase burden and require administrative changes. Commenters additionally urged CMS to review the use discharge codes 01 and 02. Two commenters also noted that the measure specifications use ICD–9, and not ICD–10, codes and recommended a crosswalk between the two.

Response: We would like to clarify that this proposed measure only captures discharges to home- and community-based settings based on the presence of Patient Discharge Status Codes ''01'' and ''81'' on the Medicare FFS claim. Code ''01'' on the Medicare FFS claim is used to determine discharge to home/self-care (routine discharge). Code ''81'' on the Medicare FFS claim is used to determine discharge to home or self-care with a planned acute care hospital readmission. This proposed measure does not include any claims where the HHA used Patient Discharge code ''02'' because that code assesses discharges to hospital inpatient care, a discharge setting that is not included in the outcome of this discharge to community measure. Codes ''01'' and ''81'' were chosen for the calculation of this measure because they are commonly used for all home health Medicare FFS claims. We disagree that the inclusion of code ''81'' in the measure will create a new burden for HHAs because HHAs should already be using that code if it accurately describes the beneficiary's discharge status.

We agree with commenters that it is important to assess the impact of the ICD–9 to ICD–10 transition on the discharge to community measure. We are committed to maximizing accuracy and validity of our measures. We are developing an ICD–9 to ICD–10 crosswalk for the discharge to community measure, as well as other measures that use ICD codes.

Comment: Several commenters expressed concern that there was overlap between the current OASIS-derived measure Discharge to Community HH QI measure and the proposed claims-based cross-setting Discharge to Community measure. The commenters noted that using two separate measures might be confusing to consumers and providers, making it challenging for HHAs to track and improve performance on these metrics. The commenters recommended that only one measure be publicly-reported or that we do not use one of the two measures. One commenter noted that the Discharge to Community measure was essentially a hospitalization measure and supported the use of a single acute care hospitalization measure in the HH QRP.

Response: We acknowledge that we currently have two measures addressing the topic of ''discharge to community'' but note that the overlap between the two measures is limited. We do not believe that the two measures will be confusing to providers and consumers. The proposed discharge to community measure, Discharge to Community PAC HH QRP, is unique in that it incorporates both within-stay and post-discharge hospitalization and mortality in the measure. The claims based discharge to community measure assesses broader outcomes; it first examines whether or not a patient was discharged to the community from the PAC setting and for patients discharged to the community, this measure examines whether they remained alive in the community without an unplanned readmission in the 31-day window following discharge to the community. The overall goal of CMS is to develop measures that are meaningful to patients and consumers, and assist them in making informed choices when selecting post-acute providers. Since the goal of PAC for most patients and family members is to be discharged to the community and remain in the community, from a patient/consumer perspective, it is important to assess whether a patient remained in the community after discharge and to separately report discharge to community rates. For these reasons, we believe that the measure, Discharge to Community-PAC HH QRP, is sufficiently different from OASIS derived measure so as not to be duplicative. Nonetheless, we intend to engage in public communication efforts for providers and other stakeholders to clarify the intent of the cross-setting measure and to distinguish it from the current OASIS-based measure so that HHAs are able to appropriately track and improve performance on these measure metrics.

Comment: One commenter suggested that the discharge to community measure examine emergency room visits in the post-discharge observation window, in addition to unplanned readmissions. The commenter noted that this addition would impose no additional data collection burden on HHAs or hospitals, since these data are already collected by CMS.

Response: The discharge to community measure captures patients that are discharged to the community and remain in the community post-discharge. An emergency department visit that does not result in hospitalization would not be considered a failure to remain in the community. Nevertheless, we will assess emergency department visit rates in the post-discharge observation window to monitor for increasing rates, and potential indication of poor quality of care or inappropriate community discharges.

Comment: One commenter supported including functional status in the risk adjustment for the discharge to community measure. They noted that functional status is associated with increased risk of 30-day all-cause hospital readmissions, and since readmissions and discharge to community are closely related, functional status risk adjustment is also important for this measure.

Response: We appreciate the commenter's support. As mandated by

the IMPACT Act, we are moving toward the goal of collecting standardized patient assessment data for functional status across PAC settings. Once standardized functional status data become available across settings, it is our intent to use these data to assess patients' functional gains during their PAC stay, and to examine the relationship between functional status, discharge destination, and patients' ability to discharge to community. As we examine these relationships between functional outcomes and discharge to community outcomes in the future, we will assess the feasibility of leveraging these standardized patient assessment data to incorporate functional outcomes into the discharge to community measure in all PAC settings. Standardized cross-setting patient assessment data will also allow us to examine interrelationships between the quality and resource use measures in each PAC setting, to understand how these measures are correlated.

Comment: One commenter encouraged us to provide PAC settings with access to measure performance data as early as possible so providers have time to adequately review these data, and implement strategies to decrease readmissions where necessary.

Response: We intend to provide initial confidential feedback to PAC providers, prior to public reporting of this measure, based on Medicare FFS claims data from discharges in CY 2016.

Comment: Some commenters expressed concern that the Discharge to Community HH QRP measure differs from the version for other PAC settings, and recommended that the denominator be limited to those patients admitted to home health within 30 days of discharge from an acute care hospital to allow for valid comparisons between PAC settings. Another commenter noted that home health patients are already ''in the community'' and that agencies have limited control over patient outcomes after discharge.

Response: The Discharge to Community measure is aligned across PAC settings in terms of risk-adjustment, exclusions, numerator and measure intent. For the target population and denominator, which is the risk-adjusted expected number of discharges to community, our analyses revealed that the majority of HHA patients (56 percent) did not have an acute care stay within the 30 days preceding their HHA episode. Further, there was significant heterogeneity in HHA size, with many small agencies. As a result, requiring a prior acute stay for this measure would result in approximately 31.9 percent of HHAs not having the minimum number of episodes necessary to report a measure result with two years of data. In general, our policy is to develop measures that can capture the quality of care furnished to the maximum number of Medicare beneficiaries.

We adjusted this proposed measure for a recent prior acute care stay in the risk adjustment model to accommodate the inclusion of both patients with and without a prior proximal hospitalization. For patients for whom index inpatient claims are not available, earlier inpatient claims, as well as physician and other claims, will be used to capture comorbidities and other covariates. Finalized measures such as the Acute Care Hospitalization (NQF #0171) and Emergency Department Use without Hospitalization (NQF #0173) have also found prior hospitalizations to be a significant predictor in the risk adjustment model but do not require that all patients have a prior acute care stay. Due to this measurement approach, we did not leverage the prior proximal hospitalization in this proposed measure. Similar to this proposed discharge to community measure, these finalized measures, NQF #0173 and NQF #0171, do not require episodes to have a prior acute care stay.

We recognize that home health patients are by definition not in institutional settings, and we note that the proposed measure assesses continued successful community tenure post-discharge. To ensure we are able to adequately assess continued successful community tenure post-discharge, this proposed measure is risk-adjusted to address initial patient characteristics that are predictors of failed community discharge.

Comment: A few commenters requested clarification on whether patients who are discharged to home under hospice care qualify as a discharge to community for the purposes of the measure. One commenter suggested that patients who die on hospice within the post-discharge observation window be excluded from the discharge to community measures. Two commenters recommended that the measure exclude any patients who have been discharged to the community and expire within the post-discharge observation window.

Response: The discharge to community measure excludes patients discharged to home- or facility-based hospice care. Thus, discharges to hospice are not considered discharges to community, but rather are excluded from the measure calculation. With respect to the suggestion that any patients who expire within the post-discharge window be excluded, we wish to note that including 31-day post-discharge mortality outcomes is intended to identify successful discharges to community, and to avoid the potential unintended consequence of inappropriate community discharges. We do not expect facilities to achieve a 0 percent death rate in the measure's post-discharge observation window; the focus is to identify unexpectedly high rates of death for quality monitoring purposes.

Comment: One commenter noted the importance of patient education, engagement, coaching, accountability and commitment to their goals of care is critical to a successful discharge to the community.

Response: We appreciate the comments and acknowledge the importance of patient engagement in successful community discharge. We intend to provide provider education for appropriate coding of discharge status to aid in their understanding of how discharge codes are used in the measure.

Comment: One commenter recommended that patients discharged to long term care facilities paid by sources other than Medicare be excluded from the home health version of this measure.

Response: The discharge to community measure only captures discharges to home and community based settings as discharges to community, based on Patient Discharge Status Codes 01 and 81on the Medicare FFS PAC claim.[1] Code ''01'' on the Medicare FFS claim is used to determine discharge to home/self-care (routine discharge). Code ''81'' on the Medicare FFS claim is used to determine discharge to home or self-care with a planned acute care hospital readmission. Codes ''01'' and ''81'' do not include discharges to long-term care nursing facilities or any other institutional setting.

Final Decision: After careful consideration of the public comments, we are finalizing our proposal to adopt the measure, Discharge to Community-Post Acute Care for the Home Health Quality Reporting Program, beginning with the CY 2018 HH QRP.

3. Measure That Addresses the IMPACT Act Domain of Resource Use and Other Measures: Potentially Preventable 30-Day Post-Discharge Readmission Measure for Post-Acute Care Home Health Quality Reporting Program

Section 1899B(d)(1)(C) of the Act requires that no later than the specified application date (which under section 1899B(a)(1)(E)(ii) is October 1, 2016 for

SNFs, IRFs and LTCHs and January 1, 2017 for HHAs) the Secretary specify measures to address the domain of all-condition risk-adjusted potentially preventable hospital readmission rates. We proposed the measure Potentially Preventable 30-Day Post-Discharge Readmission (PPR) Measure for HH QRP as a Medicare FFS claims-based measure to meet this requirement beginning with the CY 2018 payment determination.

The proposed measure assesses the facility-level risk-standardized rate of unplanned, potentially preventable hospital readmissions for Medicare FFS beneficiaries that take place within 30 days of a HH discharge. The HH admission must have occurred within up to 30 days of discharge from a prior proximal hospital stay, which is defined as an inpatient admission to an acute care hospital (including IPPS, CAH, or a psychiatric hospital). Hospital readmissions include readmissions to a short-stay acute-care hospital or a LTCH, with a diagnosis considered to be unplanned and potentially preventable. This proposed measure is claims-based, requiring no additional data collection or submission burden for HHAs. Because the measure denominator is based on HH admissions, each Medicare beneficiary may be included in the measure multiple times within the measurement period. Readmissions counted in this measure are identified by examining Medicare FFS claims data for readmissions to either acute care hospitals (IPPS or CAH) or LTCHs that occur during a 30-day window beginning two days after HH discharge. This measure is conceptualized uniformly across the PAC settings, in terms of the measure definition, the approach to risk adjustment, and the measure calculation. Our approach for defining potentially preventable hospital readmissions is described in more detail below.

Hospital readmissions among the Medicare population, including beneficiaries that utilize PAC providers, are common, costly, and often preventable.[67] [68] The MedPAC estimated that 17 to 20 percent of Medicare beneficiaries discharged from the hospital were readmitted within 30 days. MedPAC found that more than 75 percent of 30-day and 15-day readmissions and 84 percent of 7-day readmissions were considered ''potentially preventable.'' [69] In addition, MedPAC calculated that annual Medicare spending on potentially preventable readmissions would be $12 billion for 30-day, $8 billion for 15-day, and $5 billion for 7-day readmissions.[70] For hospital readmissions from one post-acute care setting, SNFs, MedPAC deemed 76 percent of these readmissions as ''potentially avoidable''—associated with $12 billion in Medicare expenditures.[71] Mor et al. analyzed 2006 Medicare claims and SNF assessment data (Minimum Data Set), and reported a 23.5 percent readmission rate from SNFs, associated with $4.3 billion in expenditures.[72] An analysis of data from a nationally representative sample of Medicare FFS beneficiaries receiving home health services in 2004 show that home health patients receive significant amounts of acute and post-acute services after discharge from home health care. Within 30 days of discharge from home health, 29 percent of patients were admitted to a hospital.[73] Focusing on readmissions, Madigan and colleagues studied 74,580 Medicare home health patients with a rehospitalization within 30 days of the index hospital discharge. The 30-day rehospitalization rate was 26 percent with the largest proportion related to a cardiac-related diagnosis (42 percent).[74] Fewer studies have investigated potentially preventable readmission rates from other post-acute care settings.

We have addressed the high rates of hospital readmissions in the acute care setting, as well as in PAC settings. For example, we developed the following measure: Rehospitalization During the First 30 Days of Home Health (NQF #2380), as well as similar measures for other PAC providers (NQF #2502 for IRFs, NQF #2510 for SNFs NQF #2512 for LTCHs).[75] These measures are endorsed by the NQF, and the NQF-endorsed measure (NQF #2380) was adopted into the HH QRP in the CY 2014 HH PPS final rule (80 FR 68691 through 68692). Note that these NQF-endorsed measures assess all-cause unplanned readmissions.

Several general methods and algorithms have been developed to assess potentially avoidable or preventable hospitalizations and readmissions for the Medicare population. These include the HHS Agency for Healthcare Research and Quality's (AHRQ's) Prevention Quality Indicators, approaches developed by MedPAC, and proprietary approaches, such as the 3M™ algorithm for Potentially Preventable Readmissions.[76] [77] [78] Recent work led by Kramer et al. for MedPAC identified 13 conditions for which readmissions were deemed as potentially preventable among SNF and IRF populations.[79] [80] Although much of the existing literature addresses hospital readmissions more broadly and potentially avoidable hospitalizations for specific settings like long-term care, these findings are relevant to the development of potentially preventable readmission measures for PAC.[81] [82] [83]

[67] Friedman, B., and Basu, J.: The rate and cost of hospital readmissions for preventable conditions. Med. Care Res. Rev. 61(2):225–240, 2004. doi:10.1177/1077558704263799.

[68] Jencks, S.F., Williams, M.V., and Coleman, E.A.: Rehospitalizations among patients in the Medicare Fee-for-Service Program. N. Engl. J. Med. 360(14):1418–1428, 2009. doi:10.1016/j.jvs.2009.05.045.

[69] MedPAC: Payment policy for inpatient readmissions, in Report to the Congress: Promoting Greater Efficiency in Medicare. Washington, DC, pp. 103–120, 2007. Available from *http://www.medpac.gov/documents/reports/Jun07_EntireReport.pdf*.

[70] Ibid.

[71] Ibid.

[72] Mor, V., Intrator, O., Feng, Z., et al. The revolving door of rehospitalization from skilled nursing facilities. Health Aff. 29(1):57–64, 2010. doi:10.1377/hlthaff.2009.0629.

[73] Wolff, J. L., Meadow, A., Weiss, C.O., Boyd, C.M., Leff, B. Medicare Home Health Patients' Transitions Through Acute And Post-Acute Care Settings.'' Medicare Care 11(46) 2008; 1188–1193.

[74] Madigan, E. A., N. H. Gordon, et al. Rehospitalization in a national population of home health care patients with heart failure.'' Health Serv Res 47(6): 2013; 2316–2338.

[75] National Quality Forum: All-Cause Admissions and Readmissions Measures. pp. 1–319, April 2015. Available from *http://www.qualityforum.org/Publications/2015/04/All-Cause_Admissions_and_Readmissions_Measures_-_Final_Report.aspx*.

[76] Goldfield, N.I., McCullough, E.C., Hughes, J.S., et al. Identifying potentially preventable readmissions. Health Care Finan. Rev. 30(1):75–91, 2008. Available from *http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4195042/*.

[77] National Quality Forum: Prevention Quality Indicators Overview. 2008.

[78] MedPAC: Online Appendix C: Medicare Ambulatory Care Indicators for the Elderly. pp. 1–12, prepared for Chapter 4, 2011. Available from *http://www.medpac.gov/documents/reports/Mar11_Ch04_APPENDIX.pdf?sfvrsn=0*.

[79] Kramer, A., Lin, M., Fish, R., et al. Development of Inpatient Rehabilitation Facility Quality Measures: Potentially Avoidable Readmissions, Community Discharge, and Functional Improvement. pp. 1–42, 2015. Available from *http://www.medpac.gov/documents/contractor-reports/development-of-inpatient-rehabilitation-facility-quality-measures-potentially-avoidable-readmissions-community-discharge-and-functional-improvement.pdf?sfvrsn=0*.

[80] Kramer, A., Lin, M., Fish, R., et al. Development of Potentially Avoidable Readmission and Functional Outcome SNF Quality Measures. pp. 1–75, 2014. Available from *http://www.medpac.gov/documents/contractor-reports/mar14_snfqualitymeasures_contractor.pdf?sfvrsn=0*.

[81] Allaudeen, N., Vidyarthi, A., Maselli, J., et al. Redefining readmission risk factors for general medicine patients. J. Hosp. Med. 6(2):54–60, 2011. doi:10.1002/jhm.805.

[82] Gao, J., Moran, E., Li, Y.-F., et al. Predicting potentially avoidable hospitalizations. Med. Care 52(2):164–171, 2014. doi:10.1097/MLR.0000000000000041.

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Potentially Preventable Readmission (PPR) Measure Definition: We conducted a comprehensive environmental scan, analyzed claims data, and obtained input from a TEP to develop a definition and list of conditions for which hospital readmissions are potentially preventable. The Ambulatory Care Sensitive Conditions and Prevention Quality Indicators, developed by AHRQ, served as the starting point in this work. For patients in the 30-day post-PAC discharge period, a potentially preventable readmission (PPR) refers to a readmission for which the probability of occurrence could be minimized with adequately planned, explained, and implemented post discharge instructions, including the establishment of appropriate follow-up ambulatory care. Our list of PPR conditions is categorized by 3 clinical rationale groupings:

- Inadequate management of chronic conditions;
- Inadequate management of infections; and
- Inadequate management of other unplanned events.

Additional details regarding the definition for potentially preventable readmissions are available in the document titled ''Proposed Measure Specifications for Measures Proposed in the CY 2017 HH QRP proposed rule'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIQualityMeasures.html*.

This proposed measure focuses on readmissions that are potentially preventable and also unplanned. Similar to the Rehospitalization During the First 30 Days of Home Health measure (NQF #2380), this proposed measure uses the current version of the CMS Planned Readmission Algorithm as the main component for identifying planned readmissions. A complete description of the CMS Planned Readmission Algorithm, which includes lists of planned diagnoses and procedures, can be found on the CMS Web site at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*. In addition to the CMS Planned Readmission Algorithm, this proposed measure incorporates procedures that are considered planned in post-acute care settings, as identified in consultation with TEPs. Full details on the planned readmissions criteria used, including the CMS Planned Readmission Algorithm and additional procedures considered planned for post-acute care, can be found in the document titled ''Proposed Measure Specifications for Measures Proposed in the CY 2017 HH QRP proposed rule'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIQualityMeasures.html*.

The proposed measure, Potentially Preventable 30-Day Post-Discharge Readmission Measure for HH QRP, assesses potentially preventable readmission rates while accounting for patient demographics, principal diagnosis in the prior hospital stay, comorbidities, and other patient factors. While estimating the predictive power of patient characteristics, the model also estimates an agency-specific effect, common to patients treated in each agency. This proposed measure is calculated for each HHA based on the ratio of the predicted number of risk-adjusted, unplanned, potentially preventable hospital readmissions that occur within 30 days after an HH discharge, including the estimated agency effect, to the estimated predicted number of risk-adjusted, unplanned hospital readmissions for the same patients treated at the average HHA. A ratio above 1.0 indicates a higher than expected readmission rate (worse), while a ratio below 1.0 indicates a lower than expected readmission rate (better). This ratio is referred to as the standardized risk ratio (SRR). The SRR is then multiplied by the overall national raw rate of potentially preventable readmissions for all HH episodes. The resulting rate is the risk-standardized readmission rate (RSRR) of potentially preventable readmissions.

An eligible HH episode is followed until: (1) The 30-day post-discharge period ends; or (2) the patient is readmitted to an acute care hospital (IPPS or CAH) or LTCH. If the readmission is unplanned and potentially preventable, it is counted as a readmission in the measure calculation. If the readmission is planned, the readmission is not counted in the measure rate.

This measure is risk-adjusted. The risk adjustment modeling estimates the effects of patient characteristics, comorbidities, and select health care variables on the probability of readmission. More specifically, the risk-adjustment model for HHAs accounts for demographic characteristics (age, sex, original reason for Medicare entitlement), principal diagnosis during the prior proximal hospital stay, body system specific surgical indicators, comorbidities, length of stay during the patient's prior proximal hospital stay, intensive care and coronary care unit (ICU and CCU) utilization, ESRD status, and number of acute care hospitalizations in the preceding 365 days.

The proposed measure is calculated using 3 consecutive calendar years of FFS data, to ensure the statistical reliability of this measure for smaller agencies. In addition, we proposed a minimum of 20 eligible episodes for public reporting of the proposed measure. For technical information about this proposed measure including information about the measure calculation, risk adjustment, and exclusions, we refer readers to our Proposed Measure Specifications for Measures Proposed in the CY 2017 HH QRP proposed rule at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIQualityMeasures.html*

A TEP convened by our measure contractor provided recommendations on the technical specifications of this proposed measure, including the development of an approach to define potentially preventable hospital readmission for PAC. Details from the TEP meetings, including TEP members' ratings of conditions proposed as being potentially preventable, are available in the TEP summary report available on the CMS Web site at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*. We also solicited stakeholder feedback on the development of this measure through a public comment period held from November 2 through December 1, 2015. Comments on the measure varied, with some commenters supportive of the proposed measure, while others were either not in favor of the measure or suggested potential modifications to the measure specifications, such as including standardized function data. A summary of the public comments is also available on the CMS Web site at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

[83] Walsh, E.G., Wiener, J.M., Haber, S., et al. Potentially avoidable hospitalizations of dually eligible Medicare and Medicaid beneficiaries from nursing facility and home-and community-based services waiver programs. J. Am. Geriatr. Soc. 60(5):821–829, 2012. doi:10.1111/j.1532–5415.2012.03920.

The NQF-convened MAP encouraged continued development of the proposed measure. Specifically, the MAP stressed the need to promote shared accountability and ensure effective care transitions. More information about the MAP's recommendations for this measure is available at *http://www.qualityforum.org/Publications/2016/02/MAP_2016_Considerations_for_Implementing_Measures_in_Federal_Programs_-_PAC-LTC.aspx*.

At the time of the MAP, the risk-adjustment model was still under development. Following completion of that development work, we were able to test for measure validity and reliability as identified in the measure specifications document provided above. Testing results are within range for similar outcome measures finalized in public reporting and value-based purchasing programs, including the Rehospitalization During the First 30 Days of Home Health Measure (NQF #2380) adopted into the HH QRP.

We reviewed the NQF's consensus endorsed measures and were unable to identify any NQF-endorsed measures focused on potentially preventable hospital readmissions. We are unaware of any other measures for this IMPACT Act domain that have been endorsed or adopted by other consensus organizations. Therefore, we proposed the Potentially Preventable 30-Day Post-Discharge Readmission Measure for HH QRP under the Secretary's authority to specify non-NQF-endorsed measures under section 1899B(e)(2)(B) of the Act, for the HH QRP for the CY 2018 payment determination and subsequent years given the evidence previously discussed above.

Due to timeline limitations we have not yet submitted the proposed measure to the NQF for consideration of endorsement, but we intend to do so in the future. We also stated in the proposed rule that if this proposed measure is finalized, we intend to provide initial confidential feedback to providers, prior to public reporting of this proposed measure, based on 3 calendar years of claims data from discharges in CYs 2014, 2015 and 2016. We also stated that we intend to publicly report this measure using claims data from CYs 2015, 2016 and 2017.

We invited public comment on our proposal to adopt the measure, Potentially Preventable 30-Day Post-Discharge Readmission Measure for HH QRP. The following is summary of the comments we received.

Comment: MedPAC and other commenters expressed general support for the proposed Potentially Preventable 30-Day Post-Discharge Readmission Measure for HH QRP. One commenter specifically stated their support for the infectious conditions defined as potentially preventable, stating that many of these conditions are preventable using appropriate infection prevention interventions.

Response: We agree that the measure will provide strong incentives for care coordination and will appropriately capture preventable readmissions, including infection-related readmissions.

Comment: Several commenters expressed concern over the overlap between the proposed PPR measure and other HH QRP measures, including the existing all-cause readmission measure. Commenters noted that public reporting of more than one hospital readmission measure for HHAs may result in confusion among the public; the commenters also noted that HHAs could face confusion over two distinct but similar measures, which could potentially pose challenges for quality improvement efforts. One commenter noted that the proposed PPR measures and the existing all-cause measure are distinct yet overlapping, adding that the PPR measure is a subset of the all-cause readmission measure. Given this overlap, one commenter expressed concern that providers who perform poorly on the all-cause readmission measure are also likely to perform poorly on the proposed PPR measure, and suggested CMS not adopt the measure until it could evaluate the necessity of each measure. Some commenters requested that CMS clarify the overlap and intent of these measures, and provide more education to providers and the public on the multiple HH QRP readmission measures.

Response: With regard to overlap with the existing HH QRP readmission measure, we wish to clarify that there are distinct differences between the all-cause readmission measure and the PPR measure. The all-cause measure assesses readmissions occurring within the first 30 days following the start of a home health stay, during which time a patient is in the HHA's care, and the potentially preventable measure assesses readmissions during the first 30 days post-discharge from the HHA. While a small overlap between the two measures is expected, the all-cause performance rates are more heavily driven by within-stay re-hospitalizations while PPR performance rates are driven purely by post-discharge re-hospitalizations. We are committed to ensuring that measures in the HH QRP are useful in assessing quality and will continue to evaluate all readmission measures over time.

Comment: Several commenters provided feedback on the PPR definitions or lists of conditions for which readmissions would be considered potentially preventable. Some commenters believed that the definitions were too broad or were concerned about the applicability of the PPR conditions to the HH setting. MedPAC commented that the measure definitions and risk adjustment should be identical across PAC settings so that potentially preventable readmission rates can be compared across settings. In addition to general comments about the PPR definitions, we also received feedback on specific conditions and received suggestions to add or remove conditions. One commenter specifically supported the inclusion of infectious conditions in the ''inadequate management of infections'' and ''inadequate management of other unplanned events'' categories in the measure's definition of potentially preventable hospital readmissions. Other commenters specifically requested conditions—specifically patient falls and behavioral health diagnoses—be excluded from this measure until further study is conducted. Additionally, two commenters suggested that it was inappropriate for the measure to include conditions unrelated to the reason for HH admission. A few commenters recommended that CMS continue evaluating and testing the measure to ensure that the codes used for the PPR definition are clinically relevant.

Response: The PPR list of conditions for which readmissions would be considered potentially preventable is aligned for measures with the same readmission window, regardless of PAC setting. Specifically, the post-PAC discharge PPR measures that were developed for each of the PAC settings contain the same list of PPR conditions (available on the CMS Web site at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/Proposed-Measure-Specifications-for-Measures-Proposed-in-CY-2017-HH-QRP-NPRM.pdf*). Although there are some minor differences in the specifications across the measures (for example, years of data used to calculate the measures to ensure reliability and some of the measure exclusions necessary to attribute responsibility to the individual settings), the IMPACT Act PPR measures are standardized. The statistical approach for risk adjustment is also aligned across the measures;

however, there is variation in the exact risk adjusters. The risk adjustment models are empirically driven and differ between measures as a consequence of case mix differences, which is necessary to ensure that the estimates are valid. The approach for defining PPRs for these measures was based on comprehensive reviews of the scientific literature, input from clinical experts, and recommendations from our TEP, including TEP members' in-person feedback and their written ratings of the conditions.

Though readmissions may be considered potentially preventable even if they may not appear to be clinically related to the patient's original reason for HH admission, there is substantial evidence that the conditions included in the definition may be preventable with adequately planned, explained, and implemented post-discharge instructions, including the establishment of appropriate follow-up ambulatory care. Furthermore, this measure is based on Medicare FFS claims data and it may not always be feasible to determine whether a subsequent readmission is or is not clinically related to the reason why the patient was receiving inpatient rehabilitation. We intend to conduct ongoing evaluation and monitoring of this measure to ensure that the PPR definition codes remain clinically relevant.

Comment: Commenters sought clarification on whether emergency department (ED) visits were included in the measure. One commenter suggested that the PPR measure incorporate both inpatient and emergency department (ED) visits to enhance consumer understanding.

Response: The PPR measure was developed to fulfill the IMPACT Act's statutory requirement for a measure to address the domain of potentially preventable hospital readmissions. We agree that ED visits are also an important outcome, but they do not fall under the same domain as hospital readmissions and are not included in the measure.

Comment: We received several comments encouraging additional testing and evaluation of the measure prior to implementation. Specifically, several comments suggested that CMS should not finalize this measure because the measure was still under development and the MAP did not vote to support it, but instead encouraged continued development. Commenters also recommended that the measure be submitted for NQF endorsement and that CMS only propose NQF-endorsed measures for use in the HHQRP.

Response: We intend to submit this measure to NQF for consideration of endorsement.

Although the measure is not currently endorsed, we did conduct additional testing subsequent to the MAP meeting. Based on that testing, we were able to complete the risk adjustment model and evaluate facilities' PPR rates, and we made the results of our analyses available at the time of the proposed rule. We found that testing results were similar to the current home health all-cause readmission measures (NQF #2380) and allowed us to conclude that the measure is sufficiently developed, valid and reliable for adoption in the HH QRP. We would also like to clarify that the finalized risk-adjustment models and coefficients are included in the measure specifications available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/Proposed-Measure-Specifications-for-Measures-Proposed-in-CY-2017-HH-QRP-NPRM.pdf*. We will make additional testing results available in the future.

Comment: Two commenters requested that CMS cross-walk the ICD–9 to ICD–10 codes for the lists of conditions for which readmissions may be considered potentially preventable, and one further requested this information be made publicly available.

Response: Our measure development contractors have developed preliminary ICD–10 cross-walks for the lists of conditions. The current ICD–10 cross-walks can be found in the link for the technical specifications posted below, and any adjustments made to the cross-walks will be implemented in future rulemaking. With regard to the planned readmission approach, we also direct readers to the technical specifications for the measure, which is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/Proposed-Measure-Specifications-for-Measures-Proposed-in-CY-2017-HH-QRP-NPRM.pdf*.

Comment: While we received comments in support of risk adjustment, several commenters raised concern over the specific risk adjustment approach for the PPR measures. Specifically, commenters were concerned that the approach is insufficient or does not adequately take into account patient frailty, prior PAC stays, multiple comorbidities, or sociodemographic factors to address income, and caregiver support. Several commenters expressed concern that this measure would capture outcomes that are outside of HH providers' control, specifically for chronically ill patients, instances of poor patient compliance, unhealthy choices, and various SDS factors, such as lack of resources or limited access to follow up or primary care. Several commenters suggested that CMS risk adjust for cognitive impairments/behavioral health, whether or not the patient had a follow-up visit with a physician, and for functional status and activities of daily living (ADL) scores, in all settings.

Response: The risk adjustment approach developed for these measures is comprehensive and captures a variety of patient case mix characteristics, including sociodemographic characteristics (age, sex, original reason for entitlement), principal diagnosis during the prior proximal hospital stay, body system specific surgical indicators, comorbidities, and prior service utilization. The measure's comprehensive risk-adjustment approach and exclusion criteria are intended to capture many of these factors. As described above, there is substantial evidence that the conditions included in the definition may be preventable with adequately planned, explained, and implemented post-discharge instructions, including the establishment of appropriate follow-up ambulatory care. We would like to clarify that the focus of the PPR measure is to identify excess PPR rates for the purposes of quality improvement. With regard to the suggestions that the model include sociodemographic factors and the suggestion pertaining to an approach with which to convey data comparisons, we refer the readers to section V. B of this final rule where we discuss these topics. This risk adjustment approach was designed to harmonize with approaches developed and refined over several years and used for other claims-based NQF-endorsed hospital readmission measures by CMS in inpatient, as well as PAC quality reporting programs. As described for all IMPACT Act measures in section V.G., the statistical approach for risk adjustment is also aligned across the measures; however, there is variation in the exact risk adjusters. The risk-adjustment models are empirically driven and differ between measures as a consequence of case mix differences, which is necessary to ensure that the estimates are valid. The risk-adjustment model takes into account medical complexity, as patients with multiple risk factors will rate as having higher risk of readmission. For those cross-setting post-acute measures such as those intended to satisfy the IMPACT

Act domains that use the patient assessment-based data elements for risk adjustment, we have either made such items standardized, or intend to do so as feasible.

Comment: Two commenters expressed concern over using claims data for hospital readmissions, noting that these data may not be accurate. A commenter additionally suggested that CMS add a system to support providers to understand how data were calculated, to report errors, and to promote quality improvement purposes.

Response: The claims data used to calculate this measure are validated and are used for several NQF endorsed measures adopted for CMS programs, including the HH QRP, for example, the home health Acute Care Hospitalization and Emergency Department Use without Hospitalization measures (NQF 0171 and 0173, respectively). Multiple studies have been conducted to examine the validity of using Medicare hospital claims for several NQF endorsed quality measures used in public reporting such as 30-day mortality rates for pneumonia patients, 30-day all-cause readmission rates among patients with heart failure and 30-day mortality rates among patients with heart failure.[84] [85] [86] These studies supported the use of claims data as a valid means for risk adjustment and assessing hospital readmissions. Additionally, although assessment and other data sources may be valuable for risk adjustment, we are not aware of another data source aside from Medicare claims data that could be used to reliably assess the outcome of potentially preventable hospital readmissions post-HHA discharge.

Comment: Two commenters cautioned against potential unintended consequences of the measure, in particular, noting that the measure could incentivize HHAs to delay necessary readmission to the hospital. One commenter noted that the measure could cause HHAs to be selective about the patients they admit.

Response: We intend to conduct ongoing monitoring to assess for potential unintended consequences associated with the implementation of this measure. A major goal of risk adjustment is to ensure that patient case mix is taken into account in order to allow for fair comparisons of facilities. Given that this is a post-HHA discharge measure; HHAs would have no ability to delay hospital readmissions as the patient is no longer in the care of the HHA.

Final Decision: After consideration of the public comments received, we are finalizing our proposal to adopt the measure, Potentially Preventable 30-Day Post-Discharge Readmission Measure for HH QRP beginning with the CY 2018 HH QRP.

4. Proposal To Address the IMPACT Act Domain of Medication Reconciliation: Drug Regimen Review Conducted With Follow-Up for Identified Issues-Post-Acute Care Home Health Quality Reporting Program

Section 1899B(c)(1)(C) of the Act requires that no later than the specified application date (which under section 1899B(a)(1)(E)(i) is October 1, 2018 for SNFs, IRFs and LTCHs and January 1, 2017 for HHAs), the Secretary specify quality measures to address the domain of medication reconciliation. We proposed to adopt the quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC HH QRP for the HH QRP as a patient-assessment based, cross-setting quality measure to meet this requirement with data collection beginning January 1, 2017, beginning with the CY 2018 payment determination.

This measure assesses whether PAC providers were responsive to potential or actual clinically significant medication issue(s) when such issues were identified. Specifically, the quality measure reports the percentage of patient episodes in which a drug regimen review was conducted at the start of care or resumption of care and timely follow-up with a physician occurred each time potential clinically significant medication issues were identified throughout that episode. For this quality measure, a drug regimen review is defined as the review of all medications or drugs the patient is taking in order to identify potential clinically significant medication issues. This quality measure utilizes both the processes of medication reconciliation and a drug regimen review in the event an actual or potential medication issue occurred. The measure informs whether the PAC agency identified and addressed each clinically significant medication issue and if the agency responded or addressed the medication issue in a timely manner. Of note, drug regimen review in PAC settings is generally considered to include medication reconciliation and review of the patient's drug regimen to identify potential clinically significant medication issues.[87] This measure is applied uniformly across the PAC settings.

Medication reconciliation is a process of reviewing an individual's complete and current medication list. Medication reconciliation is a recognized process for reducing the occurrence of medication discrepancies that may lead to Adverse Drug Events (ADEs). Medication discrepancies occur when there is conflicting information documented in the medical records.

The World Health Organization regards medication reconciliation as a standard operating protocol necessary to reduce the potential for ADEs that cause harm to patients. Medication reconciliation is an important patient safety process that addresses medication accuracy during transitions in patient care and in identifying preventable ADEs.[88] The Joint Commission added medication reconciliation to its list of National Patient Safety Goals (2005), suggesting that medication reconciliation is an integral component of medication safety.[89] The Society of Hospital Medicine published a statement in agreement of the Joint Commission's emphasis and value of medication reconciliation as a patient safety goal.[90] There is universal agreement that medication reconciliation directly addresses patient safety issues that can result from medication miscommunication and unavailable or incorrect information.[91] [92] [93] [94]

[84] Bratzler DW, Normand SL, Wang Y, et al. An administrative claims model for profiling hospital 30-day mortality rates for pneumonia patients. PLoS One 2011;6(4):e17401.

[85] Keenan PS, Normand SL, Lin Z, et al. An administrative claims measure suitable for profiling hospital performance on the basis of 30-day all-cause readmission rates among patients with heart failure. Circulation 2008;1(1):29–37.

[86] Krumholz HM, Wang Y, Mattera JA, et al. An administrative claims model suitable for profiling hospital performance based on 30-day mortality rates among patients with heart failure. Circulation 2006;113:1693–1701.

[87] Institute of Medicine. Preventing Medication Errors. Washington DC: National Academies Press; 2006.

[88] Leotsakos A., et al. Standardization in patient safety: the WHO High 5s project. Int J Qual Health Care. 2014:26(2):109–116.

[89] The Joint Commission. 2016 Long Term Care: National Patient Safety Goals Medicare/Medicaid Certification-based Option. (NPSG.03.06.01).

[90] Greenwald, J. L., Halasyamani, L., Greene, J., LaCivita, C., et al. (2010). Making inpatient medication reconciliation patient centered, clinically relevant and implementable: a consensus statement on key principles and necessary first steps. Journal of Hospital Medicine, 5(8), 477–485.

[91] IHI. Medication Reconciliation to Prevent Adverse Drug Events [Internet]. Cambridge, MA: Institute for Healthcare Improvement; [cited 2016 Jan 11]. Available from: *http://www.ihi.org/topics/adesmedicationreconciliation/Pages/default.aspx*.

[92] Leotsakos A., et al. Standardization in patient safety: the WHO High 5s project. Int J Qual Health Care. 2014:26(2):109–116.

[92] The Joint Commission. 2016 Long Term Care: National Patient Safety Goals Medicare/Medicaid Certification-based Option. (NPSG.03.06.01).

[93] Greenwald, J. L., Halasyamani, L., Greene, J., LaCivita, C., et al. (2010). Making inpatient medication reconciliation patient centered,

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The performance of timely medication reconciliation is valuable to the process of drug regimen review. Preventing and responding to ADEs is of critical importance as ADEs account for significant increases in health services utilization and costs,[95] [96] including subsequent emergency room visits and re-hospitalizations. ADEs are associated with an estimated $3.5 billion in annual health care costs and 7,000 deaths annually.[97]

Medication errors include the duplication of medications, delivery of an incorrect drug, inappropriate drug omissions, or errors in the dosage, route, frequency, and duration of medications. Medication errors are one of the most common types of medical error and can occur at any point in the process of ordering and delivering a medication. Medication errors have the potential to result in an ADE.[98] [99] [100] [101] [102] [103] Inappropriately prescribed medications are also considered a major healthcare concern in the United States for the elderly population, with costs of roughly $7.2 billion annually.[104] [105]

There is strong evidence that medication discrepancies can occur during transfers from acute care facilities to post-acute care facilities. Discrepancies can occur when there is conflicting information documented in the medical records. Almost one-third of medication discrepancies have the potential to cause patient harm.[106] Potential medication problems upon admission to HHAs have been reported as occurring at a rate of 39 percent of reviewed charts [107] and mean medication discrepancies between 2.0 ± 2.3 and 2.1 ± 2.4.[108] Similarly, medication discrepancies were noted as patients transitioned from the hospital to home health settings.[109] An estimated fifty percent of patients experienced a clinically important medication error after hospital discharge in an analysis of two tertiary care academic hospitals.[110]

Medication reconciliation has been identified as an area for improvement during transfer from the acute care facility to the receiving post-acute care facility. PAC facilities report gaps in medication information between the acute care hospital and the receiving post-acute care setting when performing medication reconciliation.[111] [112] Hospital discharge has been identified as a particularly high risk time point, with evidence that medication reconciliation identifies high levels of discrepancy.[113] [114] [115] [116] [117] [118] Also, there is evidence that medication reconciliation discrepancies occur throughout the patient stay.[119] [120] For older patients who may have multiple comorbid conditions and thus multiple medications, transitions between acute and post-acute care settings can be further complicated,[121] and medication reconciliation and patient knowledge (medication literacy) can be inadequate post-discharge.[122] The quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC HH QRP, provides an important component of care coordination for PAC settings and would affect a large proportion of the Medicare population who transfer from hospitals into PAC settings each year. For example, in 2013, 3.2 million Medicare FFS beneficiaries had a home health episode.

A TEP convened by our measure development contractor provided input on the technical specifications of this proposed quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC HH QRP, including components of reliability, validity and the feasibility of implementing the measure across PAC settings. The TEP supported the measure's implementation across PAC settings and was supportive of our plans to standardize this measure for cross-

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setting development. A summary of the TEP proceedings is available on the PAC Quality Initiatives Downloads and Video Web site at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

We solicited stakeholder feedback on the development of this measure by means of a public comment period held from September 18, through October 6, 2015. Through public comments submitted by several stakeholders and organizations, we received support for implementation of this measure. The public comment summary report for the measure is available on the CMS Web site at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

The NQF-convened MAP met on December 14 and 15, 2015, and provided input on the use of this proposed quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC HH QRP. The MAP encouraged continued development of the quality measure for the HH QRP to meet the mandate of the IMPACT Act. The MAP agreed with the measure gaps identified by CMS including medication reconciliation, and stressed that medication reconciliation be present as an ongoing process. More information about the MAPs recommendations for this measure is available at *http://www.qualityforum.org/Setting_Priorities/Partnership/MAP_Final_Reports.aspx.*

Since the MAP's review, we have continued to refine this measure in compliance with the MAP's recommendations. The measure is both consistent with the information submitted to the MAP and supports its scientific acceptability for use in the HH QRP. Therefore, we proposed this measure for implementation in the HH QRP as required by the IMPACT Act.

We reviewed the NQF's endorsed measures and identified one NQF-endorsed cross-setting and quality measure related to medication reconciliation, which applies to the SNF, LTCH, IRF, and HH settings of care: Care for Older Adults (COA) (NQF #0553). The quality measure, Care for Older Adults (COA) (NQF #0553) assesses the percentage of adults 66 years and older who had a medication review. The Care for Older Adults (COA) (NQF #0553) measure requires at least one medication review conducted by a prescribing practitioner or clinical pharmacist during the measurement year and the presence of a medication list in the medical record. This is in contrast to the quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC HH QRP, which reports the percentage of patient episodes in which a drug regimen review was conducted at the time of admission and that timely follow-up with a physician or physician-designee occurred each time one or more potential clinically significant medication issues were identified throughout that episode.

After careful review of both quality measures, we proposed the quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC HH QRP for the following reasons:

- The IMPACT Act requires the implementation of quality measures, using patient assessment data that are standardized and interoperable across PAC settings. The quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC HH QRP, employs three standardized patient-assessment data elements for each of the four PAC settings so that data are standardized, interoperable, and comparable; whereas, the Care for Older Adults (COA) (NQF #0553) quality measure does not contain data elements that are standardized across all four PAC settings;
- The quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC HH QRP, requires the identification of clinically potential medication issues at the beginning, during and at the end of the patient's episode to capture data on each patient's complete HH episode; whereas, the Care for Older Adults (COA) (NQF #0553) quality measure only requires annual documentation in the form of a medication list in the medical record of the target population;
- The quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC HH QRP, includes identification of the potential clinically significant medication issues and communication with the physician (or physician designee) as well as resolution of the issue(s) within a rapid time frame (by midnight of the next calendar day); whereas, the Care for Older Adults (COA) (NQF #0553) quality measure does not include any follow-up or time frame in which the follow-up would need to occur;
- The quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC HH QRP, does not have age exclusions; whereas, the Care for Older Adults (COA) (NQF #0553) quality measure limits the measure's population to patients aged 66 and older; and
- The quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC HH QRP, would be reported to HHAs quarterly to facilitate internal quality monitoring and quality improvement in areas such as patient safety, care coordination and patient satisfaction; whereas, the Care for Older Adults (COA) (NQF #0553) quality measure would not enable quarterly quality updates, and thus data comparisons within and across PAC providers would be difficult due to the limited data and scope of the data collected.

Therefore, based on the evidence discussed, we proposed to adopt the quality measure entitled, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC HH QRP, for the HH QRP for CY 2018 payment determination and subsequent years. We plan to submit the quality measure to the NQF for consideration of endorsement.

The calculation of the quality measure will be based on the data collection of three standardized items that will be added to the OASIS. The collection of data by means of the standardized items will be obtained at start or resumption of care and end of care. For more information about the data submission required for this measure, we refer readers to Section I.

Form, Manner, and Timing of OASIS Data Submission and OASIS Data for Annual Payment Update

The standardized items used to calculate this quality measure would replace existing items currently used for data collection within the OASIS. The measure denominator is the number of patient episodes with an end of care assessment during the reporting period. The measure numerator is the number of episodes in the denominator where the medical record contains documentation of a drug regimen review conducted at: (1) Start or resumption of care; and (2) end of care with a look back through the home health patient episode with all potential clinically significant medication issues identified during the course of care and followed-up with a physician or physician designee by midnight of the next calendar day. This measure is not risk adjusted. For technical information about this measure, including information about the measure calculation and discussion pertaining to the standardized items used to calculate this measure, we refer readers to the

document titled ''Proposed Measure Specifications for Measures Proposed in the CY 2017 HH QRP proposed rule'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIQualityMeasures.html*.

Data for the proposed quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC HH QRP, would be collected using the OASIS with submission through the QIES ASAP system.

We invited public comment on our proposal to adopt the quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC HH QRP for CY 2018 APU determination and subsequent years. The following is summary of the comments we received regarding our proposal.

Comment: Several commenters expressed support for the proposed quality measure, expressing appreciation to CMS for proposing a quality measure to address the IMPACT Act domain, Medication Reconciliation that acknowledges the importance of medication reconciliation to address patient safety issues. Two commenters additionally emphasized the importance of preventing and responding to ADEs to reduce health services utilization and associated healthcare costs, and emphasized that medication reconciliation is fundamental to patient safety during care transitions.

Response: We agree that medication reconciliation is an important patient safety process for addressing medication accuracy during transitions in patient care and identifying preventable ADEs, which may lead to reduced health services utilization and associated costs.

Comment: We received several comments expressing concern about the timely follow-up component of this measure. Several commenters addressed the issue of timely physician response to communication about potential clinically significant medication issues and physician accountability in this process measure. Many commenters noted the challenge of obtaining a physician response within one calendar day, which may be impeded by events such as physician vacations or contact after hours or during holidays. One commenter specifically recommended a more flexible timeframe to accommodate holidays and weekends. Another commenter noted that HHAs have limited access to pharmacists, as well as multiple physicians who may be involved in a patient's care, and that this lack of access presents a barrier to timely follow-up. Several commenters recommended that HHAs only be held accountable for contacting a physician or physician-designee, but not for completing follow-up actions, within the measure timeframe. One commenter requested guidance from CMS as to whether HHAs will be held accountable for the physician's own timely response. One commenter recommended revising the OASIS–C2 guidance manual to align with the previous guidance for OASIS–C1 items M2002 and M2004 that require physician notification only.

Response: The intervention timeline of midnight of the next calendar day is consistent with clinical practice when a clinically significant medication issue arises requiring intervention. We believe that high quality care should be provided wherever healthcare services are provided, and that this measure helps to ensure that high quality care services are furnished and that patient harm is avoided. The OASIS C2 guidance manual will be updated to reflect information on how to collect and code for these revised items that will be used to calculate the proposed measure.

Comment: Four commenters expressed concern that this measure will create additional burden for HH clinicians. Three commenters specifically noted the lookback period for the measure, the entire episode of care, is a source of additional burden.

Response: This measure is calculated using items that are already collected in the OASIS and that capture good clinical care. The intent of the measure is to capture timely follow up for all ''potential clinically significant issues.'' Although we acknowledge that the measure may create a new burden for some HHAs, we believe the timely review and follow up of potential clinically significant medication issues at every assessment time period and across the patient's episode of care is essential for providing the best quality care for patients. Documenting that this review has occurred is an important component of safe and high-quality care.

Comment: We received several comments requesting CMS further clarify the definition of key terms used in the measure, most often ''potentially clinically significant'' medication issues, but also ''significant drug interactions,'' ''significant side effects,'' ''any potential adverse effects'' and ''physician-designee.'' Several commenters were concerned that these terms could be interpreted differently by clinicians, and that this could result in a challenge to collect reliable and accurate data for this quality measure. One commenter recommended that the definition of ''potentially clinically significant medication issues'' not change for drug regimen review from the published OASIS–C2 item intent and instructions, and the recently released FY17 SNF PPS final rule.

Response: For this measure, potential clinically significant medication issues are defined as those issues that, in the clinician's professional judgment, warrant interventions, such as alerting the physician and/or others, and the timely completion of any recommended actions (by midnight of the next calendar day) so as to avoid and mitigate any untoward or adverse outcomes. The process to identify ''clinically significant'' medication issues depends on the clinical situation at any given time where providers apply appropriate clinical judgment to ensure an adequate response. We recognize that there may be instances in which a provider identifies clinically significant medication issues that require immediate attention, and therefore, timely interventions would include immediate actions by the HHA. The definition of ''potentially clinically significant medication issues'' has not changed from the published OASIS–C2 item intent and instructions or the recently published FY 2017 SNF PPS Final Rule.

The OASIS–C2 manual defines ''medication interactions'' as the impact of another substance (such as another medication, nutritional supplement including herbal products, food, or substances used in diagnostic studies) upon a medication, and adverse drug reactions as ''a form of adverse consequences.'' It may be either a secondary effect of a medication that is usually undesirable and different from the therapeutic effect of the medication or any response to a medication that is noxious and unintended and occurs in doses for prophylaxis, diagnosis, or treatment''. Further the physician designee is defined by the physician's office within the legal scope of practice in the area where the agency operates. Of note, the OASIS–C2 manual is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIOASISUserManual.html*.

We note that the guidance as delineated in the guidance manual should be utilized to guide definitional interpretation and coding for these items that are used to calculate this proposed quality measure. However, guidance should not supersede the immediate actions needed by the HHA for appropriate clinical care.

Comment: Two commenters requested that we test this measure prior to implementing it as part of the quality reporting system and expressed concern that the measure was not NQF endorsed.

Response: This measure is calculated using existing OASIS items that have been slightly modified for cross-setting purposes. Therefore, since these items have been collected by HHAs in past versions of the OASIS, we believe these items will be feasible to collect. In order to test measure performance, we applied the measure specifications to the current OASIS–C1 items and found a median rate of 84.3 percent, with an interquartile range of 22.7 percent across HHAs nationwide based on 2013 data. We plan to submit the measure to NQF for consideration of endorsement.

Comment: Some commenters indicated that the quality measure focuses on drug regimen review rather than medication reconciliation. Commenters recommended that the measure explicitly include medication reconciliation to meet the medication reconciliation domain of the IMPACT Act.

Response: We believe that the proposed measure not only squarely addresses medication reconciliation, as mandated by the IMPACT Act, but does so in a manner that also allows for the assessment of drug regimen review, which is a process we believe goes hand in hand with medication reconciliation. Specifically, we believe that medication reconciliation is the initial step of the drug regimen review process and that the latter is actually dependent on the identification of an accurate medication list.

Comment: Several commenters addressed the challenge and importance of medication reconciliation across the continuum of care. They cited the importance of a discharge summary from the prior care setting that includes a current medication list, by indication, in avoiding medication discrepancies. One commenter suggested that we consider the need for increased collaboration with hospitals to address this issue. Other commenters suggested that we develop a measure that evaluates whether agencies are sending medication lists to the next level of care. Another commenter recommended that we add a medication management measure to fully address patients' medication management routine needs in order to prepare patients for discharge to PAC settings or the community.

Response: We believe that all providers should strive to ensure accurate, sufficient, and efficient patient-centered care during their care transitions across the continuum, including medication oversight. Thus while we may implement quality measures that address gaps in quality, such as information exchange during care transitions, ultimately providers must act to ensure that such coordination is taking place. We appreciate the interest in future quality measure development, including measures related to sending a medication list at discharge and adding a medication management measure. As a requirement of this measure and as with common clinical practice, HHAs are expected to document information pertaining to the process of drug regimen review, which includes medication reconciliation. However, we will take the commenters recommendations into consideration as we continue to develop additional quality measures under the domain of Medication Reconciliation

Comment: One commenter expressed concern about the appropriateness of a cross-setting measure on medication reconciliation in home-based settings, noting that relative to other PAC settings, home health agencies have limited control over medications.

Response: This measure is consistent with standard clinical practice requirements of ongoing review, documentation, and timely reconciliation of all patient medications, with appropriate follow up to address all clinically significant medication concerns. Thus, the documentation of drug regimen review, along with timely follow-up, aligns with professional practice standards expected of all PAC providers to ensure adherence to providing quality care. Further, we wish to note that this measure is based on items that have been modified from existing OASIS items, which have been collected for several years.

Comment: One commenter stated that the proposed measure would not capture process gaps to improve performance related to medication reconciliation and recommended that individual steps in the process be measured separately.

Response: This proposed measure assesses whether medication reconciliation and the other components of drug regimen review, including timely follow-up, were completed. The clinician is required to assess at the start of care, resumption of care, or at discharge assessment whether any concerns related to medication reconciliation has occurred. Completion of this measure is required at any assessment performed during a patient's time in the care of an agency. Any process gaps will be reflected in the measure outcome, as all processes of the drug regimen review and the medication reconciliation must be performed to meet the numerator criteria. Through the collection of the data, providers will be able to determine what areas of improvement are required and whether any systematic gaps in appropriate care are present for their agency.

Comment: One commenter requested that an ED visit as directed by the HHA, when a physician does not respond to a clinically-significant medication issue, should not always be included in the ''unplanned emergency department (ED) use'' statistical measurement outcome.

Response: This measure is not a measure of emergency department use nor is this measure related to the measures ''Emergency Department Use without Hospitalization'' (NQF #0173) or Emergency ''Department Use without Hospital Readmission During the First 30 Days of Home Health'' (NQF #2505) that are currently used in the Home Health Quality Reporting Program. While we understand the commenter's concern, the methodologies behind these measures are not being proposed for change, and therefore the comment is outside the scope of this rulemaking.

Comment: One commenter expressed concern that the process of documenting medication follow-up in the OASIS via a check box does not provide sufficient information on the processes completed or opportunities to assess and improve the quality of medication reconciliation. This commenter recommended that CMS delay this measure to develop an improved approach to data collection on the medication reconciliation process.

Response: The items used to assess the documentation of medication follow-up have been used in versions of the OASIS for some time. These items, as with many others in the OASIS instrument, have been carefully considered to provide the amount of information that address the important issue of drug regimen review without adding undue burden to clinicians. In order to appropriately respond to the correct response categories via checkbox, clinicians must review the medical record in order to attest that the follow up was done each time, which should provide information to the HHA about the processes and quality of review. That is, this proposed measure will inform HHA's quality improvement efforts by indicating how often these processes are completed correctly. Agencies can use these results to conduct additional review of these processes and improve the quality of medication reconciliation.

Final Decision: After consideration of the public comments, we are finalizing

our proposal to adopt the measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues for the HH QRP beginning with the CY 2018 HH QRP.

H. HH QRP Quality Measures and Measure Concepts Under Consideration for Future Years

We invited public comment on the importance, relevance, appropriateness, and applicability of each of the quality measures listed in Table 28 for use in future years in the HH QRP.

TABLE 28—HH QRP QUALITY MEASURES UNDER CONSIDERATION FOR FUTURE YEARS

IMPACT Act Domain	Accurately communicating the existence of and providing for the transfer of health information and care preferences of an individual to the individual, family caregiver of the individual, and providers of services furnishing items and services to the individual, when the individual transitions.
IMPACT Act Measure	• Transfer of health information and care preferences when an individual transitions.
IMPACT Act Domain	Incidence of major falls.
IMPACT Act Measure	• Application of NQF #0674—Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay).
IMPACT Act Domain	Functional status, cognitive function, and changes in function and cognitive function.
IMPACT Act Measure	• Application of NQF #2631—Percent of Long-Term Care Hospital (LTCH) Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function.
NQS Priority	Patient- and Caregiver-Centered Care.
Measures	• Application of NQF #2633—Change in Self-Care Score for Medical Rehabilitation Patients. • Application of NQF #2634—Change in Mobility Score for Medical Rehabilitation Patients. • Application of NQF #2635—Discharge Self-Care Score for Medical Rehabilitation Patients. • Application of NQF #2636—Discharge Mobility Score for Medical Rehabilitation Patients. • Application of NQF #0680—Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay).

We are developing a measure related to the IMPACT Act domain, ''Accurately communicating the existence of and providing for the transfer of health information and care preferences of an individual to the individual, family caregiver of the individual, and providers of services furnishing items and services to the individual, when the individual transitions.'' We are also considering application of two IMPACT Act measures to the HH QRP, to assess the incidence of falls with major injury and functional assessment and goals setting. We are additionally considering application of four standardized functional measures to the HH QRP; two that would assess change in function across the HH episode and two that would assess actual function at discharge relative to expected function. Finally, we are considering a measure related to health and well-being, Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay).

Based on input from stakeholders, we have identified additional concept areas for potential future measure development for the HH QRP. These include ''efficacy'' measures that pair processes, such as assessment and care planning, with outcomes, such as emergency treatment for injuries or increase in pain. The prevalence of mental health and behavioral problems was identified as an option to address outcomes for special populations. In addition, we are considering development of measures that assess if functional abilities were maintained during a care episode and composite measures that combine multiple evidence-based processes. We invited feedback on the importance, relevance, appropriateness, and applicability of these measure constructs.

We invited public comment on the importance, relevance, appropriateness, and applicability of each of the quality measures listed in Table 28 for use in future years in the HH QRP. The following is summary of the comments we received regarding our measure concepts under consideration for future years.

Comment: Some commenters remarked on the limited number of standardized items under consideration for measure development related to communication, cognition, and swallowing and noted that these three domains stand as major obstacles to validly determine the status, needs, and outcomes of individuals with neurological disorders. They recommended adding functional cognitive assessment items to the OASIS. One commenter further encouraged us to adopt a specific screening tool, the Montreal Cognitive Assessment (MoCA), or similar screening tools and assessment tools (that is, CARE–C) to best meet the needs of Medicare beneficiaries and the intent of the IMPACT Act.

Response: We agree that future measure development should include other areas of function, such as communication, cognition, and swallowing. We will continue to engage stakeholders in future measure development and will take these suggested quality measure concepts and recommendations regarding measure specifications into consideration in our ongoing measure development and testing efforts.

Comment: Several comments addressed future measure development related to patient functioning. One commenter expressed support for a core set of functional measures to assess patients consistently across the continuum of care. Three commenters encouraged CMS to develop measures that assess stabilization in patient functioning, and another commenter opposed development of measures that assess change in function as compared to the expected function of a patient. This commenter noted that these measure constructs imply an expectation of improvement and do not reflect the role of the home health benefit in maintaining function and reducing deterioration. Another commenter suggested that CMS should clarify if home health versions of the function measures listed in Table 29 would be developed, noting that the

NQF-endorsed measures reference ''Medical Rehabilitation Patients''. One commenter encouraged no more development of process measures, while two other supported aligning measures across Home Health Compare, CASPER, star ratings and value-based purchasing, and one further supported a single acute care hospitalization measure. Finally, one commenter recommended that future measure development be limited to measures required by the IMPACT Act.

Response: We believe that maintenance of function and avoidance or reduction in functional decline are appropriate goals for some home health patients. As we continue to develop and refine standardized function measures, we will continue to assess and account for the unique characteristics of home health patients and the home health setting. In addition, we note our support for outcome measures and the six measures proposed for removal from the HH QRP are all process measures.

Comment: Two commenters expressed support for developing measures related to the IMPACT Act domain, accurately communicating the existence of and providing for the transfer of health information and care preferences when the individual transitions. These commenters cited the importance of patient and family engagement in care decisions. One commenter further encouraged CMS to add quality measures that include consumer-reported experience of care, as well as one or more measure(s) regarding HHA interaction with and support of family caregivers. They cited the important role that family caregivers play in discharge planning and suggested measurement constructs including documenting the presence of an informal caregiver, caregivers' ability to provide supports and referrals to caregivers for available supports.

Response: We appreciate the support for future development of measures to assess accurately communicating the existence of and providing for the transfer of health information and care preferences of an individual. We concur with the importance of experience-of-care measures. We additionally acknowledge the important role of family caregivers in home health and appreciate the suggestion for future measure development.

Comment: We received two comments regarding future development of a standardized measure of falls with major injury for home health patients. One commenter noted that home health agencies would have unique challenges with measures related to falls in people over 65 in home-based settings, given limited control over the home setting and other risk factors. This commenter expressed support for the goal of minimizing patient falls, but encouraged CMS not to compare outcomes to facility-based providers, given the challenges of the home setting. Another commenter noted that if a home health appropriate version of the standardized Falls with Major Injury measure were implemented, agencies would need information from the removed HH QI measures Emergent Care for Injury Caused by Fall, and Improvement in Urinary Incontinence to assess their status in this area and potentially make improvements.

Response: We note this measure is restricted to falls with major injuries, which should be never events for home health patients. We additionally wish to clarify that data for the two removed measures, Emergent Care for Injury Caused by Fall and Improvement in Urinary Incontinence, will continue to be available to agencies through the CASPER reporting system.

Comment: One commenter recommended developing quality measures assessing outcomes beyond the immediate post-discharge timeframe, such as 60 days after the end of an episode. They noted that such a measure could reflect occupational therapists' contributions to long-term success for post-discharge.

Response: We will take these measure recommendations into consideration.

Comment: One commenter expressed support for future application of the standardized measure ''Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay).'' This commenter noted the importance of adult immunization measures in reducing rates of morbidity and mortality from preventable conditions.

Response: We appreciate the commenter's support for a future standardized measure of seasonal influenza vaccination.

We thank commenters for these suggestions. We will consider these comments when we develop future measure proposals.

I. Form Manner and Timing of OASIS Data Submission and OASIS Data for Annual Payment Update

1. Regulatory Authority

The HH conditions of participation (CoPs) at § 484.55(d) require that the comprehensive assessment be updated and revised (including the administration of the OASIS) no less frequently than: (1) The last 5 days of every 60 days beginning with the start of care date, unless there is a beneficiary-elected transfer, significant change in condition, or discharge and return to the same HHA during the 60-day episode; (2) within 48 hours of the patient's return to the home from a hospital admission of 24-hours or more for any reason other than diagnostic tests; and (3) at discharge.

It is important to note that to calculate quality measures from OASIS data, there must be a complete quality episode, which requires both a Start of Care (initial assessment) or Resumption of Care OASIS assessment and a Transfer or Discharge OASIS assessment. Failure to submit sufficient OASIS assessments to allow calculation of quality measures, including transfer and discharge assessments, is a failure to comply with the CoPs.

HHAs are not required to submit OASIS data for patients who are excluded from the OASIS submission requirements as described in the December 23, 2005, final rule ''Medicare and Medicaid Programs: Reporting Outcome and Assessment Information Set Data as Part of the Conditions of Participation for Home Health Agencies'' (70 FR 76202).

As set forth in the CY 2008 HH PPS final rule (72 FR 49863), HHAs that become Medicare certified on or after May 31 of the preceding year are not subject to the OASIS quality reporting requirement nor any payment penalty for quality reporting purposes for the following year. For example, HHAs certified on or after May 31, 2014, are not subject to the 2 percentage point reduction to their market basket update for CY 2015. These exclusions only affect quality reporting requirements and payment reductions, and do not affect the HHA's reporting responsibilities as announced in the December 23, 2005 OASIS final rules (70 FR 76202).

2. Home Health Quality Reporting Program Requirements for CY 2017 Payment and Subsequent Years

In the CY 2014 HH PPS final rule (78 FR 72297), we finalized a proposal to consider OASIS assessments submitted by HHAs to CMS in compliance with HH CoPs and Conditions for Payment for episodes beginning on or after July 1, 2012, and before July 1, 2013, as fulfilling one portion of the quality reporting requirement for CY 2014.

In addition, we finalized a proposal to continue this pattern for each subsequent year beyond CY 2014. OASIS assessments submitted for episodes beginning on July 1 of the calendar year 2 years prior to the

calendar year of the Annual Payment Update (APU) effective date and ending June 30 of the calendar year one year prior to the calendar year of the APU effective date; fulfill the OASIS portion of the HH QRP requirement.

3. Previously Established Pay-for-Reporting Performance Requirement for Submission of OASIS Quality Data

Section 1895(b)(3)(B)(v)(I) of the Act states that for 2007 and each subsequent year, the home health market basket percentage increase applicable under such clause for such year shall be reduced by 2 percentage points if a home health agency does not submit quality data to the Secretary in accordance with subclause (II) for such a year. This pay-for-reporting requirement was implemented on January 1, 2007. In the CY 2016 HH PPS final rule (80 FR 68703 through 68705), we finalized a proposal to define the quantity of OASIS assessments each HHA must submit to meet the pay-for-reporting requirement. We designed a pay-for-reporting performance system model that could accurately measure the level of an HHA's submission of OASIS data. The performance system is based on the principle that each HHA is expected to submit a minimum set of two matching assessments for each patient admitted to their agency. These matching assessments together create what is considered a quality episode of care, consisting ideally of a Start of Care (SOC) or Resumption of Care (ROC) assessment and a matching End of Care (EOC) assessment.

Section 80 of Chapter 10 of the Medicare Claims Processing Manual states, ''If a Medicare beneficiary is covered under an MA Organization during a period of home care, and subsequently decides to change to Medicare FFS coverage, a new start of care OASIS assessment must be completed that reflects the date of the beneficiary's change to this pay source.'' We wish to clarify that the SOC OASIS assessment submitted when this change in coverage occurs will not be used in our determination of a quality assessment for the purpose of determining compliance with data submission requirements. In such a circumstance, the original SOC or ROC assessment submitted while the Medicare beneficiary is covered under an MA Organization would be considered a quality assessment within the pay-for-reporting, APU, Quality Assessments Only methodology. For further information on successful submission of OASIS assessments, types of assessments submitted by an HHA that fit the definition of a quality assessment, defining the ''Quality Assessments Only'' (QAO) formula, and implementing a pay-for-reporting performance requirement over a 3-year period, please see the CY 2016 HH PPS final rule (80 FR 68704 to 68705). HHAs must score at least 70 percent on the QAO metric of pay-for-reporting performance requirement for CY 2017 (reporting period July 1, 2015, to June 30, 2016), 80 percent for CY 2018 (reporting period July 1, 2016, to June 30, 2017) and 90 percent for CY 2019 (reporting period July 1, 2017, to June 30, 2018) or be subject to a 2 percentage point reduction to their market basket update for that reporting period.

We did not propose any additional policies related to the pay-for-reporting performance requirement. However, we received several comments regarding pay for reporting, while they are out of scope of the current rule we summarize them below.

Comment: One commenter thanked CMS for clarifying how the state-based OASIS submission system had converted to a new national OASIS submission system known as the Assessment Submission and Processing (ASAP). Other commenters addressed the submission of quality data to meet pay-for-reporting requirements under the HH QRP. Two commenters expressed support for the increased threshold, and two commenters requested CMS monitor the implementation of the new thresholds, as well as release the revised Conditions of Participation as soon as possible. One commenter requested that CMS to extend the timeframe for agencies request a reconsideration.

Response: While we did not propose any additional policies related to the pay-for-reporting performance requirement, we appreciate the considerations and suggestions conveyed. On January 1, 2015, we transitioned the state based OASIS transmission to the ASAP system. We finalized the collection of OASIS data through the ASAP system in the CY 2015 HH PPS rule published in the November 6, 2014 **Federal Register** (79 FR 66031). Please see the comments received and our responses on pages 66078 and 66079. Additionally, we finalized the pay-for-reporting threshold requirements in the CY 2016 HH PPS rule, published in the November 5, 2015 **Federal Register** (80, FR 68624). Please see the comments received and our responses on page 68705).

4. Timeline and Data Submission Mechanisms for Measures for the CY 2018 Payment Determination and Subsequent Years

a. Claims Based Measures

The MSPB–PAC HH QRP, Discharge to Community-PAC HH QRP, and Potentially Preventable 30-Day Post-Discharge Readmission Measure for HH QRP, which we proposed in the proposed rule, are Medicare FFS claims-based measures. Because claims-based measures can be calculated based on data that are already reported to the Medicare program for payment purposes, no additional information collection will be required from HHAs. As previously discussed in section V.G., for the Discharge to Community-PAC HH QRP measure, we proposed to use 2 years of claims data, beginning with CYs 2015 and 2016 claims data to inform confidential feedback and CYs 2016 and 2017 claims data for public reporting. For the Potentially Preventable 30-Day Post-Discharge Readmission Measure for HH QRP, we proposed to use 3 years of claims data, beginning with CY 2014, 2015 and 2016 claims data to inform confidential feedback reports for HHAs, and CY 2015, 2016 and 2017 claims data for public reporting. For the MSPB–PAC HH QRP measure, we proposed to use one year of claims data beginning with CY 2016 claims data to inform confidential feedback reports for HHAs, and CY 2017 claims data for public reporting for the HH QRP.

b. Assessment-Based Measures Using OASIS Data Collection

As discussed in section V.G of the proposed rule, for the proposed measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC HH QRP, affecting CY 2018 payment determination and subsequent years, we proposed that HHAs would submit data by completing data elements on the OASIS and then submitting the OASIS to CMS through the QIES ASAP system beginning January 1, 2017. For more information on HH QRP reporting through the QIES ASAP system, refer to CMS Web site at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIOASISUserManual.html.*

We proposed to use standardized data elements in OASIS C2 to calculate the proposed measure: Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC HH QRP. The data elements necessary to calculate this measure using the OASIS are available on our Web site at *https://www.cms.gov/*

Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIQualityMeasures.html.

We invited public comments on the proposed HH QRP data collection requirements for the proposed measures affecting CY 2018 payment determination and subsequent years. We received no comments on this proposal.

Final Decision: We are finalizing the timeline and data submission mechanisms for measures for the CY 2018 Payment Determination and Subsequent Years.

5. Timeline and Data Submission Mechanisms for the CY 2018 Payment Determination and Subsequent Years for New HH QRP Assessment-Based Quality Measure

In the CY 2016 HH PPS final rule (80 FR 68695 through 68698), for the FY 2018 payment determination, we finalized that HHAs must submit data on the quality measure NQF #0678 Percent of Residents or Patients with Pressure Ulcers that are New or Worsened (Short Stay) using CY 2017 data, for example, patients who are admitted to the HHA on and after January 1, 2017, and discharged from the HHA up to and including December 31, 2017. However, for CY 2018 APU purposes this timeframe would be impossible to achieve, given the processes we have established associated with APU determinations, such as the opportunity for providers to seek reconsideration for determinations of non-compliance. Therefore, for both the measure NQF #0678 Percent of Residents or Patients with Pressure Ulcers that are New or Worsened (Short Stay) that we finalized in the CY 2016 HH PPS rule, and the CY 2017 HH PPS proposed measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC HH QRP, we proposed that we would collect two quarters of data for CY 2018 APU determination to remain consistent with the January release schedule for the OASIS and to give HHAs sufficient time to update their systems so that they can comply with the new data reporting requirements, and to give us a sufficient amount of time to determine compliance for the CY 2018 program. The proposed use of two quarters of data for the initial year of quality reporting is consistent with the approach we have used to implement new measures in a number of other QRPs, including the LTCH, IRF, and Hospice QRPs in which only one quarter of data was used.

We invited public comments on our proposal to adopt a calendar year data collection time frame, using an initial 6-month reporting period from January 1, 2017, to June 30, 2017 for CY 2018 payment determinations, for the application of measure NQF #0678 Percent of Residents or Patients with Pressure Ulcers that are New or Worsened (Short Stay) that we finalized in the CY 2016 HH PPS rule, and the CY 2017 HH PPS proposed measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC HH QRP. The following is summary of the comments we received regarding our proposal.

Comment: One commenter recommended that CMS not use data collected in the first 6 months of any new measure in public reporting and specifically cited the application of NQF#0678 and on Drug Regimen Review Conducted with Follow-Up for Identified Issues.

Response: We wish to clarify that this proposal specifically pertained to the use of the first 6 months of data collection for these two measures for the purpose of determining compliance with our CY 2018 HHA QRP reporting requirements. Timeframes for which data are used for public reporting purposes is outside the scope of this proposal. For additional information regarding proposals related to public reporting we refer readers to section V.J. of this rule.

Final Decision: Based on the comments, we are finalizing as proposed a calendar year data collection time frame, using an initial 6-month reporting period from January 1, 2017, to June 30, 2017 for determining compliance with our CY 2018 reporting requirements, for the application of measure NQF #0678 Percent of Residents or Patients with Pressure Ulcers that are New or Worsened (Short Stay) that we finalized in the CY 2016 HH PPS rule, and the CY 2017 HH PPS proposed measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC HH QRP.

6. Data Collection Timelines and Requirements for the CY 2019 Payment Determinations and Subsequent Years

In CY 2014 HH PPS final rule (78 FR 72297), we finalized our use of a July 1—June 30 time frame for APU determinations. In alignment with the previously established timeframe data collection for a given calendar year APU determination time period, beginning with the CY 2019 payment determination, we proposed for both the finalized measure, NQF #0678 Percent of Residents or Patients with Pressure Ulcers that are New or Worsened (Short Stay), and the proposed measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC HH QRP, to use 12 months of data collection, specifically assessments submitted July 1, 2017 through June 30, 2018, for the CY 2019 payment determination. We further proposed to continue to use the same 12-month timeframe of July 1–June 30 for these measures for subsequent years for APU determinations.

We invited comment on the proposals for the data collection timelines and requirements. We did not receive any comments relevant to those proposals.

Final Decision: We are finalizing our use of a July 1–June 30 time frame for HH QRP payment determinations. This is in alignment with the previously established data collection timeline for a given calendar year HH QRP payment determination time period, beginning with the CY 2019 for measures finalized for adoption in the HH QRP.

7. Data Review and Correction Timeframes for Data Submitted Using the OASIS Instrument

In addition, to remain consistent with the SNF, LTCH and IRF QRPs, as well as to comply with the requirements of section of section 1899B(g) of the Act, we proposed to implement calendar year provider review and correction periods for the OASIS assessment-based quality measures implemented into the HH QRP in satisfaction of the IMPACT Act, that is, finalized NQF #0678 Percent of Residents or Patients with Pressure Ulcers that are New or Worsened (Short Stay) and the proposed Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC HH QRP. More specifically, we proposed that HHAs would have approximately 4.5 months after the reporting quarter to correct any errors of their assessment-based data (that appear on the CASPER generated Review and Correct Quality Measure reports) to calculate the measures. During the time of data submission for a given quarterly reporting period and up until the quarterly submission deadline, HHAs could review and perform corrections to errors in the assessment data used to calculate the measures and could request correction of measure calculations. However, once the quarterly submission deadline occurred, the data are ''frozen'' and calculated for public reporting and providers can no longer submit any corrections. As detailed in Table 29, the first calendar year reporting quarter is January 1, 2017, through March 31, 2017. The final deadline for submitting corrected data would be August 15, 2017, for CY Quarter 1, and subsequently and

sequentially, November 15, 2017, for CY 2017 Quarter 2, February 15, 2018, for CY 2017 Quarter 3 and May 15, 2018, for CY 2017 Quarter 4. We noted that the proposal to review and correct data does not replace other requirements associated with timely data submission. We also stated that we would encourage HHAs to submit timely assessment data during a given quarterly reporting period and review their data and information early during the review and correction period so that they can identify errors and resubmit data before the data submission deadline.

TABLE 29—PROPOSED CY DATA COLLECTION/SUBMISSION QUARTERLY REPORTING PERIODS AND DATA SUBMISSION DEADLINES* AFFECTING FINALIZED AND ASSESSMENT-BASED MEASURES

Quality measures	Data collection source	Data collection/submission quarterly reporting period*	Quarterly review and correction periods and data submission quarterly deadlines*
NQF #0678:Application of Percent of Patients or Residents with Pressure Ulcers that are New or Worsened.	OASIS	CY 17 Q1 1/1/2017–3/31/2017	CY 2017 Q1 Deadline: August 15, 2017
		CY 17 Q2 4/1/2017–6/30/17	CY 2017 Q2 Deadline: November 15, 2017
Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC HH QRP.		CY 17 Q3 7/1/2017–9/30/2017	CY 2017 Q3 Deadline: February 15, 2018
		CY 17 Q4 10/1/2017–12/31/2017	CY 2017 Q4 Deadline May 15, 2018

*We note that the submission deadlines provided pertain to the correction of data and that the submission of OASIS data must continue to adhere to all submission deadline requirements as imposed under the Conditions of Participation.

We invited public comments on our proposal to adopt a calendar year data collection time frame, with a 4.5-month period of time for review and correction beginning with CY 2017 for the measure NQF #0678 Percent of Residents or Patients with Pressure Ulcers that are New or Worsened (Short Stay) that we finalized in the CY 2016 HH PPS rule, and the CY 2017 HH PPS proposed measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC HH QRP for the HH QRP.

We did not receive any comments relevant to this proposal.

Final Decision: We are finalizing, as proposed, our proposal to establish a 4.5 month period of time for review and correction beginning with CY 2017 as outlined in Table 29 for the measure NQF #0678 Percent of Residents or Patients with Pressure Ulcers that are New or Worsened (Short Stay) that we finalized in the CY 2016 HH PPS rule, and the CY 2017 HH PPS proposed measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC HH QRP for the HH QRP.

Further, we proposed that the OASIS assessment-based measures already finalized for adoption into the HH QRP follow a similar CY schedule of data reporting using quarterly data collection/submission reporting periods followed by 4.5 months during which providers will have an opportunity to review and correct their data up until the quarterly data submission deadlines as provided in Table 30 for all reporting years unless otherwise specified. We stated that this policy would apply to all proposed and finalized assessment-based measures in the HH QRP.

TABLE 30—PROPOSED CY DATA COLLECTION SUBMISSION QUARTERLY REPORTING PERIODS, QUARTERLY REVIEW AND CORRECTION PERIODS AND DATA SUBMISSION DEADLINES FOR MEASURES SPECIFIED IN SATISFACTION OF THE IMPACT ACT IN SUBSEQUENT YEARS

CY Data collection quarter	Data collection/submission quarterly reporting period	Quarterly review and correction periods and data submission quarterly deadlines*	Correction deadlines*
Quarter 1	January 1–March 31	April 1–August 15	August 15.
Quarter 2	April 1–June 30	July 1–November 15	November 15.
Quarter 3	July 1–September 30	October 1–February 15	February 15.
Quarter 4	October 1–December 31	January 1–May 15	May 15.

*We note that the submission deadlines provided pertain to the correction of data and that the submission of OASIS data must continue to adhere to all submission deadline requirements as imposed under the Conditions of Participation.

We invited public comment on our use of CY quarterly data collection/submission reporting periods with quarterly data submission deadlines that follow a period of approximately 4.5 months of time to enable the review and correction of such data for OASIS assessment-based measures. We did not receive any comments on this proposal.

Final Decision: In alignment with the previously established timeframe data collection for a given calendar year APU determination time period, we are finalizing our proposal to use CY quarterly data collection/submission reporting periods with quarterly data submission deadlines that follow a period of approximately 4.5 months of time to enable the review and correction of such data for OASIS assessment-based measures as outlined in Table 30.

J. Public Display of Quality Measure Data for the HH QRP and Procedures for the Opportunity To Review and Correct Data and Information

Medicare home health regulations, as codified at § 484.250(a), require HHAs to submit OASIS assessments and Home Health Care Consumer Assessment of Healthcare Providers and Systems Survey® (HHCAHPS) data to meet the quality reporting requirements of section 1895(b)(3)(B)(v) of the Act. Section 1899B(g) of the Act requires that

data and information of provider performance on quality measures and resource use and other measures be made publicly available beginning not later than 2 years after the applicable specified application date. In future rulemaking, we intend to propose a policy to publicly display performance information for individual HHAs on IMPACT Act measures, as required under the Act. In addition, sections 1895(b)(3)(B)(v)(III) and 1899B(g) of the Act require the Secretary to establish procedures for making data submitted under subclause (II) available to the public. Under section 1899B(g)(2) of the Act, such procedures must ensure, including through a process consistent with the process applied under section 1886(b)(3)(B)(viii)(VII) of the Act, which refers to public display and review requirements in the Hospital IQR Program, that a home health agency has the opportunity to review and submit corrections to its data and information that are to be made public for the agency prior to such data being made public through a process consistent with the Hospital Inpatient Quality Reporting Program (Hospital IQR). We recognize that public reporting of quality data is a vital component of a robust quality reporting program and are fully committed to ensuring that the data made available to the public are meaningful. Further, we agree that measures for comparing performance across home health agencies requires should be constructed from data collected in a standardized and uniform manner. In the proposed rule, we proposed procedures that would allow individual HHAs to review and correct their data and information on IMPACT Act measures that are to be made public before those measure data are made public.

1. Review and Correction of Data Used To Calculate the Assessment-Based Measures Prior to Public Display

As provided in section V.I.7., and in Table 28, for assessment-based measures, we proposed to provide confidential feedback reports to HHAs that contain performance information that the HHAs can review, during the review and correction period, and correct the data used to calculate the measures for the HH QRP that the HHA submitted via the QIES ASAP system. In addition, during the review period, the HHA would be able to request correction of any errors in the assessment-based measure rate calculations.

We also proposed that these confidential feedback reports that would be available to each HHA using the Certification and Survey Provider Enhanced Reporting (CASPER) System. We refer to these reports as the HH Quality Measure (QM) Reports. We intend to provide monthly updates to the data contained in these reports that pertain to assessment-based data, as data become available. The reports will contain both agency- and patient-level data used to calculate the assessment-based quality measures. The CASPER facility level QM reporting would include the numerator, denominator, agency rate, and national rate. The CASPER patient-level QM Reports would also contain individual patient information that HHAs can use to identify patients that were included in the quality measures so as to identify any potential errors. In addition, we would make other reports available to HHAs through the CASPER System, including OASIS data submission reports and provider validation reports, which would contain information on each HHA's data submission status, including details on all items the HHA submitted in relation to individual assessments and the status of the HHA's assessment (OASIS) records that they submitted. When available, additional information regarding the content and availability of these confidential feedback reports would be provided on the HH QRP Web site *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/index.html*.

As previously proposed, for those measures that use assessment-based data, HHAs would have 4.5 months after the conclusion of each reporting quarter to review and update their reported measure data for the quarter, including correcting any errors that they find on the CASPER-generated Review and Correct, QM reports pertaining to their assessment-based data used to calculate the assessment-based measures. However, at the conclusion of this 4.5 month review and correction period, the data reported for that quarter would be ''frozen'' and used to calculate measure rates for public reporting. We would encourage HHAs to submit timely assessment data during each quarterly reporting period and to review their data and information early during the 4.5 month review and correction period so they can identify errors and resubmit data before the data submission deadline.

We believe that the proposed data submission period along with a review and correction period, consisting of the reporting quarter plus approximately 4.5 months, is sufficient time for HHAs to submit, review and, where necessary, correct their data and information. We also proposed that, in addition to the data submission/correction and review period, HHAs would have a 30-day preview period prior to public display during which they can preview the performance information on their measures that will be made public. We further proposed to provide this preview report using the Certification and Survey Provider Enhanced Reporting (CASPER) System because HHAs are familiar with this system. The CASPER preview reports for the reporting quarter would be available after the 4.5 month review and correction period ends, and would be refreshed quarterly or annually for each measure, depending on the length of the reporting period for that measure. We proposed to give HHAs 30 days to review this information, beginning from the date on which they can access the preview report. Corrections to the underlying data would not be permitted during this time; however, HHAs would be able to ask for a correction to their measure calculations during the 30-day preview period. If we determine that the measure, as it is displayed in the preview report, contains a calculation error, we would suppress the data on the public reporting Web site, recalculate the measure and publish the corrected rate at the time of the next scheduled public display date. This process is consistent with informal processes used in the Hospital IQR program. If finalized, we intend to utilize a subregulatory mechanism, such as our HH QRP Web site, to explain the technical details for how and when providers may contest their measure calculations. We further proposed to increase the current preview period of 15 days to 30 days beginning with the public display of the measures finalized for the CY 2018 payment determination. This preview period would include all measures that are to be publicly displayed under the current quarterly refresh schedule used for posting quality measure data on the Medicare.gov Home Health Compare site.

We invited public comment on these proposals; the following is a summary of the comments received.

Comment: MedPAC supported public reporting of the cross-setting quality measures. We received one comment recommending that prior to public reporting of any data collected under these requirements that CMS conduct analysis to determine whether it is possible to compare the data across settings as intended.

Response: We strive to promote high quality and efficiency in the delivery of

health care to the beneficiaries we serve. Performance improvement leading to the highest quality health care requires continuous evaluation to identify and address performance gaps and reduce the unintended consequences that may arise in treating a large, vulnerable, and aging population. QRPs, coupled with public reporting of quality information, are critical to the advancement of health care quality improvement efforts. CMS is committed to ensuring valid, reliable, and relevant quality measures and are fundamental to the effectiveness of our QRPs. This includes ongoing analysis of collected data prior to public reporting, including comparability of data.

Final Decision: After considering the comments received, we are finalizing our proposal to allow individual HHAs to review and correct their assessment-based measure data including and information on IMPACT Act measures that are to be made public before those measure data are made public.

2. Review and Correction of Data Used To Calculate Claims-Based Measures Prior to Public Display

In addition to assessment-based measures, we proposed claims-based measures for the HH QRP. As noted previously, section 1899B(g)(2) of the Act requires prepublication provider review and correction procedures that are consistent with those followed in the Hospital IQR program. Under the Hospital IQR Program's procedures, for claims-based measures, we give hospitals 30 days to preview their claims-based measures and data in a preview report containing aggregate hospital-level data. We proposed to adopt a similar process for the HH QRP.

Prior to the public display of our claims-based measures, in alignment with the Hospital IQR, HAC and Hospital VBP programs, we proposed to make available through the CASPER system a confidential preview report that will contain information pertaining to their claims-based measure rate calculations, including agency and national rates. This information would be accompanied by additional confidential information based on the most recent administrative data available at the time we extract the claims data for purposes of calculating the rates.

We proposed to create data extracts using claims data for these claims based measures, at least 90 days after the last discharge date in the applicable period (12 calendar months preceding), which we will use for the calculations. For example, if the last discharge date in the applicable period for a measure is December 31, 2017, for data collection January 1, 2017, through December 31, 2017, we would create the data extract on approximately March 31, 2018, at the earliest, and use that data to calculate the claims-based measures for the 2017 reporting period. We proposed that beginning with data for measures that will be publicly displayed by January 1, 2019, and for which will need to coincide with the quarterly refresh schedule on Home Health Compare, the claims-based measures will be calculated at least 90 days after the last discharge date using claims data from the applicable reporting period. This timeframe allows us to balance the need to provide timely program information to HHAs with the need to calculate the claims-based measures using as complete a data set as possible. Since HHAs would not be able to submit corrections to the underlying claims snapshot or add claims (for those measures that use HH claims) to this data set, at the conclusion of the 90-day period following the last date of discharge used in the applicable period, we would consider the HH claims data to be complete for purposes of calculating the claims-based measures. We wish to convey the importance that HHAs ensure the completeness and correctness of their claims prior to the claims ''snapshot''. We seek to have as complete a data set as possible. We recognize that the proposed approximately 90 day ''run-out'' period is less than the Medicare program's current timely claims filing policy under which providers have up to 1 year from the date of discharge to submit claims. We considered a number of factors in determining that the proposed approximately 90 day run-out period is appropriate to calculate the claims-based measures. After the data extract is created, it takes several months to incorporate other data needed for the calculations (particularly in the case of risk-adjusted, and/or episode-based measures). We then need to generate and check the calculations. Because several months lead time is necessary after acquiring the data to generate the claims-based calculations, if we were to delay our data extraction point to 12 months after the last date of the last discharge in the applicable period, we would not be able to deliver the calculations to HHAs sooner than 18 to 24 months after the last discharge. We believe this would create an unacceptably long delay, both for HHAs and for us to deliver timely calculations to HHAs for quality improvement.

As noted, under the proposed procedure, during the 30-day preview period, HHAs would not be able to submit corrections to the underlying claims data or add new claims to the data extract. This is for two reasons. First, for certain measures, some of the claims data used to calculate the measure are derived not from the HHA's claims, but from the claims of another provider. For example, the proposed measure Potentially Preventable 30-Day Post-Discharge Readmission Measure for HH QRP uses claims data submitted by the hospital to which the patient was readmitted. HHAs are not able to make corrections to these hospital claims, although the agency could request that the hospital reconfirm that its submissions are correct. Second, even where HHA claims are used to calculate the measures, it would not be not possible to correct the data after it is extracted for the measures calculation. This is because it is necessary to take a static ''snapshot'' of the claims in order to perform the necessary measure calculations.

As noted previously, we proposed to provide HHAs a 30-day preview period to review their confidential preview reports. HHAs would have 30 days from the date the preview report is made available to review this information. The 30-day preview period would be the only time when HHAs would be able to see their claims-based measure rates before they are publicly displayed. HHAs could request that we correct our measure calculation during the 30-day preview period if the HHA believes the measure rate is incorrect. If we agree that the measure rate, as it is displayed in the preview report, contains a calculation error, we would suppress the data on the public reporting Web site, recalculate the measure, and publish the corrected measure rate at the time of the next scheduled public display date. We stated that if this proposal was finalized, we intended to utilize a subregulatory mechanism, such as our HH QRP Web site, to explain the technical details regarding how and when providers may contest their measure calculations. We refer readers to the discussion in V.I.2 for additional information on these preview reports.

In addition, because the claims-based measures used for the HH QRP are re-calculated on an annual basis, these confidential CASPER QM preview reports for claims-based measures would be refreshed annually. An annual refresh is being utilized to ensure consistency in our display of claims based measures, and it will include both claims-based measures that satisfy the IMPACT Act, as well as all other HH QRP claims-based measures.

We invited public comment on these proposals for the public display of

quality measure data. The following is summary of the comments we received.

Comment: One commenter expressed concern about the 90 day post-discharge time frame proposed for calculating claims-based measures and the subsequent prohibition on correcting or filing new claims. They recommended that we continue to use our current claim filing and correction practices.

Response: We seek to have as complete a data set as possible. We recognize that the 90-day ''run-off'' period, when we will run the data extract to calculate the claims-based measures, is shorter than the one year period that providers have under Medicare's timely claims filing policy to submit and correct claims. We considered a number of factors in determining that a 90-day run-off period is appropriate to calculate the claims-based measures. After the data extract is created, it takes several months to incorporate other data needed for the calculations (particularly in the case of risk-adjusted or episode-based measures). We then need to generate and check the calculations. Because several months lead time is necessary after acquiring the data to generate the claims-based calculations, if we were to delay our data extraction point to 12 months after the last date of the last discharge in the applicable period, we will not be able to deliver the calculations to HHAs sooner than 18 to 24 months after the last discharge. We believe this will create an unacceptably long delay both for HHAs and for us to deliver timely calculations to HHAs for internal quality improvement.

Final Decision: After careful consideration of the public comments, we are finalizing as proposed, our policies and procedures for the review and correction of claims-based measures prior to public display.

K. Mechanism for Providing Feedback Reports to HHAs

Section 1899B(f) of the Act requires the Secretary to provide confidential feedback measure reports to post-acute care providers on their performance on the measures specified under paragraphs (c)(1) and (d)(1), beginning 1 year after the specified application date that applies to such measures and PAC providers. We proposed to build upon the current confidential quality measure reports we already generate for HHAs so as to also provide data and information on the measures implemented in satisfaction of the IMPACT Act. As a result, HHAs could review their performance on these measures, as well as those already adopted in the HH QRP. We proposed that these additional confidential feedback reports would be made available to each HHA through the CASPER System. Data contained within these CASPER reports would be updated, as previously described, on a monthly basis as the data become available except for claims-based measures, which will only be updated on an annual basis.

We intend to provide detailed procedures to HHAs on how to obtain their new confidential feedback reports in CASPER on the HH QRP Web site at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/Home-Health-Quality-Reporting-Requirements.html*. We also proposed to use the QIES ASAP system to provide these new confidential quality measure reports in a manner consistent with how HHAs have obtained such reports to date. The QIES ASAP system is a confidential and secure system with access granted to providers, or their designees.

We invited public comment on this proposal to satisfy the requirement to provide confidential feedback reports to HHAs specific to the requirements of the Act. The following is summary of the comments we received.

Comment: Two commenters requested that CMS provide patient-level data for the three proposed claims-based measures more frequently than once a year, and suggested quarterly updates. They noted that more frequent reporting would support using the measures for quality improvement.

Response: The decision to update claims-based measures on an annual basis was to ensure that the amount of data received during the reporting period was sufficient to generate reliable measure rates. However, we will look into the feasibility of providing HHA's with information more frequently.

Final Decision: As a result of the comments received, we are finalizing our proposal to provide confidential feedback reports to HHAs through the CASPER system as proposed above.

L. Home Health Care CAHPS® Survey (HHCAHPS)

In the CY 2016 HH PPS final rule (80 FR 68623), we stated that the home health quality measures reporting requirements for Medicare-certified agencies includes the Home Health Care CAHPS® (HHCAHPS) Survey for the CY 2017 and 2018 Annual Payment Update (APU) periods. We continue to maintain the stated HHCAHPS data requirements for CY 2017 and CY 2018 that were stated in CY 2016 and in previous HH PPS rules, for the continuous monthly data collection and quarterly data submission of HHCAHPS data.

1. Background and Description of HHCAHPS

As part of the HHS Transparency Initiative, we implemented a process to measure and publicly report patient experiences with home health care, using a survey developed by the AHRQ's Consumer Assessment of Healthcare Providers and Systems (CAHPS®) program and endorsed by the NQF in March 2009 (NQF Number 0517) and NQF re-endorsed in 2015. The HHCAHPS Survey is approved under OMB Control Number 0938–1066. The HHCAHPS survey is part of a family of CAHPS® surveys that asks patients to report on and rate their experiences with health care. The Home Health Care CAHPS® (HHCAHPS) survey presents home health patients with a set of standardized questions about their home health care providers and about the quality of their home health care.

Prior to this survey, there was no national standard for collecting information about patient experiences that enabled valid comparisons across all HHAs. The history and development process for HHCAHPS has been described in previous rules and is also available on the official HHCAHPS Web site at *https://homehealthcahps.org* and in the annually updated *HHCAHPS Protocols and Guidelines Manual,* which is downloadable from *https://homehealthcahps.org*.

Since April 2012, for public reporting purposes, we report five measures from the HHCAHPS Survey—three composite measures and two global ratings of care that are derived from the questions on the HHCAHPS survey. The publicly reported data are adjusted for differences in patient mix across HHAs. We update the HHCAHPS data on Home Health Compare on *www.medicare.gov* quarterly. Each HHCAHPS composite measure consists of four or more individual survey items regarding one of the following related topics:

- Patient care (Q9, Q16, Q19, and Q24);
- Communications between providers and patients (Q2, Q15, Q17, Q18, Q22, and Q23); and
- Specific care issues on medications, home safety, and pain (Q3, Q4, Q5, Q10, Q12, Q13, and Q14).

The two global ratings are the overall rating of care given by the HHA's care providers (Q20), and the patient's willingness to recommend the HHA to family and friends (Q25).

The HHCAHPS survey is currently available in English, Spanish, Chinese,

Russian, and Vietnamese. The OMB number on these surveys is the same (0938–1066). All of these surveys are on the Home Health Care CAHPS® Web site, *https://homehealthcahps.org*. We continue to consider additional language translations of the HHCAHPS in response to the needs of the home health patient population.

All of the requirements about home health patient eligibility for the HHCAHPS survey and conversely, which home health patients are ineligible for the HHCAHPS survey are delineated and detailed in the *HHCAHPS Protocols and Guidelines Manual,* which is downloadable at *https://homehealthcahps.org*. Home health patients are eligible for HHCAHPS if they received at least two skilled home health visits in the past 2 months, which are paid for by Medicare or Medicaid.

Home health patients are ineligible for inclusion in HHCAHPS surveys if one of these conditions pertains to them:

- Are under the age of 18;
- Are deceased prior to the date the sample is pulled;
- Receive hospice care;
- Receive routine maternity care only;
- Are not considered survey eligible because the state in which the patient lives restricts release of patient information for a specific condition or illness that the patient has; or
- Are ''No Publicity'' patients, defined as patients who on their own initiative at their first encounter with the HHAs make it very clear that no one outside of the agencies can be advised of their patient status, and no one outside of the HHAs can contact them for any reason.

We stated in previous rules that Medicare-certified HHAs are required to contract with an approved HHCAHPS survey vendor. This requirement continues, and Medicare-certified agencies also must provide on a monthly basis a list of their patients served to their respective HHCAHPS survey vendors. Agencies are not allowed to influence at all how their patients respond to the HHCAHPS survey.

As previously required, HHCAHPS survey vendors are required to attend introductory and all update trainings conducted by CMS and the HHCAHPS Survey Coordination Team, as well as to pass a post-training certification test. We have approximately 30 approved HHCAHPS survey vendors. The list of approved HHCAHPS survey vendors is available at *https://homehealthcahps.org*.

2. HHCAHPS Oversight Activities

We stated in prior final rules that all approved HHCAHPS survey vendors are required to participate in HHCAHPS oversight activities to ensure compliance with HHCAHPS protocols, guidelines, and survey requirements. For CY 2017 and forward, we continue to state that HHCAHPS survey vendors are to participate in HHCAHPS oversight activities. The purpose of the oversight activities is to ensure that approved HHCAHPS survey vendors follow the *HHCAHPS Protocols and Guidelines Manual.* When all HHCAHPS survey vendors follow the HHCAHPS Protocols and Guidelines Manual, it is most likely that the national survey implementation will occur the same way for all HHA providers participating in the HHCAHPS Survey.

In the CY 2013 HH PPS final rule (77 FR 67094, 67164), we codified the current guideline that all approved HHCAHPS survey vendors fully comply with all HHCAHPS oversight activities. We included this survey requirement at § 484.250(c)(3).

3. HHCAHPS Requirements for the CY 2017 APU

For the CY 2017 APU, we require continuous monthly HHCAHPS data collection and reporting for four quarters. The data collection period for the CY 2017, APU includes the second quarter 2015 through the first quarter 2016 (the months of April 2015 through March 2016). HHAs are required to submit their HHCAHPS data files to the HHCAHPS Data Center for the second quarter 2015 by 11:59 p.m., EST on October 15, 2015; for the third quarter 2015 by 11:59 p.m., EST on January 21, 2016; for the fourth quarter 2015 by 11:59 p.m., EST on April 21, 2016; and for the first quarter 2016 by 11:59 p.m., EST on July 21, 2016. These deadlines are firm; no exceptions are permitted.

For the CY 2017 APU, we require that all HHAs with fewer than 60 HHCAHPS-eligible unduplicated or unique patients in the period of April 1, 2014, through March 31, 2015, are exempt from the HHCAHPS data collection and submission requirements for the CY 2017 APU, upon completion of the CY 2017 HHCAHPS Participation Exemption Request form, and upon CMS verification of the HHA patient counts. Agencies with fewer than 60 HHCAHPS-eligible, unduplicated or unique patients in the period of April 1, 2014, through March 31, 2015, are required to submit their patient counts on the CY 2017 HHCAHPS Participation Exemption Request form posted on *https://homehealthcahps.org* from April 1, 2015, to 11:59 p.m., eastern daylight time (e.d.t.) to March 31, 2016. This deadline is firm, as are all of the quarterly data submission deadlines for the HHAs that participate in HHCAHPS.

We automatically exempt HHAs receiving Medicare certification after the period in which HHAs do their patient count. HHAs receiving Medicare-certification on or after April 1, 2015, are exempt from the HHCAHPS reporting requirement for the CY 2017 APU. These newly-certified HHAs do not need to complete the HHCAHPS Participation Exemption Request Form for the CY 2017 APU.

4. HHCAHPS Requirements for the CY 2018 APU

For the CY 2018 APU, we require continuous monthly HHCAHPS data collection and reporting for four quarters. The data collection period for the CY 2018, APU includes the second quarter 2016 through the first quarter 2017 (the months of April 2016 through March 2017). HHAs will be required to submit their HHCAHPS data files to the HHCAHPS Data Center for the second quarter 2016 by 11:59 p.m., e.d.t. on October 20, 2016; for the third quarter 2016 by 11:59 p.m., EST on January 19, 2017; for the fourth quarter 2016 by 11:59 p.m., e.s.t. on April 20, 2017; and for the first quarter 2017 by 11:59 p.m., e.d.t. on July 20, 2017. These deadlines are firm; no exceptions will be permitted.

For the CY 2018 APU, we require that all HHAs with fewer than 60 HHCAHPS-eligible unduplicated or unique patients in the period of April 1, 2015 through March 31, 2016, are exempt from the HHCAHPS data collection and submission requirements for the CY 2018 APU, upon completion of the CY 2018 HHCAHPS Participation Exemption Request form, and upon CMS verification of the HHA patient counts. Agencies with fewer than 60 HHCAHPS-eligible, unduplicated or unique patients in the period of April 1, 2015, through March 31, 2016, are required to submit their patient counts on the CY 2018 HHCAHPS Participation Exemption Request form posted on *https://homehealthcahps.org* from April 1, 2016, to 11:59 p.m., e.d.t. to March 31, 2017. This deadline is firm, as are all of the quarterly data submission deadlines for the HHAs that participate in HHCAHPS.

We automatically exempt HHAs receiving Medicare certification after the period in which HHAs do their patient count. HHAs receiving Medicare-certification on or after April 1, 2016, are exempt from the HHCAHPS

reporting requirement for the CY 2018 APU. These newly-certified HHAs do not need to complete the HHCAHPS Participation Exemption Request Form for the CY 2018 APU.

5. HHCAHPS Requirements for the CY 2019 APU

For the CY 2019 APU, we require continuous monthly HHCAHPS data collection and reporting for four quarters. The data collection period for the CY 2018, APU includes the second quarter 2017 through the first quarter 2018 (the months of April 2017 through March 2018). HHAs will be required to submit their HHCAHPS data files to the HHCAHPS Data Center for the second quarter 2017 by 11:59 p.m., e.d.t. on October 19, 2017; for the third quarter 2017 by 11:59 p.m., e.s.t. on January 18, 2018; for the fourth quarter 2017 by 11:59 p.m., e.d.t. on April 19, 2018; and for the first quarter 2018 by 11:59 p.m., e.d.t. on July 19, 2018. These deadlines are firm; no exceptions will be permitted.

For the CY 2019 APU, we require that all HHAs with fewer than 60 HHCAHPS-eligible unduplicated or unique patients in the period of April 1, 2016 through March 31, 2017, are exempt from the HHCAHPS data collection and submission requirements for the CY 2019 APU, upon completion of the CY 2019 HHCAHPS Participation Exemption Request form, and upon CMS verification of the HHA patient counts. Agencies with fewer than 60 HHCAHPS-eligible, unduplicated or unique patients in the period of April 1, 2016, through March 31, 2017, are required to submit their patient counts on the CY 2019 HHCAHPS Participation Exemption Request form posted on *https://homehealthcahps.org* from April 1, 2017, to 11:59 p.m., e.d.t. to March 31, 2018. This deadline is firm, as are all of the quarterly data submission deadlines for the HHAs that participate in HHCAHPS.

We automatically exempt HHAs receiving Medicare certification after the period in which HHAs do their patient count. HHAs receiving Medicare-certification on or after April 1, 2017, are exempt from the HHCAHPS reporting requirement for the CY 2019 APU. These newly-certified HHAs do not need to complete the HHCAHPS Participation Exemption Request Form for the CY 2019 APU.

6. HHCAHPS Requirements for the CY 2020 APU

For the CY 2020 APU, we require continued monthly HHCAHPS data collection and reporting for four quarters. The data collection period for the CY 2020, APU includes the second quarter 2018 through the first quarter 2019 (the months of April 2018 through March 2019). HHAs will be required to submit their HHCAHPS data files to the HHCAHPS Data Center for the second quarter 2018 by 11:59 p.m., e.d.t. on October 18, 2018; for the third quarter 2018 by 11:59 p.m., e.s.t. on January 17, 2019; for the fourth quarter 2018 by 11:59 p.m., e.d.t. on April 18, 2019; and for the first quarter 2019 by 11:59 p.m., e.d.t. on July 19, 2019. These deadlines are firm; no exceptions will be permitted.

For the CY 2020 APU, we require that all HHAs with fewer than 60 HHCAHPS-eligible unduplicated or unique patients in the period of April 1, 2017, through March 31, 2018, are exempt from the HHCAHPS data collection and submission requirements for the CY 2020 APU, upon completion of the CY 2020 HHCAHPS Participation Exemption Request form, and upon CMS verification of the HHA patient counts. Agencies with fewer than 60 HHCAHPS-eligible, unduplicated or unique patients in the period of April 1, 2017, through March 31, 2018, are required to submit their patient counts on the CY 2020 HHCAHPS Participation Exemption Request form posted on *https://homehealthcahps.org* from April 1, 2018, to 11:59 p.m., e.d.t. to March 31, 2019. This deadline is firm, as are all of the quarterly data submission deadlines for the HHAs that participate in HHCAHPS.

We automatically exempt HHAs receiving Medicare certification after the period in which HHAs do their patient count. HHAs receiving Medicare-certification on or after April 1, 2018 are exempt from the HHCAHPS reporting requirement for the CY 2020 APU. These newly-certified HHAs do not need to complete the HHCAHPS Participation Exemption Request Form for the CY 2020 APU.

7. HHCAHPS Reconsiderations and Appeals Process

HHAs should monitor their respective HHCAHPS survey vendors to ensure that vendors submit their HHCAHPS data on time, by accessing their HHCAHPS Data Submission Reports on *https://homehealthcahps.org*. This helps HHAs ensure that their data are submitted in the proper format for data processing to the HHCAHPS Data Center.

We continue the OASIS and HHCAHPS reconsiderations and appeals process that we have finalized and that we have used for prior all periods cited in the previous rules, and utilized in the CY 2012 to CY 2016 APU determinations. We have described the HHCAHPS reconsiderations and appeals process requirements in the APU Notification Letter that we send to the affected HHAs annually in September. HHAs have 30 days from their receipt of the letter informing them that they did not meet the HHCAHPS requirements to reply to us with documentation that supports their requests for reconsideration of the annual payment update to us. It is important that the affected HHAs send in comprehensive information in their reconsideration letter/package because we will not contact the affected HHAs to request additional information or to clarify incomplete or inconclusive information. If clear evidence to support a finding of compliance is not present, then the 2 percent reduction in the annual payment update will be upheld. If clear evidence of compliance is present, then the 2 percent reduction for the APU will be reversed. We notify affected HHAs by December 31 of the decisions that affects payments in the annual year beginning on January 1. If we determine to uphold the 2 percent reduction for the annual payment update, the affected HHA may further appeal the 2 percent reduction via the Provider Reimbursement Review Board (PRRB) appeals process, which is described in the December letter.

8. Summary

We did not receive comments for HHCAHPS in the 60-day comment period. We are finalizing the HHCAHPS Survey section as proposed. There are no changes to the HHCAHPS participation requirements, or to the requirements pertaining to the implementation of the Home Health CAHPS® Survey. In this rule, we only updated the information to reflect the dates for future APU years. We again strongly encourage HHAs to keep up-to-date about the HHCAHPS by regularly viewing the official Web site for HHCAHPS at *https://homehealthcahps.org*. HHAs can also send an email to the HHCAHPS Survey Coordination Team at *hhcahps@rti.org* or to CMS at *homehealthcahps@cms.hhs.gov*, or telephone toll-free (1–866–354–0985) for more information about the HHCAHPS Survey.

VI. Collection of Information Requirements

While this final rule contains information collection requirements, this rule does not add new, nor revise any of the existing information collection requirements, or burden estimate. The information collection

requirements discussed in this rule for the OASIS–C1 data item set had been previously approved by the Office of Management and Budget (OMB) on February 6, 2014 and scheduled for implementation on October 1, 2014. The extension of OASIS–C1/ICD–9 version was reapproved under OMB control number 0938–0760 with a current expiration date of March 31, 2018. To facilitate the reporting of OASIS data as it relates to the implementation of ICD–10, we submitted a new request for approval to OMB for the OASIS–C1/ICD–10 version under the Paperwork Reduction Act (PRA) process. The extension of OASIS–C1/ICD–9 will be discontinued as the OASIS–C1/ICD–10 version was approved under OMB Control Number 0938–1279 with a current expiration date of May 31, 2018. To satisfy requirements in the IMPACT Act that HHAs submit standardized patient assessment data in accordance with section 1899B(b) and to create consistency in the lookback period across selected OASIS items, we have created a modified version of the OASIS, OASIS–C2. The OASIS–C2 version will replace the OASIS–C1/ICD–10 and will be effective for data collected with an assessment completion date (M0090) on and after January 1, 2017. We are requesting a new OMB control number for the OASIS–C2 version under the PRA process (81 FR 18855). The new information collection request is currently pending OMB approval.

VII. Regulatory Impact Analysis

A. Statement of Need

Section 1895(b)(1) of the Act requires the Secretary to establish a HH PPS for all costs of HH services paid under Medicare. In addition, section 1895(b)(3)(A) of the Act requires (1) the computation of a standard prospective payment amount include all costs for HH services covered and paid for on a reasonable cost basis and that such amounts be initially based on the most recent audited cost report data available to the Secretary, and (2) the standardized prospective payment amount be adjusted to account for the effects of case-mix and wage levels among HHAs. Section 1895(b)(3)(B) of the Act addresses the annual update to the standard prospective payment amounts by the applicable percentage increase. Section 1895(b)(4) of the Act governs the payment computation. Sections 1895(b)(4)(A)(i) and (b)(4)(A)(ii) of the Act require the standard prospective payment amount to be adjusted for case-mix and geographic differences in wage levels. Section 1895(b)(4)(B) of the Act requires the establishment of appropriate case-mix adjustment factors for significant variation in costs among different units of services. Lastly, section 1895(b)(4)(C) of the Act requires the establishment of wage adjustment factors that reflect the relative level of wages, and wage-related costs applicable to HH services furnished in a geographic area compared to the applicable national average level.

Section 1895(b)(3)(B)(iv) of the Act provides the Secretary with the authority to implement adjustments to the standard prospective payment amount (or amounts) for subsequent years to eliminate the effect of changes in aggregate payments during a previous year or years that was the result of changes in the coding or classification of different units of services that do not reflect real changes in case-mix. Section 1895(b)(5) of the Act provides the Secretary with the option to make changes to the payment amount otherwise paid in the case of outliers because of unusual variations in the type or amount of medically necessary care. Section 1895(b)(3)(B)(v) of the Act requires HHAs to submit data for purposes of measuring health care quality, and links the quality data submission to the annual applicable percentage increase.

Section 421(a) of the MMA requires that HH services furnished in a rural area, for episodes and visits ending on or after April 1, 2010, and before January 1, 2016, receive an increase of 3 percent of the payment amount otherwise made under section 1895 of the Act. Section 210 of the MACRA amended section 421(a) of the MMA to extend the 3 percent increase to the payment amounts for serviced furnished in rural areas for episodes and visits ending before January 1, 2018.

Section 3131(a) of the Affordable Care Act mandates that starting in CY 2014, the Secretary must apply an adjustment to the national, standardized 60-day episode payment rate and other amounts applicable under section 1895(b)(3)(A)(i)(III) of the Act to reflect factors such as changes in the number of visits in an episode, the mix of services in an episode, the level of intensity of services in an episode, the average cost of providing care per episode, and other relevant factors. In addition, section 3131(a) of the Affordable Care Act mandates that rebasing must be phased-in over a 4-year period in equal increments, not to exceed 3.5 percent of the amount (or amounts) as of the date of enactment (2010) under section 1895(b)(3)(A)(i)(III) of the Act, and be fully implemented in CY 2017.

The HHVBP Model will apply a payment adjustment based on an HHA's performance on quality measures to test the effects on quality and costs of care. The HHVBP Model was implemented in January 2016 as described in the CY 2016 HH PPS final rule.

B. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA, March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity).

Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule: (1) Having an annual effect on the economy of $100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as ''economically significant''); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). The net transfer impacts related to the changes in payments under the HH PPS for CY 2017 are estimated to be −$130 million. The savings impacts related to the HHVBP model are estimated at a total projected 5-year gross savings of $378

million assuming a very conservative savings estimate of a 6 percent annual reduction in hospitalizations and a 1.0 percent annual reduction in SNF admissions. Therefore, we consider this rulemaking as ''economically significant'' as measured by the $100 million threshold, and hence also a major rule under the Congressional Review Act. Accordingly, we have prepared a Regulatory Impact Analysis that to the best of our ability presents the costs and benefits of the rulemaking. In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

In addition, section 1102(b) of the Act requires us to prepare a 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 RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. This final rule is applicable exclusively to HHAs. Therefore, the Secretary has determined this rule would not have a significant economic impact on the operations 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 2016, that threshold is approximately $146 million. This final rule is not anticipated to have an effect on State, local, or tribal governments, in the aggregate, or on the private sector of $146 million or more.

1. HH PPS

The update set forth in this rule applies to Medicare payments under HH PPS in CY 2017. Accordingly, the following analysis describes the impact in CY 2017 only. We estimate that the net impact of the policies in this rule is approximately $130 million in decreased payments to HHAs in CY 2017. We applied a wage index budget neutrality factor and a case-mix weight budget neutrality factor to the rates as discussed in section III.C.3 of this final rule. Therefore, the estimated impact of the 2017 wage index and the recalibration of the case-mix weights for 2017 is zero. We estimate the impact due to the final payment procedures for furnishing Negative Pressure Wound Therapy (NPWT) using a disposable device, as outlined in section III.E.3 of this final rule, is less than a one-tenth of one percent increase in payments for CY 2017. Therefore, the −$130 million impact reflects the distributional effects of the 2.5 percent HH payment update percentage ($450 million increase), the effects of the fourth year of the four-year phase-in of the rebasing adjustments to the national, standardized 60-day episode payment amount, the national per-visit payment rates, and the NRS conversion factor for an impact of −2.3 percent ($420 million decrease), and the effects of the −0.97 percent adjustment to the national, standardized 60-day episode payment rate to account for nominal case-mix growth for an impact of −0.9 percent ($160 million decrease). The $130 million in decreased payments is reflected in the last column of the first row in Table 31 as a 0.7 percent decrease in expenditures when comparing CY 2016 payments to estimated CY 2017 payments.

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 one year. For the purposes of the RFA, we estimate that almost all HHAs are small entities as that term is used in the RFA. Individuals and states are not included in the definition of a small entity. The economic impact assessment is based on estimated Medicare payments (revenues) and HHS's practice in interpreting the RFA is to consider effects economically ''significant'' only if greater than 5 percent of providers reach a threshold of 3 to 5 percent or more of total revenue or total costs. The majority of HHAs' visits are Medicare-paid visits and therefore the majority of HHAs' revenue consists of Medicare payments. Based on our analysis, we conclude that the policies in this rule would result in an estimated total impact of 3 to 5 percent or more on Medicare revenue for greater than 5 percent of HHAs. Therefore, the Secretary has determined that this HH PPS final rule would have a significant economic impact on a substantial number of small entities. Further detail is presented in Table 31, by HHA type and location.

With regards to options for regulatory relief, we note that in the CY 2014 HH PPS final rule, we finalized rebasing adjustments to the national, standardized 60-day episode rate, non-routine supplies (NRS) conversion factor, and the national per-visit payment rates for each year, 2014 through 2017 as described in section II.C and III.C.3 of this final rule. Since the rebasing adjustments are mandated by section 3131(a) of the Affordable Care Act, we cannot offer HHAs relief from the rebasing adjustments for CY 2017. For the 0.97 percent reduction to the national, standardized 60-day episode payment amount for CY 2017 described in section III.C.3 of this final rule, we believe it is appropriate to reduce the national, standardized 60-day episode payment amount to account for the estimated increase in nominal case-mix in order to move towards more accurate payment for the delivery of home health services where payments better align with the costs of providing such services. In the alternatives considered section for the CY 2016 HH PPS proposed rule (80 FR 39839), we note that we considered reducing the 60-day episode rate in CY 2016 only to account for nominal case-mix growth between CY 2012 and CY 2014. However, we instead finalized a reduction to the 60-day episode rate over a three-year period (CY 2016, CY 2017, and CY 2018) to account for estimated nominal case-mix growth between CY 2012 and CY 2014 in order to lessen the impact on HHAs in a given year (80 FR 68646).

Executive Order 13563 specifies, to the extent practicable, agencies should assess the costs of cumulative regulations. However, given potential utilization pattern changes, wage index changes, changes to the market basket forecasts, and unknowns regarding future policy changes, we believe it is neither practicable nor appropriate to forecast the cumulative impact of the nominal case-mix reductions on Medicare payments to HHAs for future years at this time. Changes to the Medicare program may continue to be made as a result of the Affordable Care Act, or new statutory provisions. Although these changes may not be specific to the HH PPS, the nature of the Medicare program is such that the changes may interact, and the complexity of the interaction of these changes would make it difficult to predict accurately the full scope of the impact upon HHAs for future years beyond CY 2017.

2. HHVBP Model

Under the HHVBP Model, the first payment adjustment will apply in CY 2018 based on PY1 (CY 2016) data and the final payment adjustment will apply in CY 2022 based on PY5 (CY 2020)

data. In the CY 2016 HH PPS final rule, the overall impact of HHVBP Model from CY 2018–CY 2022 was approximately a reduction of $380 million. That estimate was based on the 5 performance years of the Model and only 2 payment adjustment years. We now estimate that this will be approximately a decrease of $378 million. This estimate represents the 5 performance years (CY 2016–CY 2020) and applying the payment adjustments from CY 2018 through CY 2021. We assume that the behavior changes and savings will continue into 2021 because HHAs will continue to receive quality reports until July 2021. Although behavior changes and savings could persist into CY 2022, HHAs would not be receiving quality reports so we did not include it in our savings assumptions.

C. Detailed Economic Analysis

1. HH PPS

This rule provides updates for CY 2017 to the HH PPS rates contained in the CY 2016 HH PPS final rule (80 FR 68624 through 68719). The impact analysis of the final rule presents the estimated expenditure effects of policy changes in this rule. We use the latest data and best analysis available, but we do not make adjustments for future changes in such variables as number of visits or case-mix.

This analysis incorporates the latest estimates of growth in service use and payments under the Medicare HH benefit, based primarily on Medicare claims data from 2015. We note that certain events may combine to limit the scope or accuracy of our impact analysis, because such an analysis is future-oriented and, thus, susceptible to errors resulting from other changes in the impact time period assessed. Some examples of such possible events are newly-legislated general Medicare program funding changes made by the Congress, or changes specifically related to HHAs. In addition, changes to the Medicare program may continue to be made as a result of the Affordable Care Act, or new statutory provisions. Although these changes may not be specific to the HH PPS, the nature of the Medicare program is such that the changes may interact, and the complexity of the interaction of these changes could make it difficult to predict accurately the full scope of the impact upon HHAs. Finally, due to current data limitations we are unable to, with great confidence, estimate the distributional effects of the payment procedures for furnishing NPWT using a disposable device as finalized in section III.E of this rule. However, we note that the overall impact of this final policy was less than one-tenth of one percent and if distributional effects were able to be determined, they would in all likelihood round to zero.

Table 31 represents how HHA revenues are likely to be affected by the policy changes in this rule. For this analysis, we used an analytic file with linked CY 2015 OASIS assessments and HH claims data for dates of service that ended on or before December 31, 2015 (as of June 30, 2016). The first column of Table 31 classifies HHAs according to a number of characteristics including provider type, geographic region, and urban and rural locations. The second column shows the number of facilities in the impact analysis. The third column shows the payment effects of the CY 2017 wage index. The fourth column shows the payment effects of the CY 2017 case-mix weights. The fifth column shows the effects the 0.97 percent reduction to the national, standardized 60-day episode payment amount to account for nominal case-mix growth. The sixth column shows the effects of the rebasing adjustments to the national, standardized 60-day episode payment rate, the national per-visit payment rates, and NRS conversion factor. For CY 2017, the average impact for all HHAs due to the effects of rebasing is an estimated 2.3 percent decrease in payments. The seventh column shows the effects of revising the FDL ratio used to determine whether an episode of care receives an outlier payment from 0.45 to 0.55. The eighth column shows the effects of the change to the outlier methodology. The ninth column shows the effects of the CY 2017 home health payment update percentage.

The last column shows the combined effects of all the policies in this rule. Overall, it is projected that aggregate payments in CY 2017 would decrease by 0.7 percent. As illustrated in Table 31, the combined effects of all of the changes vary by specific types of providers and by location. We note that some individual HHAs within the same group may experience different impacts on payments than others due to the distributional impact of the CY 2017 wage index, the extent to which HHAs had episodes in case-mix groups where the case-mix weight decreased for CY 2017 relative to CY 2016, the percentage of total HH PPS payments that were subject to the low-utilization payment adjustment (LUPA) or paid as outlier payments, and the degree of Medicare utilization.

TABLE 31—ESTIMATED HOME HEALTH AGENCY IMPACTS BY FACILITY TYPE AND AREA OF THE COUNTRY, CY 2017

	Number of agencies [1]	CY 2017 wage index [2] (%)	CY 2017 case-mix weights [3] (%)	60-Day episode rate nominal case-mix reduction [4]	Rebasing [5] (%)	Revised outlier FDL (%)	Revised outlier method-ology (%)	HH payment update percent-age [6]	Total (%)
All Agencies	11,327	0.0	0.0	−0.9	−2.3	0.0	0.0	2.5	−0.7
Facility Type and Control:									
Free-Standing/Other Vol/NP	1,108	−0.2	−0.1	−0.9	−2.2	0.0	0.8	2.5	−0.1
Free-Standing/Other Proprietary	8,876	0.1	0.0	−0.9	−2.3	0.0	−0.4	2.5	−1.0
Free-Standing/Other Government	357	0.2	0.1	−0.9	−2.2	0.0	0.1	2.5	−0.2
Facility-Based Vol/NP	682	−0.1	0.0	−0.9	−2.2	0.0	0.8	2.5	0.1
Facility-Based Proprietary	102	0.1	0.0	−0.9	−2.3	0.0	0.3	2.5	−0.3
Facility-Based Government	202	0.1	0.0	−0.9	−2.3	0.0	0.6	2.5	0.0
Subtotal: Freestanding	10,341	0.0	0.0	−0.9	−2.3	0.0	−0.1	2.5	−0.8
Subtotal: Facility-based	986	−0.1	0.0	−0.9	−2.2	0.0	0.7	2.5	0.0
Subtotal: Vol/NP	1,790	−0.2	0.0	−0.9	−2.2	0.0	0.8	2.5	0.0
Subtotal: Proprietary	8,978	0.1	0.0	−0.9	−2.3	0.0	−0.4	2.5	−1.0
Subtotal: Government	559	0.1	0.1	−0.9	−2.3	0.0	0.4	2.5	−0.1
Facility Type and Control: Rural:									
Free-Standing/Other Vol/NP	278	0.2	0.0	−0.9	−2.3	0.0	0.5	2.5	0.0
Free-Standing/Other Proprietary	808	0.3	0.0	−0.9	−2.4	0.0	−0.2	2.5	−0.7
Free-Standing/Other Government	250	0.3	0.1	−0.9	−2.2	0.0	0.1	2.5	−0.1
Facility-Based Vol/NP	312	0.4	0.1	−0.9	−2.3	0.0	0.4	2.5	0.2
Facility-Based Proprietary	50	−0.3	0.1	−0.9	−2.3	0.0	0.5	2.5	−0.4

TABLE 31—ESTIMATED HOME HEALTH AGENCY IMPACTS BY FACILITY TYPE AND AREA OF THE COUNTRY, CY 2017—Continued

	Number of agencies [1]	CY 2017 wage index [2] (%)	CY 2017 case-mix weights [3] (%)	60-Day episode rate nominal case-mix reduction [4]	Rebasing [5] (%)	Revised outlier FDL (%)	Revised outlier methodology (%)	HH payment update percentage [6]	Total (%)
Facility-Based Government	144	0.1	0.1	−0.9	−2.3	0.0	0.3	2.5	−0.2
Facility Type and Control: Urban:									
Free-Standing/Other Vol/NP	829	−0.2	−0.1	−0.9	−2.2	0.0	0.8	2.5	−0.1
Free-Standing/Other Proprietary	8,063	0.0	0.0	−0.9	−2.3	0.0	−0.4	2.5	−1.1
Free-Standing/Other Government	107	0.0	0.0	−0.9	−2.2	0.0	0.0	2.5	−0.6
Facility-Based Vol/NP	370	−0.2	0.0	−0.9	−2.2	0.0	0.9	2.5	0.1
Facility-Based Proprietary	52	0.3	0.0	−0.9	−2.2	0.0	0.1	2.5	−0.2
Facility-Based Government	58	0.1	0.0	−0.9	−2.3	0.0	0.9	2.5	0.3
Facility Location: Urban or Rural:									
Rural	1,842	0.3	0.0	−0.9	−2.3	0.0	0.0	2.5	−0.4
Urban	9,479	0.0	0.0	−0.9	−2.3	0.0	0.0	2.5	−0.7
Facility Location: Region of the Country:									
Northeast	863	−0.3	−0.1	−0.9	−2.1	0.0	0.7	2.5	−0.2
Midwest	3,038	−0.1	0.1	−0.9	−2.4	0.0	0.4	2.5	−0.4
South	5,363	−0.1	−0.1	−0.9	−2.3	0.0	−0.6	2.5	−1.5
West	2,013	0.6	0.1	−0.9	−2.3	0.0	0.3	2.5	0.3
Other	50	−0.3	−0.4	−0.9	−2.3	0.0	0.8	2.5	−0.6
Facility Location: Region of the Country (Census Region):									
New England	355	−0.8	−0.1	−0.9	−2.1	−0.1	0.1	2.5	−1.4
Mid Atlantic	508	0.0	−0.1	−0.9	−2.1	0.0	1.1	2.5	0.5
East North Central	2,306	−0.1	0.1	−0.9	−2.4	0.0	0.4	2.5	−0.4
West North Central	732	−0.1	0.0	−0.9	−2.3	0.0	0.5	2.5	−0.3
South Atlantic	1,818	−0.4	−0.2	−0.9	−2.3	0.0	−0.6	2.5	−1.9
East South Central	426	0.0	−0.1	−0.9	−2.5	0.0	0.0	2.5	−1.0
West South Central	3,119	0.3	0.0	−0.9	−2.3	0.0	−0.8	2.5	−1.2
Mountain	682	0.1	−0.1	−0.9	−2.3	0.0	−0.3	2.5	−1.0
Pacific	1,331	0.7	0.2	−0.9	−2.3	0.0	0.5	2.5	0.7
Facility Size (Number of 1st Episodes):									
<100 episodes	2,926	−0.1	0.2	−0.9	−2.3	0.0	0.5	2.5	−0.1
100 to 249	2,599	0.0	0.1	−0.9	−2.4	0.0	0.1	2.5	−0.6
250 to 499	2,423	0.0	0.1	−0.9	−2.3	0.0	−0.1	2.5	−0.7
500 to 999	1,831	0.0	0.0	−0.9	−2.3	0.0	−0.1	2.5	−0.8
1,000 or More	1,548	0.0	−0.1	−0.9	−2.3	0.0	0.0	2.5	−0.8

Source: CY 2015 Medicare claims data for episodes ending on or before December 31, 2015 (as of June 30, 2016) for which we had a linked OASIS assessment.

[1] The number of rural HHAs (1,842) plus the number of urban HHAs (9,479) does not add up to the total number of HHAs (11,327) due to six HHAs that have a missing value for the urban/rural indicator in the impact analysis file.

[2] The impact of the CY 2017 home health wage index is offset by the wage index budget neutrality factor described in section III.C.3 of this final rule.

[3] The impact of the CY 2017 home health case-mix weights reflects the recalibration of the case-mix weights as outlined in section III.B of this final rule offset by the case-mix weights budget neutrality factor described in section III.C.3 of this final rule.

[4] The 0.97 percent reduction to the national, standardized 60-day episode payment amount in CY 2017 is estimated to have a 0.9 percent impact on overall HH PPS expenditures.

[5] The impact of rebasing includes the rebasing adjustments to the national, standardized 60-day episode payment rate (−2.74 percent after the CY 2017 payment rate was adjusted for the wage index and case-mix weight budget neutrality factors and the nominal case-mix reduction), the national per-visit rates (+2.9 percent), and the NRS conversion factor (−2.82 percent). The estimated impact of the NRS conversion factor rebasing adjustment is an overall -0.01 percent decrease in estimated payments to HHAs

[6] The CY 2017 home health payment update percentage reflects the home health market basket update of 2.8 percent, reduced by a 0.3 percentage point multifactor productivity (MFP) adjustment as required under section 1895(b)(3)(B)(vi)(I) of the Act, as described in section III.C.1 of this final rule.

Region Key:

New England = Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont;

Middle Atlantic = Pennsylvania, New Jersey, New York; South Atlantic = Delaware, District of Columbia, Florida, Georgia, Maryland, North Carolina, South Carolina, Virginia, West Virginia; East North Central = Illinois, Indiana, Michigan, Ohio, Wisconsin; East South Central = Alabama, Kentucky, Mississippi, Tennessee; West North Central = Iowa, Kansas, Minnesota, Missouri, Nebraska, North Dakota, South Dakota; West South Central = Arkansas, Louisiana, Oklahoma, Texas; Mountain = Arizona, Colorado, Idaho, Montana, Nevada, New Mexico, Utah, Wyoming; Pacific = Alaska, California, Hawaii, Oregon, Washington; Other = Guam, Puerto Rico, Virgin Islands

2. HHVBP Model

Table 32 displays our analysis of the distribution of possible payment adjustments at the 3-percent, 5-percent, 6-percent, 7-percent, and 8-percent rates that are being used in the Model using the 2013 and 2014 OASIS measures, hospitalization measure and Emergency Department (ED) measure from QIES, and Home Health CAHPS data. The impacts below also account for the finalized proposals to change the smaller-volume cohort size determination, calculate achievement thresholds and benchmarks at the state level, and revise the applicable measures. We determined the distribution of possible payment adjustments based on ten (10) OASIS quality measures, two (2) claims-based measures in QIES, the three (3) New Measures (with the assumption that all HHAs reported on all New Measures and received full points), and QIES Roll Up File data in the same manner as they will be in the Model. The five (5) HHCAHPS measures were based on archived data. The size of the cohorts was determined using the 2014 Quality Episode File based on OASIS assessments (the Model will use the year before each performance year), whereby the HHAs reported at least five measures with over 20 observations. The basis of the payment adjustment was derived from complete 2014 claims data. We note that this impact analysis is based on the aggregate value of all nine (9) states.

Table 33 displays our analysis of the distribution of possible payment adjustments based on the same 2013–2014 data used to calculate Table 32, providing information on the estimated impact of this final rule. We note that this impact analysis is based on the aggregate value of all nine (9) states. All

Medicare-certified HHAs that provide services in Massachusetts, Maryland, North Carolina, Florida, Washington, Arizona, Iowa, Nebraska, and Tennessee are required to compete in this Model. Value-based incentive payment adjustments for the estimated 1,900 plus HHAs in the selected states that will compete in the HHVBP Model are stratified by size as described in section IV.B. of this final rule. As finalized in section IV.B. of this final rule, there must be a minimum of eight (8) HHAs in any cohort.

Those HHAs that are in states who do not have at least eight small HHAs will not have a smaller-volume cohort and thus there will only be one cohort that will include all the HHAs in that state. As indicated in Table 33, Massachusetts, Maryland, North Carolina, Tennessee and Washington will only have one cohort and Florida, Arizona, Iowa, and Nebraska will have a smaller-volume cohort and a larger-volume cohort. For example, Iowa has 29 HHAs eligible to be exempt from being required to have their beneficiaries complete HHCAHPS surveys because they provided HHA services to less than 60 beneficiaries in 2013. Therefore, those 29 HHAs would be competing in Iowa's smaller-volume cohort if the performance year was 2014.Using 2013–2014 data and the payment adjustment of 5-percent (as applied in CY 2019), based on the ten (10) OASIS quality measures, two (2) claims-based measures in QIES, the five (5) HHCAHPS measures (based on the archived data), and the three (3) New Measures (with the assumption that all HHAs submitted data), Table 33 illustrates that smaller-volume HHAs in Iowa would have a mean payment adjustment of positive 0.62 percent and the payment adjustment ranges from −2.3 percent at the 10th percentile to +3.8 percent at the 90th percentile. As a result of using the OASIS quality and claims-based measures, the same source data (from QIES rather than archived data) that the Model will use for implementation, and adding the assumption that all HHAs will submit data for each of the New Measures when calculating the payment adjustments, the range of payment adjustments for all cohorts in this final rule is lower than that included in CY 2016 HH PPS rule. This difference is largely due to the lowered variation in TPS caused by the assumption that all HHAs will submit data for each of the New Measures.

Table 34 provides the payment adjustment distribution based on proportion of dually-eligible beneficiaries, average case mix (using HCC scores), proportion that reside in rural areas, as well as HHA organizational status. Besides the observation that higher proportion of dually-eligible beneficiaries serviced is related to better performance, the payment adjustment distribution is consistent with respect to these four categories.

The payment adjustment percentages were calculated at the state and size level so that each HHA's payment adjustment was calculated as it will be in the Model. Hence, the values of each separate analysis in the tables are representative of what they would be if the baseline year was 2013 and the performance year was 2014. There were 1,839 HHAs in the nine selected states out of 1,991 HHAs that were found in the HHA data sources that yielded a sufficient number of measures to receive a payment adjustment in the Model. It is expected that a certain number of HHAs will not be subject to the payment adjustment because they may be servicing too small of a population to report on an adequate number of measures to calculate a TPS.

TABLE 32—ADJUSTMENT DISTRIBUTION BY PERCENTILE LEVEL OF QUALITY TOTAL PERFORMANCE SCORE AT DIFFERENT MODEL PAYMENT ADJUSTMENT RATES

[Percentage]

Payment Adjustment Distribution	Range	10%	20%	30%	40%	Median	60%	70%	80%	90%
3% Payment Adjustment For Performance year 1 of the Model	3.08	−1.23	−0.87	−0.56	−0.30	−0.02	0.27	0.61	1.11	1.85
5% Payment Adjustment For Performance year 2 of the Model	5.12	−2.04	−1.45	−0.94	−0.50	−0.03	0.46	1.01	1.85	3.08
6% Payment Adjustment For Performance year 3 of the Model	6.15	−2.45	−1.74	−1.13	−0.61	−0.04	0.55	1.21	2.22	3.70
7% Payment Adjustment For Performance year 4 of the Model	7.18	−2.86	−2.03	−1.32	−0.71	−0.04	0.64	1.42	2.59	4.32
8% Payment Adjustment For Performance year 5 of the Model	8.25	−3.27	−2.32	−1.50	−0.81	−0.05	0.73	1.62	2.96	4.93

TABLE 33—HHA COHORT PAYMENT ADJUSTMENT DISTRIBUTIONS BY STATE/COHORT

[Based on a 5-percent payment adjustment]

COHORT	# of HHA	Average payment adj. %	10%	20%	30%	40%	Median	60%	70%	80%	90%
HHA Cohort in States with no small cohorts (percent)											
MA	127	0.00	−2.20	−1.50	−1.10	−0.70	−0.30	0.00	0.80	1.40	2.70
MD	53	0.56	−1.50	−1.10	−0.80	−0.10	0.20	0.50	1.40	2.00	3.60
NC	172	0.16	−1.90	−1.50	−1.00	−0.50	0.10	0.50	0.90	1.70	2.40
TN	135	0.36	−2.00	−1.30	−0.80	−0.40	−0.10	0.30	0.90	2.00	3.10
WA	59	0.71	−1.70	−0.70	−0.30	0.20	0.50	0.80	1.70	2.30	2.90
Smaller-volume HHA Cohort in states with small cohort (percent)											
AZ small	9	0.53	−1.20	−0.70	−0.70	−0.50	−0.30	−0.10	0.60	0.90	5.00
FL small	130	−0.14	−2.20	−1.70	−1.20	−0.60	−0.20	0.10	0.40	1.20	1.80
IA small	29	0.62	−2.30	−1.10	−0.80	0.00	0.30	0.90	1.70	2.30	3.80
NE small	16	0.48	−1.70	−1.60	−1.20	−0.60	−0.40	1.30	2.20	2.40	4.00
Larger-volume HHA Cohort in states with small cohorts (percent)											
AZ large	112	−0.06	−2.20	−1.50	−1.10	−0.70	−0.30	0.10	0.50	1.30	2.30
FL large	889	0.37	−2.10	−1.50	−0.90	−0.40	0.00	0.60	1.30	2.20	3.30
IA large	107	−0.21	−2.30	−1.60	−1.30	−0.70	−0.20	0.10	0.50	1.00	1.80
NE large	49	0.31	−1.80	−1.20	−0.90	−0.60	−0.10	0.30	0.70	1.80	3.70

TABLE 34—PAYMENT ADJUSTMENT DISTRIBUTIONS BY CHARACTERISTICS
[Based on a 5-percent payment adjustment]

COHORT	# of HHA	Average payment adj. %	10%	20%	30%	40%	Median	60%	70%	80%	90%
Low % Dually-eligible	621	0.18	−1.80	−1.30	−0.90	−0.50	0.00	0.40	0.90	1.50	2.50
Medium % Dually-eligible	841	−0.15	−2.20	−1.70	−1.20	−0.80	−0.40	0.00	0.50	1.20	2.20
High % Dually-eligible	416	1.21	−1.80	−0.80	−0.20	0.50	1.10	1.80	2.60	3.30	4.20
Low acuity	459	0.97	−1.70	−1.00	−0.40	0.10	0.70	1.30	2.10	2.90	4.00
Mid acuity	1089	0.83	−2.10	−1.50	−1.00	−0.60	−0.10	0.30	0.80	1.50	2.60
High acuity	338	−0.16	−2.10	−1.60	−1.30	−0.90	−0.50	−0.10	0.50	1.30	2.40
All non-rural	989	0.57	−2.10	−1.50	−0.90	−0.40	0.10	1.00	1.80	2.70	3.80
Up to 35% rural	141	0.01	−2.10	−1.50	−1.10	−0.60	−0.20	0.20	0.70	1.40	2.30
Over 35% rural	172	0.54	−1.80	−1.30	−0.90	−0.50	0.00	0.50	1.10	1.70	2.90
Church	62	0.80	−1.70	−0.90	−0.80	0.10	0.40	1.10	1.70	2.60	3.70
Private NP	168	0.22	−1.90	−1.30	−0.90	−0.30	0.10	0.50	0.90	1.70	2.50
Other	84	0.40	−1.60	−1.10	−0.70	−0.40	0.20	0.60	1.00	1.80	2.60
Private FP	1315	0.20	−2.10	−1.50	−1.00	−0.60	−0.10	0.30	1.00	1.90	3.10
Federal	72	0.37	−2.20	−1.60	−1.10	−0.40	0.20	0.60	1.40	2.10	2.80
State	5	−0.39	−2.50	−1.90	−1.40	−0.50	0.30	0.50	0.60	0.80	1.00
Local	57	0.50	−1.50	−1.10	−0.70	0.00	0.30	0.60	0.90	1.40	2.40

D. Accounting Statement and Table

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars_a004_a-4*), in Table 35, we have prepared an accounting statement showing the classification of the transfers and costs associated with the HH PPS provisions of this final rule. Table 35 provides our best estimate of the decrease in Medicare payments under the HH PPS as a result of the changes presented in this final rule for the HH PPS provisions.

TABLE 35—ACCOUNTING STATEMENT—HH PPS CLASSIFICATION OF ESTIMATED TRANSFERS AND COSTS, FROM THE CYS 2016 TO 2017*

Category	Transfers
Annualized Monetized Transfers.	−$130 million.
From Whom to Whom?	Federal Government to HHAs.

Table 36 provides our best estimate of the decrease in Medicare payments under the HHVBP Model.

TABLE 36—ACCOUNTING STATEMENT—HHVBP MODEL CLASSIFICATION OF ESTIMATED TRANSFERS AND COSTS FOR CY 2018–2022

Category	Transfers
5-Year Gross Transfers.	−$378 million.
From Whom to Whom?	Federal Government to Hospitals and SNFs.

E. Conclusion

1. HH PPS

In conclusion, we estimate that the net impact of the HH PPS policies in this rule is a decrease of 0.7 percent, or $130 million, in Medicare payments to HHAs for CY 2017. The −$130 million impact reflects the effects of the 2.5 percent CY 2017 HH payment update percentage ($450 million increase), a 0.9 percent decrease in payments due to the 0.97 percent reduction to the national, standardized 60-day episode payment rate in CY 2017 to account for nominal case-mix growth from 2012 through 2014 ($160 million decrease), and a 2.3 percent decrease in in payments due to the third year of the 4-year phase-in of the rebasing adjustments required by section 3131(a) of the Affordable Care Act ($420 million decrease).

This analysis, together with the remainder of this preamble, provides a final Regulatory Flexibility Analysis.

2. HHVBP Model

In conclusion, we estimate there would be no net impact (to include either a net increase or reduction in payments) in this final rule in Medicare payments to HHAs competing in the HHVBP Model for CY 2017. However, the overall economic impact of the HHVBP Model provision is an estimated $378 million in total savings from a reduction in unnecessary hospitalizations and SNF usage as a result of greater quality improvements in the home health industry over the life of the HHVBP Model. The financial estimates were based on the analysis of hospital, home health and skilled nursing facility claims data from nine states using the most recent 2014 Medicare claims data. A study published in 2002 by the Journal of the American Geriatric Society (JAGS), ''Improving patient outcomes of home health care: findings from two demonstration trials of outcome-based quality improvement,'' formed the basis for CMMI's projections.[123] That study observed a hospitalization relative rate of decline of 22-percent to 26-percent over the 3-year and 4-year demonstration periods (the 1st year of each being the base year) for the national and New York trials. The Innovation Center assumed a conservative savings estimate of up to a 6-percent ultimate annual reduction in hospitalizations and up to a 1.0-percent ultimate annual reduction in SNF admissions and took into account costs incurred from the beneficiary remaining in the HHA if the hospitalization did not occur; resulting in total projected 6 performance year gross savings of $378 million. Based on the JAGS study, which observed hospitalization reductions of over 20-percent, the 6-percent ultimate annual hospitalization reduction assumptions are considered reasonable.

VIII. Federalism Analysis

Executive Order 13132 on Federalism (August 4, 1999) establishes certain requirements that an agency must meet when it promulgates a final rule that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. We have reviewed this final rule under the threshold criteria of Executive Order 13132, Federalism, and have determined that it will not have

[123] Shaughnessy, *et al.* ''Improving patient outcomes of home health care: findings from two demonstration trials of outcome-based quality improvement,'' available at *http://www.ncbi.nlm.nih.gov/pubmed/12164991.*

substantial direct effects on the rights, roles, and responsibilities of states, local or tribal governments.

List of Subjects

42 CFR Part 409

Health facilities, Medicare.

42 CFR Part 484

Health facilities, Health professions, Medicare, and 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 409—HOSPITAL INSURANCE BENEFITS

■ 1. The authority citation for part 409 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 2. Section 409.50 is revised to read as follows:

§ 409.50 Coinsurance for durable medical equipment (DME) and applicable disposable devices furnished as a home health service.

The coinsurance liability of the beneficiary or other person for the following home health services is:

(a) DME—20 percent of the customary (insofar as reasonable) charge.

(b) An applicable disposable device (as defined in section 1834(s)(2) of the Act)—20 percent of the payment amount for furnishing Negative Pressure Wound Therapy (NPWT) using a disposable device (as that term is defined in § 484.202 of this chapter).

PART 484—HOME HEALTH SERVICES

■ 3. The authority citation for part 484 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395(hh)) unless otherwise indicated.

■ 4. Section 484.202 is amended by adding the definition of ''Furnishing Negative Pressure Wound Therapy (NPWT) using a disposable device'' in alphabetical order to read as follows:

§ 484.202 Definitions.

* * * * *

Furnishing Negative Pressure Wound Therapy (NPWT) using a disposable device means the application of a new applicable disposable device, as that term is defined in section 1834(s)(2) of the Act, which includes the professional services (specified by the assigned CPT® code) that are provided.

* * * * *

■ 5. Section 484.205 is amended by revising paragraph (b) introductory text to read as follows;

§ 484.205 Basis of payment.

* * * * *

(b) *Episode payment* The national, standardized prospective 60-day episode payment represents payment in full for all costs associated with furnishing home health services previously paid on a reasonable cost basis (except the osteoporosis drug listed in section 1861(m) of the Act as defined in section 1861(kk) of the Act) as of August 5, 1997 unless the national 60-day episode payment is subject to a low-utilization payment adjustment set forth in § 484.230, a partial episode payment adjustment set forth at § 484.235, or an additional outlier payment set forth in § 484.240. All payments under this system may be subject to a medical review adjustment reflecting beneficiary eligibility, medical necessity determinations, and HHRG assignment. DME provided as a home health service as defined in section 1861(m) of the Act continues to be paid the fee schedule amount. Separate payment is made for ''furnishing NPWT using a disposable device,'' as that term is defined in § 484.202, which is not included in the episode payment.

* * * * *

■ 6. Section 484.240 is amended by revising paragraph (d) to read as follows:

§ 484.240 Methodology used for the calculation of the outlier payment.

* * * * *

(d) CMS imputes the cost for each episode by multiplying the national per-15 minute unit amount of each discipline by the number of 15 minute units in the discipline and computing the total imputed cost for all disciplines.

* * * * *

■ 7. Section 484.305 is amended by revising the definition of ''Benchmark'' and by removing the definition of ''Starter set'' to read as follows:

§ 484.305 Definitions.

* * * * *

Benchmark refers to the mean of the top decile of Medicare-certified HHA performance on the specified quality measure during the baseline period, calculated for each state.

* * * * *

■ 8. Section 484.315 is amended by revising paragraph (a) to read as follows:

§ 484.315 Data reporting for measures and evaluation under the Home Health Value-Based Purchasing (HHVBP) Model.

(a) Competing home health agencies will be evaluated using a set of quality measures.

* * * * *

§ 484.320 [Amended]

■ 9. Section 484.320 is amended by—:

■ a. Amending paragraphs (a), (b), and (c) by removing the phrase, ''in the starter set,'' and

■ b. Amending paragraph (d) by removing the phrase, ''in the starter set''.

■ 10. Section 484.335 is added to read as follows:

§ 484.335 Appeals process for the Home Health Value-Based Purchasing (HHVBP) Model.

(a) *Requests for recalculation*—(1) *Matters for recalculation.* Subject to the limitations on review under section 1115A of the Act, a HHA may submit a request for recalculation under this section if it wishes to dispute the calculation of the following:

(i) Interim performance scores.

(ii) Annual total performance scores.

(iii) Application of the formula to calculate annual payment adjustment percentages.

(2) *Time for filing a request for recalculation.* A recalculation request must be submitted in writing within 15 calendar days after CMS posts the HHA-specific information on the HHVBP Secure Portal, in a time and manner specified by CMS.

(3) *Content of request.* (i) The provider's name, address associated with the services delivered, and CMS Certification Number (CCN).

(ii) The basis for requesting recalculation to include the specific quality measure data that the HHA believes is inaccurate or the calculation the HHA believes is incorrect.

(iii) Contact information for a person at the HHA with whom CMS or its agent can communicate about this request, including name, email address, telephone number, and mailing address (must include physical address, not just a post office box).

(iv) The HHA may include in the request for recalculation additional documentary evidence that CMS should consider. Such documents may not include data that was to have been filed by the applicable data submission deadline, but may include evidence of timely submission.

(4) *Scope of review for recalculation.* In conducting the recalculation, CMS will review the applicable measures and performance scores, the evidence and

findings upon which the determination was based, and any additional documentary evidence submitted by the home health agency. CMS may also review any other evidence it believes to be relevant to the recalculation.

(5) *Recalculation decision.* CMS will issue a written notification of findings. A recalculation decision is subject to the request for reconsideration process in accordance with paragraph (b) of this section.

(b) *Requests for reconsideration*—(1) *Matters for reconsideration.* A home health agency may request reconsideration of the recalculation of its annual total performance score and payment adjustment percentage following a decision on the home health agency's recalculation request submitted under paragraph (a) of this section, or the decision to deny the recalculation request submitted under paragraph (a) of this section.

(2) *Time for filing a request for reconsideration.* The request for reconsideration must be submitted via the HHVBP Secure Portal within 15 calendar days from CMS' notification to the HHA contact of the outcome of the recalculation process.

(3) *Content of request.* (i) The name of the HHA, address associated with the services delivered, and CMS Certification Number (CCN).

(ii) The basis for requesting reconsideration to include the specific quality measure data that the HHA believes is inaccurate or the calculation the HHA believes is incorrect.

(iii) Contact information for a person at the HHA with whom CMS or its agent can communicate about this request, including name, email address, telephone number, and mailing address (must include physical address, not just a post office box).

(iv) The HHA may include in the request for reconsideration additional documentary evidence that CMS should consider. Such documents may not include data that was to have been filed by the applicable data submission deadline, but may include evidence of timely submission.

(4) *Scope of review for reconsideration.* In conducting the reconsideration review, CMS will review the applicable measures and performance scores, the evidence and findings upon which the determination was based, and any additional documentary evidence submitted by the HHA. CMS may also review any other evidence it believes to be relevant to the reconsideration. The HHA must prove its case by a preponderance of the evidence with respect to issues of fact.

(5) *Reconsideration decision.* CMS reconsideration officials will issue a written determination.

Dated: October 24, 2016.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

Dated: October 25, 2016.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

[FR Doc. 2016–26290 Filed 10–31–16; 4:15 pm]

BILLING CODE 4120–01–P

FEDERAL REGISTER

Vol. 81 Thursday,
No. 213 November 3, 2016

Part III

Department of Transportation

14 CFR Parts 234, 244, 250, et al.
Enhancing Airline Passenger Protections III; Final Rule

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

14 CFR Parts 234, 244, 250, 255, 256, 257, 259, and 399

[Docket No. DOT–OST–2014–0056]

RIN 2105–AE11

Enhancing Airline Passenger Protections III

AGENCY: Office of the Secretary (OST), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: The Department of Transportation is issuing a third ''Enhancing Airline Passenger Protections'' final rule to enhance protections for air travelers and to improve the air travel environment as follows: Expanding the pool of reporting carriers for service quality data; requiring reporting carriers to include service quality data for their domestic scheduled flights operated by their code-share partners; enhancing the Department's code-share disclosure regulation to codify the statutory requirement that carriers and ticket agents must disclose any code-share arrangements on their Web sites on the first display presented in response to a search of a requested itinerary for each itinerary involving a code-share operation; and prohibiting undisclosed biasing based on carrier identity by carriers and ticket agents in any electronic displays of the fare, schedule or availability information of multiple carriers. The amendments to the reporting requirements in this rule will ensure that the Department obtains and provides to the public expanded and enhanced service quality data from the airlines. The provision to strengthen the Department's code-share disclosure rule will also enhance air travel consumer protection. Additionally, this final rule corrects certain drafting errors and makes minor changes to the Department's second Enhancing Airline Passenger Protections rule to better reflect the Department's intent. Other topics covered by the proposed rule that are not addressed by this final rule will be addressed in two separate rulemakings. Specifically, the Department will be issuing a Supplemental Notice of Proposed Rulemaking (SNPRM) to seek additional information on the disclosure of fees for basic ancillary services to consumers at all points of sale. The remaining topics discussed in the 2014 notice of proposed rulemaking (*e.g.,* customer service commitments by large ticket agents, prohibition on post-purchase price increases for ancillary services) will be addressed in another final rule that the Department plans to issue at a later date.

DATES: This final rule is effective December 5, 2016.

FOR FURTHER INFORMATION CONTACT: Clereece Kroha or Blane A. Workie, Office of the Assistant General Counsel for Aviation Enforcement and Proceedings, U.S. Department of Transportation, 1200 New Jersey Ave. SE., Washington, DC 20590, 202–366–9342 (phone), 202–366–7152 (fax), *clereece.kroha@dot.gov* (email) and *blane.workie@dot.gov.*

SUPPLEMENTARY INFORMATION:

Executive Summary

(1) Purpose of the Regulatory Action

This final rule enhances the performance quality information collected by the Department and made available to the public by expanding the reporting carrier pool and requiring performance data for code-share flights marketed by reporting carriers. These actions will ensure that smaller U.S. carriers' performance records are included in the monthly Air Travel Consumer Reports and that code-share flights' performance data will be reflected in their marketing carriers' records and rankings. This rule will also enhance information disclosure to air travel consumers by codifying the statutory requirement regarding disclosing code-share arrangements in online schedule displays, and prohibiting undisclosed bias when displaying air travel itinerary search results by carriers and ticket agents. These actions are taken under the statutory authorities for the Department to collect and collate transportation information that will contribute to the improvement of the transportation system of the United States (49 U.S.C. 329 and sections 41708 and 41709), and to prohibit unfair and deceptive practices and unfair methods of competition in the provision of air transportation (49 U.S.C. 41712).

(2) Summary of Major Provisions

In this final rule, the Department amends 14 CFR part 234 to require U.S. carriers that account for at least 0.5 percent of the domestic scheduled passenger revenue to file reports for the on-time performance and mishandled baggage for their flights and to post the on-time performance of their flights on their Web sites if they have Web sites marketing air transportation to the public. This is an expansion of the reporting carrier pool from its previous threshold of at least one percent of the domestic scheduled passenger revenue. Similarly, an amendment to 14 CFR part 250 will expand the reporting carrier pool for reporting oversales data.

In addition, this rule amends parts 234 and 250 to require all reporting carriers that market code-share flights operated by another carrier to file separate reports for on-time performance, mishandled baggage, and oversales data for those code-share flights.

With respect to disclosing code-share arrangements, this rule amends 14 CFR part 257 to codify a statutory requirement that code-share arrangements in online itinerary search results must be disclosed on the first display following the search and in a format that is easily accessible to consumers.

Finally, this rule adds 14 CFR part 256 that prohibits undisclosed bias by carriers and ticket agents when displaying fare, schedule or availability information online that includes multiple carriers.

(3) Costs and Benefits

The Regulatory Impact Analysis estimates the total discounted costs, which could be monetized over a 10-year period. Cost could only be robustly estimated for the reporting requirements, and may not include some other potential costs which the Department expects to have minimal impact. The costs of the reporting requirements are estimated to total $7.74 million over ten years, which amounts to an annualized cost of $0.96 million, when discounted using a seven percent rate. Given these estimates, the rule is not expected to be economically significant. The benefits could not be quantified and monetized with reasonable accuracy for the rule. Benefits were evaluated qualitatively for all provisions. A summary of this rule's benefits and costs is presented in the following table.

SUMMARY OF RULE'S BENEFITS AND COSTS

Major provision	Benefits	Ten year costs (Discounted 7%)
Additional Reporting Carriers for Service Quality Data.	Improved ability of consumers, especially in rural communities, to examine the past performance of flights. Potential improved Department enforcement due to more complete picture of industry performance.	Costs to carriers to report the information estimated at $7.74 million (10-year cost discounted at 7 percent).* Costs for some carriers to train employees and costs to consumers to use the information are not estimated.
Data Reporting for Domestic Code-Share Partner Operations.	Improved ability of consumers, especially in rural communities, to examine the past performance of flights. Potential for improved Department enforcement due to more complete picture of industry performance.	See above.
Transparency in Display of Code-Share Operations as Required by 49 U.S.C. 41712(c).	Helps ensure that all consumers purchasing via telephone, mobile websites, and applications are aware of code-share arrangements at beginning of booking process; some consumers may avoid time for additional flight searches.	Up-front programming costs to redesign mobile websites and applications to incorporate the code-share disclosure information for those carriers which had not interpreted statue as applying to mobile websites and mobile applications; potential costs for telephone reservations.
Prohibition of Undisclosed Bias.	Decrease in potential distortion in market of consumer unknowingly choosing non-optional flights because of display order.	Based on assumptions with uncertainties, programing costs to add statement(s) for some carriers and travel agents are estimated to range from $947,000 to $2.8 million (undiscounted).

* Costs were estimated for these two provisions together as their impacts are inter-related.

Background

On May 23, 2014, the U.S. Department of Transportation (DOT) issued a notice of proposed rulemaking (NPRM), 79 FR 29970, to improve the air travel environment of consumers based on its statutory authority to prohibit unfair or deceptive practices in air transportation, 49 U.S.C. 41712. This NPRM addressed several recommendations to the Department regarding aviation consumer protection made by two DOT Federal advisory committees—the Future of Aviation Advisory Committee (FAAC) and the Advisory Committee on Aviation Consumer Protection (ACACP). It also addressed two issues identified in the second Enhancing Airline Passenger Protections final rule—(1) disclosure of fees for certain ancillary services at all points of sale; and (2) post purchase price increases for ancillary services. See 76 FR 23110. More specifically, the Department's NPRM addressed and solicited public comments on the following issues: (1) Codification of the Department's interpretation of the statutory term ''ticket agent''; (2) Disclosure of certain ancillary service fee information to consumers in all channels of sales; (3) Expanding the reporting carrier pool for service quality data; (4) Requiring reporting of service quality data for code-share flights by the marketing carriers; (5) Applying customer service commitments to large ticket agents; (6) Enhancing the disclosure of code-share operations; (7) Disclosing carriers marketed by large ticket agents; (8) Prohibiting undisclosed carrier display bias by large ticket agents; (9) Prohibiting post purchase price increases for certain ancillary services.

In response to this NPRM, the Department received over 750 comments from the following: U.S. air carriers and U.S. air carrier associations; foreign air carriers and foreign air carrier associations; consumer rights advocacy groups; travel agents, travel agent associations, and global distribution systems (GDSs); airports and various airport-related industry groups; and a number of individual consumers.

The Department has carefully reviewed and considered the comments received. To ensure that the subjects identified in the NPRM are addressed through rulemaking as efficiently as possible, we have decided to split the issues addressed in the 2014 NPRM into three separate rulemakings. First, in this final rule, we are finalizing regulations on several subjects on which we have completed our review and analysis, including completing a regulatory analysis. Specifically, we are finalizing rules: Expanding the reporting carrier pool; requiring reporting of code-share flights by the marketing carriers; enhancing the disclosure of code-share operations; and prohibiting undisclosed display bias. Although we are not promulgating a requirement regarding disclosing on ticket agent Web sites that not all airlines are marketed by ticket agents at this time, that proposal is also addressed in this rulemaking. Second, we will be issuing a Supplemental Notice of Proposed Rulemaking (SNPRM) addressing disclosure of certain ancillary service fee information to consumers in all channels of sales (GDS issue). See RIN 2105–AE56. We believe the SNPRM is necessary in light of the complexity of the issues and additional considerations identified by comments submitted on the NPRM. The NPRM also proposed revisions to baggage fee disclosure provisions section 14 CFR 399.85(a)–(c). Any revisions to that section relating to baggage disclosure requirements will be addressed in the SNPRM as that rulemaking is focused on ancillary service fee disclosures. Finally, for several subjects on which we believe that we have obtained sufficient information but need additional time to complete the regulatory analysis, we are postponing the issuance of a final rule until a later date. These subjects include the following: Codification of the Department's interpretation of the statutory term ''ticket agent''; applying customer service commitments to large ticket agents; and prohibiting post purchase price increases for certain ancillary services, which includes addressing the ''mistaken fares'' issue. See RIN 2105–AE57.

For those subjects that we are finalizing in this final rule, in the table below we provide a summary of the regulatory provisions and a summary of the regulatory analysis. Following that, we summarize the commenters' positions that are germane to the specific issues raised in the NPRM and the Department's responses.

SUMMARY OF REGULATORY PROVISIONS

Subject	Final rule
Additional Reporting Carriers for Service Quality Data.	• Expands the pool of reporting carriers from any carrier that accounts for at least 1% of domestic scheduled passenger revenue to any carrier that accounts for at least 0.5% of domestic scheduled passenger revenue. • Mandates reporting of data for scheduled flights to and from all large, medium, small, and non-hub U.S. airports.
Data Reporting for Domestic Code-Share Partner Operations.	• Requires reporting carriers to separately report data for their domestic scheduled flights operated by their code-share partners: ○ On-time Performance. ○ Mishandled Baggage. ○ Oversales. • Allows a simplified data report for on-time performance of code-share flights if the operating carrier of the flights is a reporting carrier itself.
Transparency in Display of Code-Share Operations as Required by 49 U.S.C. 41712(c).	• Amends the Department's code-share disclosure regulation to codify the statutory requirement that carriers and ticket agents must disclose any code-share arrangements on their websites. ○ Requires disclosure on the first display presented in response to a search of a requested itinerary for each itinerary involving a code-share operation. ○ Disclosure must be in a format that is easily visible to a viewer. • Adopts a simplified format for display of code-share disclosures via mobile websites and apps by permitting disclosure of only corporate name of the operating carrier. • Enhances code-share disclosure in oral communication by requiring the disclosure be provided at the first time the flight is offered by a carrier or ticket agent or inquired by a consumer.
Prohibition of Undisclosed Bias	• Prohibits undisclosed biasing by carriers and ticket agents in any online displays of the fare, schedule or availability information of multiple carriers.

Summary of Regulatory Analysis

The Final Regulatory Evaluation examined the economic impact, in terms of all benefits accruing to airline passengers, and costs to U.S. and foreign air carriers and other entities regulated under this proceeding. Although benefits could not be quantified and monetized with reasonable accuracy for the provisions in the rule, benefits were evaluated qualitatively for all provisions. Meanwhile, the total discounted costs which could be monetized over a 10-year period could only be robustly estimated for Provisions 1 and 2. The costs of Provisions 1 and 2 are estimated to total $7.74 million over ten years, which amounts to an annualized cost of $0.96 million, when discounted using a seven percent rate. Other costs are expected to be minimal. Benefits were not able to be quantified for the most part. Nonetheless, the Department believes that the rule is in the public interest as it will provide consumers with more information to make decisions about air transportation purchases.

Discussion

(1) Expanding the Definitions of ''Reporting Carrier'' and ''Reportable Flight'' Under 14 CFR Part 234

The NRPM: 14 CFR parts 234 and 250 require certain large U.S. carriers—the ''reporting carriers''—to report data to the Department concerning on-time performance, mishandled baggage, and oversales. Currently, U.S. carriers with at least 1.0 percent of total annual domestic scheduled-passenger revenue are required to report. In the NPRM, we proposed to amend the definition of ''reporting carrier'' under part 234 to include carriers that account for at least 0.5 percent of total annual domestic scheduled-passenger revenue. The purpose of this proposal is to increase the data reported by air carriers and published by the Department in order to provide the public with more information for making travel decisions. The proposed amendment to the definition of ''reporting carrier'' will not only affect the pool of carriers reporting on-time performance and mishandled baggage data to the Department and posting on-time performance information on the carrier's Web site pursuant to 14 CFR part 234, but will also affect the pool of carriers reporting oversales data to the Department under 14 CFR part 250. We sought public comments on whether 0.5 percent is a reasonable threshold to achieve our goal of maximizing the scope of data collection from the industry while balancing that benefit for consumers against the reporting burden for additional carriers, particularly smaller ones. If 0.5 percent is not the most reasonable threshold, we asked whether a more reasonable approach would be an even larger expansion, *e.g.,* to 0.25 percent, or a smaller expansion to 0.75 percent, or even requiring all carriers that provide domestic scheduled passenger service to report to the Department. We especially invited comments that provide specific cost estimates or analysis by smaller carriers that would potentially be impacted by this proposal. We also requested comments regarding whether a carrier's share of domestic scheduled passenger revenue remains an appropriate benchmark or if we should use a carrier's share of domestic scheduled passenger enplanements instead.

The current rule states that March 31 is the cutoff date for compiling a carrier's annual domestic scheduled passenger revenue percentage. However, for years, DOT's Bureau of Transportation Statistics (BTS) has been using June 30, instead of March 31, as the cutoff date. Currently carriers must report revenue information, including domestic scheduled passenger revenue, to DOT on a quarterly basis using Form 41. DOT uses this information to calculate each carrier's share of total domestic scheduled passenger revenue over the time period of July 1st to June 30th each year, and determines which carriers account for at least 1 percent of total domestic scheduled passenger revenue. The Department then provides notice to new reporting carriers of their obligation to report. In the NPRM we proposed to codify the June 30 as the cutoff date in the definition of ''reporting carrier.''

Finally, in relation to the burden associated with implementing a reporting mechanism within a carrier's operation system, we requested comments on how much time a newly reporting carrier will likely need to prepare for the new reporting duties. Although not proposed in the rule text, we stated in the preamble of the NPRM that we were contemplating that should

this proposal be finalized, we would permit carriers that have not been reporting carriers but become a reporting carrier under a new threshold to file their first reports by February 15 for the first January that is at least six months after the effective date of this rule.

In addition to expanding the pool of reporting carriers, the NPRM sought comments on whether we should expand the scope of ''reportable flights'' in relation to airports to include not only large hub airports (U.S. airports that account for at least 1% of domestic enplanements) that are mandated by the current rule, but also medium, small, and non-hub airports, or, alternatively, to include domestic scheduled flights to and from all U.S. airports where the reporting carriers operate. We also invited the public to provide information on the costs and benefits related to this matter.

Comments: Among the consumer rights advocacy groups that provided comments on this proposal, four groups, U.S. Public Interest Research Group (U.S. PIRG) and Consumers Union (in their joint comments) and Travelers United and National Consumers League (in their joint comments), support the expansion of the reporting carrier threshold to 0.5% of total domestic scheduled passenger revenue. Consumers Union and U.S. PIRG state that the information from newly covered carriers will be useful to consumers and regulators alike and that with current technology the compliance cost would be minimal and manageable. They also comment that, if feasible, the Department should require reports from all carriers providing domestic scheduled passenger flights from all airports. Travelers United and National Consumers League support the expansion because it would be beneficial to consumers by including airlines such as Spirit and Allegiant in the Department's Air Travel Consumer Report (ATCR) and it would enhance transparency and accountability of airline performance for consumers. Flyersrights.org recommends that the Department should require all carriers with over $100 million in revenue to file reports and that the reports should cover reporting carriers' flights to all airports. Flyersrights.org also states that flight cancellations that often cause significant delays to passengers should not be statistically reported as zero delay as the organization states they are under the existing reporting requirements.

Among the comments submitted by airlines and airline associations, Airlines for America (A4A), Hyannis Air Service dba Cape Air (Cape Air), JetBlue Airways, Frontier Airlines, and Southwest Airlines in general support the proposal to expand the reporting carrier pool. A4A states that the Department should require all carriers providing domestic scheduled service to file reports because it would increase the total amount of information available to the public and any carrier that has the resources to obtain an operating certificate and to offer scheduled service should not find it overly burdensome to report to the Department basic information about its operations. A4A also supports eliminating ''reportable'' flights and simply mandating that reporting carriers report on all flights. Cape Air supports the expansion to 0.5% but does not believe a threshold beyond that level would provide substantial benefit to the public in comparison to the costs because expanding beyond the 0.5% threshold would create significant burden to small businesses. Frontier Airlines supports the expansion as the performance data are important for consumers to compare carriers. Frontier points out that under the existing reporting carrier threshold, Frontier is a reporting carrier but its competitors such as Spirit Airlines and Allegiant Air are not reporting carriers.[1] JetBlue Airways supports including all carriers providing domestic scheduled passenger service in the universe of reporting carriers to increase transparency and available information to consumers. Southwest Airlines also supports the expansion, stating that today all carriers collect data and track on-time performance as a matter of business necessity and the performance indicators that are reported to the Department affect passengers without regard to the size of the carrier.

In opposition to the proposed expansion, Republic Airways Holdings Inc. and its subsidiaries, Republic Airlines, Chautauqua Airlines, and Shuttle America (herein collectively ''Republic'') jointly filed comments asserting that the reporting requirements should not be extended to regional carriers that do not market flights and handle customer service under ''fee for service/capacity purchase agreements'' or ''CPAs'' as CPA carriers do not have information such as baggage handling or oversales. Republic further states that requiring CPA carriers to report data that mainline carriers are already reporting would be duplicative, imposing costs on CPA carriers and increasing potential consumer confusion with no corresponding regulatory benefits. As an alternative, Republic suggests that if the Department requires the CPA carriers to file reports, it should require the mainline carriers to provide certain data to CPA carriers. Regarding the cost and benefit aspect of the proposal, Republic states that the proposal will impose new technology and personnel costs and notes that the regulatory evaluation accompanying the NPRM concedes that the monetized cost of the two reporting-related proposals would far exceed their monetized benefits. With respect to the time needed by newly reporting carriers to prepare for filing the first report, Republic states that the Department should provide at least 18 months lead time so carriers have sufficient time to develop, test, and implement the reporting system. Allegiant Air opposes the expansion of reportable flights to cover smaller airports. Allegiant states that the expansion of reportable flights beyond large hub airports does not satisfy cost-benefit analysis given the small number of passengers utilizing these airports, and it would place a burden on small carriers serving these markets, and ultimately result in higher prices for consumers. American Airlines, Delta Air Lines, and United Airlines submitted joint comments opposing any change in the current mishandled baggage reporting methodology. In its separate comment, Delta Air Lines asserts that any change to the current mishandled baggage reporting rules are unjustified and misleading.

Several airport associations also commented on this proposal, all supporting the expansion of the reporting carrier pool to include all commercial airlines. Airports Council International-North America (ACI–NA) states that the information is the same to passengers no matter the type of aircraft or the size of the airline. ACI–NA justifies its position by asserting that regional airlines now provide over half of daily domestic flights, and serve 70% of U.S. airports. Meanwhile, according to ACI–NA, technological enhancements in the last 25 years provide justification to require all carriers to report. The American Association of Airport Executives (AAAE) points out that the Government Accountability Office (GAO) concludes that airlines not required to report to DOT have higher delay, cancellation, and diversion rates,

[1] On October 30, 2015, BTS issued its Reporting Technical Directive #25, effective January 1, 2016. Under that Directive, there are now 12 reporting carriers meeting the one percent domestic scheduled passenger revenue threshold: Alaska, American, Delta, ExpressJet, Frontier, Hawaiian, JetBlue, SkyWest, Southwest, Spirit, United, and Virgin America.

and smaller communities are left out of the equation. Regarding costs and benefits, AAAE states that in the past paperwork was a limiting factor but modern technology now makes the process much easier and more efficient. California Airports Council states that with the significant growth of regional airlines at airports of all sizes, it is crucial for DOT to include all carriers' operations in consumer protection regulations and notifications. San Francisco International Airport also supports the expansion of the reporting carrier pool to cover all commercial airlines. It states that this expansion will improve the amount and quality of information available to passengers while encouraging open and fair competition among air carriers. It also points out that air carriers providing scheduled commercial service in the United States in 2014 are universally equipped with technology sufficient to provide service quality data and doing so should not create a burden.

Marks Systems, Inc., d/b/a masFlight (masFlight), an industry provider of aviation operations analysis, recommends that the Department adopt a 0.25 percent threshold to capture all low-fare and significant regional carriers and to ensure fairness across the industry in transparency and regulatory compliance. In supporting this position, masFlight provides data from 2013 demonstrating that under the 0.25 percent threshold, an additional five carriers would be captured compared to the proposed 0.5 percent threshold (Shuttle America, Horizon, PSA, Chautauqua, and Sun Country), leaving only two carriers that are under the 0.25 percent threshold (GoJet and Compass). MasFlight cites the Initial Regulatory Impact Analysis for the NPRM that estimates the initial cost for a new reporting carrier to be $33 million over a 10-year period, and asserts that this potential compliance cost would be excessive to a carrier that accounts for less than 0.25 percent of domestic scheduled passenger revenue. MasFlight also suggests that the Department maintain its current benchmark using domestic scheduled passenger revenue instead of changing to domestic scheduled passenger enplanements to minimize compliance cost. MasFlight supports expanding the definition of reportable flight to cover all U.S. airports.

DOT Responses: Since their implementation, the reporting requirements in part 234 (for on-time performance and mishandled baggage) and part 250 (for oversales) have been effective tools for the Department to collect airline service and performance data. The Department also uses the information to monitor the quality of service provided to the flying public by each reporting carrier and to furnish the information to consumers via the Air Travel Consumer Report. This data also provides the Department necessary information used in connection with rulemakings and other important policy decisions. As stated in the NPRM, the current 1.0 percent domestic scheduled passenger revenue threshold was initially adopted in 1987 as a compromise in order to reduce the burden imposed on small businesses because at that time, small carriers were less likely to maintain their flight performance data in a computerized form. 52 FR 34056 (September 9, 1987). The comments we received on this NPRM do not dispute that the more information the Department receives through its reporting mechanism, including service quality of small airlines, and information on flights to and from small airports, the greater the benefit to the public. We are confident that lowering the threshold for reporting to add certain smaller carriers' performance data to the data currently collected by BTS will enable the Department to obtain and provide to the flying public a more complete picture of the performance of scheduled passenger service in general. We are also optimistic that including smaller airlines' performance data in the Department's data collection will specifically benefit small communities and regional markets that are primarily served by these smaller airlines by increasing the level of public scrutiny of their performance quality and increasing their competitiveness.

Furthermore, expanding the pool of reporting carriers responds to the recommendation by GAO in its September 2011 Report to Congressional Requesters.[2] In that report, GAO states that the Department should collect and publicize more comprehensive on-time performance data to include information on most flights, to airports of all sizes. The Department shares GAO's view that expanding the reporting carrier pool would enhance the Department's ability to analyze the cause of flight disruptions such as delays and cancellations, particularly with respect to airports in smaller communities, at which consumers are more likely to be inconvenienced by flight irregularities due to less-frequent service.

[2] *Airline Passenger Protections: More Data and Analysis Needed to Understand Effects of Flight Delays,* September 2011, GAO. *http://www.gao.gov/products/GAO-11-733.*

The comments opposing expansion of the reporting carrier pool mainly focus on the burden it will place on smaller carriers. In that regard and consistent with the approach taken by the Department in the 1987 final rule, we have determined that there is a balance between obtaining the most useful information on flight performance quality and avoiding excessive burden and cost to smaller airlines. The Department concludes that the 0.5 percent threshold is appropriate in striking that balance, taking into consideration the technological advances during the past 29 years in tracking and recording flight performance data. Our decision also takes into account the fact that we are adopting the proposal requiring marketing carriers to report flight performance data for domestic flights operated under the marketing carrier's code by code-share partners, including smaller, non-reporting carriers, which will be discussed in the next section of this preamble. The chart below contains information on certificated carriers affected by these thresholds based on annual scheduled passenger revenue as reported to BTS for the 12-month period ending June 30, 2015:

Reporting Carriers Meeting the Existing 1% Threshold	
1	Alaska.
2	American.
3	Delta.
4	Express Jet.
5	Frontier.
6	Hawaiian.
7	JetBlue.
8	SkyWest.
9	Southwest.
10	Spirit.
11	United.
12	Virgin America.
Carriers Meeting the Expanded 0.5% Threshold	
1	Air Wisconsin.
2	Allegiant.
3	Endeavor.
4	Mesa.
5	Envoy.
6	Republic.
7	Shuttle America.
Carriers Meeting the 0.25% Threshold (Not Adopted)	
1	Horizon.
2	PSA.
3	Sun Country.
Carriers Accounting for Less Than 0.25% of Domestic Scheduled Passenger Revenue	
1	Compass.
2	GoJet.

Although the costs of maintaining and filing performance data with the Department has been reduced

significantly compared to what it was in 1987, the Department is aware that it is still not a negligible expense for smaller carriers under the 0.5 percent threshold. Technology developments such as automation of performance data tracking reduces the cost of human capital needed for the tasks. However, the initial cost of setting up a sophisticated system to aggregate the data meeting the Department's reporting criteria and adding personnel to file monthly and quarterly reports with the Department may disproportionately burden smaller carriers.

In addition to the concerns about the burden to smaller carriers, we have also decided not to adopt a threshold lower than 0.5 percent as endorsed by some commenters because most of the flights operated by those carriers falling below the 0.5 percent threshold will be captured under the code-share flights reporting requirement, which is discussed in the next section. According to the current data, if we adopt a 0.5 percent threshold, five smaller certificated carriers providing scheduled domestic passenger services (Horizon, PSA, Sun Country, Compass, and GoJet) [3] will not be required to file reports directly with the Department. Four of these five carriers operate code-share flights on behalf of their marketing-carrier partners, which are all reporting carriers. Horizon operates solely for Alaska Airlines, PSA operates solely for American Airlines, Compass operates for American Airlines and Delta Air Lines, and GoJet operates for United Airlines and Delta Air Lines. All of those four smaller carriers' flight performance data will be reported by their marketing carriers. Sun Country is the only carrier among the five that does not operate code-share flights and will not have its performance data reported to the Department under the 0.5 percent threshold. Sun Country accounted for only 0.32% of domestic scheduled passenger revenue. In other words, adopting a 0.5 percent threshold will allow the Department to capture in substance 99.68% of the flight performance data for domestic scheduled flights. We recognize that Horizon, PSA, Compass, and GoJet will likely incur certain expenses to assist their marketing carriers in compiling the reports. However, we consider the cost-sharing structure between the smaller operating carrier and large marketing carrier to be an effective and efficient way for the Department to obtain the data while limiting the burden imposed on smaller carriers.

Finally, as technology development appears to be the primary factor affecting the costs incurred by a carrier in tracking, compiling, and filing performance data with the Department, we will continue to monitor the effect of new technology on the cost of recordkeeping and the scope of carriers covered by the reporting requirements. We will consider expanding the reporting requirements to other carriers providing scheduled service if it becomes economically sound and necessary to obtain data beneficial to consumers.

The Department appreciates the Republic carriers' comments regarding the CPA carriers' lack of firsthand information on customer service related data as these carriers may not handle customer services such as baggage handling or oversales. The Department further notes that the relationship between a CPA carrier and its code-share marketing-carrier partner is different from carrier to carrier, depending on each CPA's terms and conditions, and such a relationship has the potential to further evolve in the future. For example, a CPA carrier that currently does not handle baggage may begin to handle baggage in the future. As such, the Department does not believe it is appropriate to exempt the CPA operating carriers entirely from reporting baggage handling and oversales data at this time. Larger CPA carriers such as SkyWest or ExpressJet currently file reports including data that they obtain from their marketing partners, which indicates to the Department that a cooperative information collection and compilation structure between marketing and operating carriers is technically and economically workable. We anticipate that in the future carriers may include provisions in their CPA contracts for the marketing carrier to provide baggage handling and oversales data to the reporting operating carrier in a timely manner if that is relevant to the carriers' relationship. In the meantime, the Department expects carriers to work together in good faith to share information with each other in order to facilitate the required reporting.

With respect to the question of whether the Department should use domestic scheduled passenger enplanements as a benchmark to define ''reporting carrier'' in lieu of the current benchmark of domestic scheduled passenger revenue, we received no comments supporting such a change and we do not see any compelling reason for such a change. While keeping the current benchmark, we also adopt in this final rule the longstanding practice by BTS to use June 30 as the cutoff date for compiling a carrier's annual domestic scheduled-passenger revenue percentage, as opposed to March 31 as stated in the current rule. No adverse comments were received.

With respect to the definition of ''reportable flight'' that currently only covers flights to and from large hub airports, the vast majority of comments are in support of including all airports in the reporting regime. We are unconvinced by Allegiant Air's assertion that we should exempt flights to and from smaller airports from the reporting requirements on the basis that such reporting imposes an excessive cost on the carriers. Exempting flights to and from smaller airports will render our inclusion of smaller carriers in the reporting carrier pool less meaningful. Further, we note that the current reporting carriers all have chosen to file reports for scheduled passenger flights to all U.S. commercial airports where they operate. As such, there is an argument to be made that a reporting carrier would incur more cost to separate flights operated out of large hubs from flights operated out of other airports for reporting purpose as compared to reporting all flights operated out of all airports. For these reasons, we adopt in this final rule a mandate to report the on-time performance and mishandled baggage information for domestic scheduled flights marketed by a reporting carrier to and from all U.S. large, medium, small, and non-hub airports pursuant to part 234. By expanding the reportable flights under part 234 to these categories of airports, we are covering all domestic scheduled flights to and from U.S. commercial airports that have an annual passenger enplanements of 10,000 or more. We note that this expansion of airports covered under part 234 does not affect the scope of airports covered under 14 CFR 250.10, reporting oversales information, which covers and will continue to cover all domestic scheduled flights and all international scheduled flights departing a U.S. airport and using an aircraft that has a designed passenger capacity of 30 or more passenger seats.

In response to Flyersrights.org's comment that flight cancellations are currently not statistically reported as flight delays, the Department wishes to clarify that the ATCR categorically treats

[3] The list of carriers (based on 2015 domestic scheduled passenger revenue data) is for the purpose for illustrating the size and number of carriers that currently would and would not be affected by this change. Each year the Department's Bureau of Transportation Statistic's Office of Airline Information updates the list of reporting air carriers. Although the carriers that fall above or below the threshold may change from year to year, as historical data demonstrates, we don't expect the number of affected carriers to change drastically.

cancelled flights as flights not operated ''on time,'' along with flights that are diverted or are delayed for 15 minutes or more. See, *Air Travel Consumer Reports, Footnote D of Footnotes for Tables 1 Through 6 (Flight Delays) and 8 (Cancellations).* In other words, under the current reporting structure, a cancelled flight counts as a delayed flight in a carrier's on-time performance percentage. Thus, we do not believe any change to that structure is necessary.

The Department appreciates the comments submitted by United, Delta, and American, jointly, and by Delta, individually, on the rationale for the Department's proposal to change the matrix and the methodology of collecting mishandled baggage information. However, this rulemaking addresses which airlines and flights are subject to the reporting requirements contained in Parts 234 and 250, and it does not address what methodology the carriers are required to use to collect and report the data. A separate rulemaking, ''Reporting of Data for Mishandled Baggage and Wheelchairs and Scooters Transported in Aircraft Cargo Compartments,'' RIN 2105–AE41 (formerly 2139–AA13), Docket No. DOT–RITA–2011–0001, addresses the methodology for collection of mishandled baggage information. The Department fully reviewed and considered all substantive comments submitted to that docket (DOT–RITA–2011–0001), including comments by United, Delta, and American. The final rule on reporting of data for mishandled baggage and wheelchairs and scooters transported in aircraft cargo compartments is being published contemporaneously with this final rule. Because the Department's proposal to change the mishandled baggage reporting matrix was resolved in a separate rulemaking and the instant rulemaking on transparency of ancillary service fees and other consumer issues will not result in any change to the matrix on how to report mishandled baggage, please see the Department's final rule on ''Reporting of Data for Mishandled Baggage and Wheelchairs and Scooters Transported in Aircraft Cargo Compartments'' for responses to comments concerning the reporting matrix.

With respect to the compliance dates of this reporting threshold change, we have carefully considered the comments submitted and consulted with BTS on its estimated timeframe to fully implement a system capable of accepting and accommodating the newly included reporting carriers under this final rule. We have reached the conclusion that the new reporting carriers should be required to file their initial reports for on-time performance and mishandled baggage by February 15, 2018, for January 2018 operations; to file their initial reports for oversales by April 30, 2018, for the first quarter of 2018; and to load on-time performance disclosure data for each domestic scheduled flight marketed on their Web sites on Saturday, February 24, 2018, for flights operated in January 2018. Consistent with the existing rule, carriers must load all subsequent flight performance information on the fourth Saturday of the month following the month that is being reported. Oral disclosure of on-time performance information upon consumers' reasonable inquiry during the course of reservations or ticketing discussions or transactions should begin no later than February 25, 2018. We believe this provides sufficient lead time to the new reporting carriers to set up the infrastructure and train their personnel to handle the reporting of this data. We also believe that requiring the initial monthly reports to start in January and the initial quarterly reports to start in the first quarter provides the benefit of preserving the consistency of the Department's data for a full calendar year during the transition. We note that with the exception of Allegiant Air, all new reporting carriers do not directly market flights they operate to the public and therefore are under no obligation to implement the disclosure requirements contained in 14 CFR 234.11.

(2) Carriers To Report Data for Certain Flights Operated by Their Code-Share Partners

The NPRM: The current reporting structures in Parts 234 and 250 only require reporting carriers to report performance data for flights they operate and not for flights marketed under the reporting carrier's code but operated by a code-share partner. The NPRM proposed to require reporting carriers that market flights operated by their domestic code-share partners to file a second and separate set of on-time performance, mishandled baggage, and oversales data reports that include the relevant data for both flights they operate and flights operated by their domestic code-share partners. We asked whether the second set of data should only contain data for code-share flights and whether it should include separate flight statistics for each code-share partner. We also solicited comments on whether ''double counting'' is an issue under this proposal (*e.g.,* a regional carrier operating a flight for more than one marketing carrier and therefore the same flight would be reported twice by the marketing carriers). Furthermore, we asked the public to provide comment about how to deal with the situation where a flight carries two large carriers' codes and is operated by one of the two carriers (mainline-to-mainline code-share). Finally, as for the proposal to expand the reporting carrier pool, we asked what a reasonable implementation period is for the marketing carriers to comply with this new reporting requirement.

Comments: All consumer rights advocacy groups that submitted comments on this proposal are generally in support of including code-share flights service quality data in the marketing carrier's reports. Consumers Union and U.S. PIRG cite the monthly ATCR, which provides critical and helpful information to consumers about airline performance (including delayed and canceled flights, mishandled baggage, consumer complaints, and denied boardings), and state that this change will make the report even more useful for consumers. They also agree with the Department's proposition that this change will increase airline incentives to improve performance, not only in their own operations but also in the operations of the carriers with whom they partner. Further, Consumers Union and U.S. PIRG assert that the performance information on code-share flights would be of maximum usefulness if it is provided in aggregate for the mainline carrier and all of its code-share partners, and also disaggregated for each code-share partner separately. Consumers Union and U.S. PIRG question the soundness of the Department's proposal to limit the reporting of code-share flights data to non-stop flights operated by code-share partners and avers that the Department should include all flight segments that are marketed by mainline carriers.

Travelers United and National Consumers League also support this proposal, stating that code-share flights now account for more than half of domestic flights, yet the poorest performance records of regional partners operating under legacy carriers' codes are not reflected in legacy carriers' performance reports. Travelers United and National Consumers League also strongly urge the Department to include international flights operated by code-share partners in the reporting mandate because joint ventures in international operations should not enjoy immunity from clear, understandable reporting requirements.

Among comments submitted by carriers and carrier associations, A4A agrees with the Department's regulatory objective but believes there are equally

effective but less burdensome ways of achieving that objective. A4A states that the proposed reporting requirement for code-share flights would result in the submission of duplicate data by different carriers, create difficulty for the reporting carriers to certify and submit data provided by their code-share partners, and make it difficult for both carriers and BTS to process the newly required data. In that regard, A4A proposes an alternative means for the Department to collect data for code-share flights and attribute this data to the records of the marketing carriers. Under A4A's proposal, each mainline marketing carrier would provide to BTS a monthly list of the operating carriers and flight numbers of code-share flights operated by another carrier under the reporting carrier's code; BTS would then combine this list with the information submitted directly by the operating code-share partners to generate and publish the desired service information regarding the code-share flights of the mainline carrier. A4A avers that this approach would eliminate the prospect of two carriers submitting duplicate information, and BTS would have the complete data set earlier in the month and would not have to scrub the data to account for duplicate reports.

A4A opposes including data for mainline-to-mainline code-share flights in a carrier's report. In support of this proposition, A4A points out that this type of code-share flight represents a small proportion of overall traffic (roughly 2%) and therefore, including or excluding this data will not likely change a carrier's data and ranking in the ATCR. Additionally, A4A states that reporting data for these flights would be exceptionally difficult due to lack of systems and data exchange. Further, A4A states that in the mainline-to-mainline code-share situations, the consumer purchased the ticket from a marketing carrier that does not operate the flight is typically very aware of the operating carrier brand and that the operating carrier is different from the marketing carrier, and if the consumer is interested in the other mainline operating carrier's statistics he/she can review reports for that carrier. Additionally, A4A states that the marketing carrier in the denied boarding context has no control over the inventory of the operating carrier if it does not have a capacity purchase agreement with that carrier. A4A concludes that for these reasons, the burden of collecting, sharing, verifying, and reporting data on both the operating and the marketing carriers in a mainline-to-mainline code-share would be disproportionately burdensome relative to any public benefit.

Regarding the time needed for carriers to prepare for the new reporting requirement, A4A argues that the implementation time proposed by the Department is a fraction of the time needed. According to A4A's estimate, if each carrier reports for itself, six months may be adequate for on-time performance and oversales reports; for baggage reporting, even using the current matrix, it will take 24–36 months. A4A also submitted comments opposing the Department's proposal to change the mishandled baggage reporting matrix contained in Docket DOT–RITA–2011–0001 and those comments were considered in connection with that rulemaking.

The Republic carriers (Republic, Shuttle America, and Chautauqua), Frontier Airlines, JetBlue Airways, and Southwest Airlines are all in support of the proposal. Republic supports the proposal to have the mainline marketing carriers report the service quality data for flights operated by their CPA code-share partners. In conjunction with its comments on the expansion of the reporting carrier pool, Republic states that the flights operated under CPAs are sold, marketed, and handled by the mainline carriers under their names and designator codes. In addition, Republic asserts that the mainline carriers also schedule and monitor the arrival and departure times for all flights operated under their codes. Therefore, according to Republic, the CPA operating carriers do not have possession of the customer service quality data required by the reports and have no ability to obtain such data from their marketing carriers. Frontier Airlines believes that this proposal will fill another data gap in the current monthly ATCR whereby reporting carriers only provide data for mainline operations but not code-share operations. Frontier further states that without this data the ATCR only provides a partial picture of the travel experience under the mainline carrier's brand. Frontier submits that the gap in data under the current reporting structure may incentivize mainline carriers to engage in certain unfair practices to boost their performance. In support of this proposal and the proposal to expand the reporting carrier pool, JetBlue states that at certain airports a majority of flights are sold to consumers by a legacy carrier and operated by a regional partner. JetBlue states that under the current rule, basic data, such as on-time performance, mishandled bags and other metrics, are not reported by either of these carriers, even though the consumer bought the ticket from a legacy carrier (*i.e.,* a Part 234 reporting carrier). Southwest Airlines also supports the proposal and notes that it operates 100% of its domestic scheduled flights yet many legacy carriers have extensive code-share operations. Southwest argues that the current reporting structure may lead to consumer confusion or misrepresentation and hinder competition. Furthermore, Southwest believes that airports are also judged for on-time performance in a market or region where airports are competing for customers; therefore, airport data should be complete and relevant. Regarding the costs and benefits of this proposal, Southwest states that the cost to mainline carriers may not be significant as they are already calculating the revenue derived from each code-share partner and they should be able to calculate those flights' on-time performance. In closing, Southwest states that if the Department concludes that such a requirement is too burdensome, it would support A4A's proposed alternatives.

Cape Air, Delta Air Lines, and United Airlines submitted comments in opposition to this proposal. Cape Air asserts that it is not beneficial to require existing carriers to report their code-share flights because to include the data for smaller regional flights with the statistics of major carriers would skew the report by giving equal weight to flights that carry significantly fewer passengers, and the report would not reflect the experience of the majority of customers traveling on the reporting carrier's flights. Delta proposes that regional operating carriers should be required to report data for their flights as the marketing carriers are in a poor position to verify the accuracy and quality of data received from code-share partners. Delta also argues that dual reporting will result in duplicate data by different carriers. Regarding the Department's question on whether double counting is an issue under this proposal, Delta states that double counting is a problem with respect to mainline-to-mainline code-share flights. Delta suggests that these flights should be exempted from reporting as the Department's primary regulatory interest on this issue is to collect and publish data from regional code-share flights. As with A4A's comment, Delta points out that these mainline-to-mainline flights only represent 2% of reportable flights and consumers are well informed that the mainline operating carrier is different from the marketing carrier.

United Airlines also opposes the proposal to require mainline marketing carriers to report code-share flights data. United argues that the Department has provided little data or anecdotal evidence to support the hypothesis that the current reporting structure results in consumer confusion or misrepresentation. In addressing the 2011 GAO report and its recommendation for the Department to collect and publicize more comprehensive on-time performance data, United argues that such a goal can be accomplished by expanding the reporting carrier pool to include smaller carriers, as proposed in this rulemaking. United further argues that the GAO report only recommended additional on-time performance data collection and did not recommend that the Department expand the universe of mishandled baggage and oversales reporting to include code-share flights. United states that if the Department adopts the proposed requirement on code-share flights reporting, certain modifications should be made, in which the mainline carriers should not be responsible for reporting data for flights that they do not operate and the operating regional carriers should be reporting this data. With respect to the time a carrier may need for preparing for its initial report under this new reporting requirement, United avers that significant lead time is needed—at least 18–24 months for on-time performance and oversales data reporting, and at least 36 months for the mishandled baggage reporting, assuming the Department adopts its proposal for reporting mishandled baggage as proposed in DOT–RITA–2011–0001. With respect to preparing reports for code-share flights following the initial report, United asserts that the carriers will need more than the current 15-day window. In that regard, United suggests that should the Department adopt the proposal to require marketing carriers to report data for code-share flights, the report deadline for this data should be expanded to at least 30 days after the end of the month. United also opposes imposing the reporting requirement on ''non-branded'' (mainline-to-mainline) code-share flights in which both operating carrier and non-operating carrier market and sell seats on the flights.

All airports and airport associations that filed comments support this proposal. ACI–NA points out that over half of flights by the three largest carriers are operated by code-share partners and this change will provide more comprehensive information on which to base travel decisions without unduly burdening air carriers. AAAE asserts that requiring reporting of code-share performance data will have an overall positive operational impact, as on-time performance at large hub airports can differ between mainline and code-share flights. The commenter further asserts that including code-share flights performance data in the marketing carriers' reports will benefit consumers because consumers cannot discern the difference between mainline carriers and code-share operating carriers as mainline carriers manage marketing, ticketing, and ground operations. California Airports Council points out that regional carriers now provide the vast majority of scheduled services to California airports, and over half of all daily domestic flights in the United States. The organization argues that the current reporting requirements do not always provide accurate and comprehensive data to consumers as almost 50% of the domestic flights marketed by the nation's three largest airlines are operated by code-sharing partners. As an example, California Airports Council states that United Airlines' on-time arrival rate at San Francisco International Airport (SFO) would have been 6% lower in July 2014 if code-share flights were included compared to what was reported under the current regulation. The commenter states that some of its member airports serving small communities and SFO have a much lower on-time performance rate than the national average and that the relatively poor on-time performance of certain flights at those airports is being obscured by the current reporting process.

MasFlight also commented on this proposal, stating that monthly air carrier information published by the Department that correctly groups both mainline and regional flights under the marketing carrier's code would be valuable from a consumer perspective and provide an apples-to-apples comparison among airlines. However, masFlight states that such an objective can be accomplished in less costly ways as the Department's proposed method duplicates work, requires transfer of information among partner carriers and creates new overhead investment by the Department itself. MasFlight distinguishes two types of code-share arrangements, ''regional code-share operations'' in which mainline carriers contract for exclusive or near exclusive capacity on flights operated by regional partners, and ''partnership operations'' in which the marketing carrier has limited inventory on the operating partner's flight. MasFlight supports the Department's view as stated in the NPRM that regional carriers' operating quality should be attributed to the marketing carriers' performance records but argues that only marketing carriers that control over 25% of the seats on a flight should have the operating records attributed to them.

DOT Responses: The Department's monthly ATCR provides airline service quality data to the public and ranks reporting carriers' performance based on several categories. Three of the six categories ranked and reported in the ATCR—flight delays, mishandled baggage, and oversales—are based on data collected by BTS pursuant to 14 CFR part 234 and part 250. The ATCR's performance tables, particularly the rankings, are widely accepted as important indicators of the carriers' quality of service, and are frequently referred to in news reports, industry analyses, academic studies, and consumer commentaries and forums. The ATCR data and rankings as reflected in news reports and institutional studies have a significant impact on a carrier's image and brand identity, which in turn has a potential effect on the decision making of many consumers when deciding to purchase air transportation. In the NPRM, we discussed the inadequate scope of current data collection, the most significant area being that a marketing carrier's flights operated by code-share partners are not included in the reported data. After reviewing the comments submitted on this subject, the Department is further convinced that it is in the public interest to address the discrepancy between legacy/mainline carriers' ATCR data that represent only 38%–55% [4] of all domestic scheduled flights that are branded with the marketing carriers' codes, and low-cost carriers' ATCR data that often contain close to 100% of all flights sold by those carriers under their codes. Consequently, we are finalizing the proposal requiring mainline marketing carriers to report the service quality data for flights operated by their code-share partners, which, in our view, will benefit consumers by providing them more information. Although consumer confusion is not always the case, we recognize that in many instances consumers may consider these code-share flights operated by code-share regional partners to be air transportation service provided by the mainline carriers to the same extent as the flights

[4] Data based on 2015 operation information collected by the Department's Bureau of Transportation Statistics, Office of Airline Information.

actually operated by the mainline carriers. This is particularly true if, as in most cases, the mainline carriers also handle flight scheduling and virtually all aspects of ground operations including customer service related issues, such as dealing with oversales situations, providing denied boarding compensation, and addressing mishandled-baggage reports. This change will also benefit consumers because including performance data for these code-share flights in the marketing carriers' ATCR records will provide both the operating carriers and the marketing carriers the incentive to universally improve performance quality, regardless of whether the flights are operated by mainline carriers themselves or their code-share partners.

The Department also carefully considered the comments submitted regarding the difference between the ''fee-for-service'' code-share arrangements and the ''multiple-marketing-carrier/brand'' code-share arrangements. In the fee-for-service code-share arrangement, the sole marketing carrier contracts with the operating carrier to purchase all seats on the flights, sets the flight number with its own airline designator code, and brands the flight with the marketing carrier's brand name, often with the suffix of ''Express'' or ''Connection'' to identify that it is a regional-carrier flight. The marketing carrier is responsible for setting the flight schedules, in consideration of and in coordination with its network capacity, potential for connections, and overall efficiency. The marketing carrier's operation control center makes decisions on flight dispatching, and often handles many ground services such as checking in at the airport, baggage handling, boarding and deplaning. Passengers with service related issues will contact the marketing carrier's customer service center for assistance. The operating carrier is only in charge of the flight operation and onboard passenger services. In the Department's view, fee-for-service code-share flights are an integral part of the marketing carriers' networks and their performance quality is an important component of the marketing carriers' overall performance quality. The public will benefit from a complete view of a marketing carrier's performance record that includes the fee-for-service flights operated by another carrier, for which the marketing carrier has control over virtually every aspect of the air transportation service except the operation of the flight itself. Fee-for-service code-share arrangements allow a marketing carrier to reach regional markets without taking on expensive investments such as purchasing/leasing and operating aircraft or training and maintaining flight crews. Marketing carriers also have economically sound reasons to retain many ground handling tasks for code-share flights, such as maintaining consistent brand quality and fully utilizing existing ground personnel and equipment. For these reasons, the performance quality of these fee-for-service code-share flights should be attributed to the marketing carrier's ATCR records and rankings.

In this final rule, we adopt the requirement for marketing carriers to report to the Department service quality data of domestic fee-for-service code-share flights marketed under their codes. Accordingly, all reporting carriers will continue to file reports for on-time performance, mishandled baggage, and oversales for flights that they operate. Those reporting carriers that market fee-for-service flights operated by another carrier will be required to submit a second set of data for those flights. We specifically address the three reporting subjects as follows:

On-time performance data: We have considered the comments by A4A and others about the burden to marketing carriers and determined that there are ways to address this issue while still obtaining the data that will achieve the goal of the Department. Specifically, for flights that are operated under the marketing carrier's code on a fee-for-service basis by a reporting carrier, the Department will reduce the marketing carriers' reporting burden by requiring them to simply identify on a monthly basis those fee-for-service flights that they market. The Department's Bureau of Transportation Statistics (BTS) will extract the on-time performance data from the reports already submitted by those flights' operating carriers that are reporting carriers. For fee-for-service flights that are operated by a non-reporting carrier, it is the marketing carrier's responsibility to provide the full set of on-time performance data for each flight in the same manner as they report for the flights they operate on their own.

Mishandled baggage and oversales data: For mishandled baggage and oversales data, because carriers are only required to file those reports in the aggregate (as opposed to filing on-time performance data on a flight by flight basis) we see no need to simplify the reporting data in the way that we did for on-time performance data. As such, the reporting carriers that market fee-for-service code-share flights must submit a second set of mishandled baggage monthly reports that contains the data for all reportable fee-for-service flights that they market, and a quarterly oversales report that contains the data for all reportable fee-for-service flights that they market. This final rule differs from the NPRM in which we proposed to have the marketing carriers report a second set of data that contains data for all flights they market, including not only the code-share flights but also the flights the marketing carriers operate. Requiring a second set of reports that contain only fee-for-service flight data potentially slightly reduces the burden on carriers by eliminating the need to prepare a report that combines data from the report on flights operated by the reporting carrier and data on flights operated by a code-share partner on a fee-for-service basis for the reporting carrier, while affording the Department the flexibility to add all flight data together, or to view flight data for reporting carriers' own flights and code-share flights separately.

In contrast to fee-for-service code-share arrangements, the multiple-marketing-carrier code-share arrangements involve more than one marketing carrier for a single flight operation. Thus, under this type of code-share arrangement, a single flight is coded with more than one carrier's designator code and flight number. In the NPRM, we mentioned only the mainline-to-mainline code-share arrangements (in which two mainline carriers both market the same flight under each carrier's code and one of the mainline carriers also operates the flight) and sought comments on whether these flights should be included in the non-operating marketing carrier's reports. After viewing a snapshot of multiple-marketing-carrier code-share flights for the first quarter of 2015 compiled from the Official Airline Guide, part 234 data, and the Origin and Destination Survey, we realize that several variations exist under the multiple-marketing-carrier code-share arrangements. Some of the flights are marketed under the codes of only two carriers, one of which operates the flight. In those situations, the carrier that is both marketing and operating the flight could be a mainline carrier (as referred to in the NPRM as ''mainline-to-mainline'' code-share) or a regional carrier that markets a small number of seats on the flight. Another variation is multiple carriers market the flight and the operating carrier and non-operating carriers all sell a certain number of seats on the same flight. Yet another variation is the situation in which the operating carrier does not market the flight but

two or more non-operating carriers market the flight. In the 2015 first quarter data we reviewed, we found one flight that carried five different carriers' designator codes. With respect to each marketing carrier's share of seats on a flight, we found great variation as well. While a large percent of these flights have a ''main'' marketing carrier that sells the great majority of the seats, many flights with two marketing carriers split the seats approximately half and half, one third and two thirds, or a quarter and three quarters.

At this point, the Department lacks information on how carriers share the control and responsibility for handling multiple-marketing-carrier code-share flights under various arrangements, such as which carrier(s) determine the flight schedule and which carrier(s) handles baggage and oversales. We can only speculate that much of this information will depend on which carrier controls what percentage of seats on a given flight. We also lack information on how consumers perceive the multiple-marketing-carrier flights with respect to their brand identity. As stated in the NPRM, our primary regulatory interest at this time is collecting and publishing data on code-share service operated by the regional-carrier partners of the larger U.S. airlines. We recognize that this primary purpose is served by capturing the fee-for-service flights' performance quality and attributing this information to the only marketing carrier's performance records. As the multiple-marketing-carrier code-share flights only count for a small percentage of the total number of code-share flights, we have decided that marketing carriers that are not the operating carrier will not be required to include those flights in their second set of reports. We will, however, continue to monitor how multiple-marketing-carrier code-share arrangements evolve both with respect to their structures and their volumes. Should we see the need to include these code-share flights in any marketing carriers' performance reports, we will address this matter in a future rulemaking.

Regarding Travelers United and National Consumer League's comment urging the Department to collect flight performance data for international flights, we note that the current part 234 reports cover only domestic scheduled flights and the current part 250 reports cover domestic scheduled flights and international scheduled flights departing a U.S. airport. To require reports for other international flights is beyond the scope of the NPRM.

With respect to Consumers Union and U.S. PIRG's question on the soundness of the Department's proposal to limit the reporting of code-share flights data to non-stop flights operated by code-share partners, we clarify that both the current reporting system and the final rule as adopted require carriers to report flight performance data on a per flight segment basis. As such, all domestic segments of a multi-segment direct flight are covered by the reporting requirement in the existing rule and in this final rule.

With respect to the compliance date of this rule by which all marketing carriers that report to the Department under parts 234 and 250 are required to file a second set of data for their fee-for-service code-share flights, we have fully considered the comments submitted and decided that it is reasonable to set the compliance date as transportation that takes place on or after January 1, 2018, coinciding with the compliance date for all reporting carriers to comply with the revised mishandled baggage reporting rule (Docket DOT–RITA–2011–0001). As with that rulemaking, we believe that choosing the first day of the year as an effective date will make future year-over-year comparisons more meaningful, and the carriers will have more than a year to work with their code-share partners to structure an internal system by which both carriers work together to compile the reports required from the marketing carriers. As such, all reporting carriers that market fee-for-service code-share flights will be required to file a second set of data that contains those code-share flights' on-time performance and mishandled baggage information for the month of January 2018 by February 15, 2018, and to file a second set of data that contains those code-share flights' oversales information for the first quarter of 2018 by April 30, 2018.

(3) Codifying 49 U.S.C. 41712(c) Regarding Web Site Disclosure of Code-Share Service and Other Amendments to 14 CFR Part 257

The NPRM: Code-sharing is an arrangement whereby a flight is operated by a carrier other than the airline whose designator code is used in schedules and on tickets. In the NPRM, we proposed to amend 14 CFR part 257 to codify 49 U.S.C. 41712(c) (added by Pub. L. 111–216, sec. 210, August 1, 2010), which requires U.S. and foreign air carriers and ticket agents to disclose code-share arrangements during Web site schedule searches ''on the first display of the Web site following a search of a required itinerary in a format that is easily visible to a viewer.'' In addition, we proposed the following interpretations of the statutory language: (1) Clarifying that this requirement covers any ticket agent ''doing business in the U.S.'' to include entities marketing to U.S. consumers via the internet even if the ticket agent does not have a physical presence in the United States; (2) clarifying that this requirement covers flight schedule information provided by carriers and ticket agents via mobile Web sites and mobile applications; and (3) clarifying that ''in a format that is easily visible for a viewer'' means the disclosure must appear in text format immediately adjacent to each code-share flight displayed. We sought comments on whether we should also specify minimum standards on the text size of the disclosure in relation to the text size of the schedule itself. DOT also proposed to explicitly state in the rule text that verbal disclosure of code-share arrangements must be made the first time a code-share flight is offered. Further, we proposed certain editorial revisions to the language of part 257 to reflect the technology changes in the airline industry's reservation and ticketing systems that have resulted in the predominant use of online reservation systems and electronic tickets.

Comments: Five consumer rights advocacy groups submitted comments generally in support of the Department's proposals. In their joint comments, Consumers Union and U.S. Public Interest Research Group agree with the Department's view that the requirement of 49 U.S.C. 41712(c) as codified in part 257 should cover all Web sites that market to U.S. consumers. They also support having code-share information displayed or disclosed with equal prominence in all oral and written communications, Web site displays, printed flight schedules, and advertisements. Flyersrights.org states that airlines should be required to disclose the routes that they are flying, particularly over conflict zones. Travelers United and National Consumers League support the proposal to cover all carriers and ticket agents doing business with the U.S. public regardless of whether the business is domiciled in the United States. In their joint comments they also support the proposal to cover advertisements for flights to, from, and within the United States that are marketed to U.S. consumers. With respect to disclosures in Web site itinerary searches, the commenters support the proposal that disclosures must be immediately adjacent to each code-share flight. They recommend that the Department should extend the code-share disclosure to

boarding passes so passengers who are not directly involved in the ticket booking process will not be confused.

A4A submitted comments on behalf of its member airlines expressing its concerns about the application of the regulation's requirements to mobile applications and noting that the statutory language does not expressly address mobile applications. A4A urges the Department to be flexible toward the application of the disclosure rule to mobile devices and software and suggests that instead of mandating minimum font sizes and requiring that the disclosure be immediately adjacent to the entire itinerary, the Department should prioritize all of the new disclosure requirements and consider how these disclosures will fit with one another and in different ticketing platforms. Delta Air Lines opposes the proposed change in rule text that specifically requires verbal disclosure of code-share arrangements to be made the first time a code-share flight is mentioned. Delta believes that the current rule requiring verbal disclosure to be made ''before booking transportation'' should be interpreted as ''at the end of the reservation process.'' Delta argues that the proposed language is a radical departure from the Department's stated policy of the past two decades, and that such a requirement will complicate and slow the reservation process, will increase reservations costs, and is contrary to the interests of consumers. Delta estimates that each disclosure statement would add approximately 5 seconds to a call and that it would incur $1 million additional annual recurring cost to its reservation department should the Department adopt the proposed language. In closing, Delta argues that the Department has shown no need for such a change and the current rule provides the appropriate notice to consumers at the appropriate time. Arab Air Carrier Association (AACA) opposes the idea that the Department should dictate code-share disclosure display format and font size on Web site itinerary search results. AACA argues that the format used by the agent should govern display formats and font sizes and any costs for changes to displays should not be passed on to carriers.

Several ticket agents and ticket agent associations also submitted comments on this proposal. Travel Technology Association, American Express Global Business Travel, and Amadeus point out that the proposed rule text omitted language in the current rule that requires the airlines to provide code-share information to computer reservation systems (also known as Global Distribution Systems or GDSs) in which they participate. The commenters state that the Department should restore the language to make it clear that airlines must share code-share information with the GDSs. With respect to code-share disclosure on mobile devices, Travel Technology Association and Amadeus state that the Department should take into consideration the limited space on mobile device displays, or the ever-changing ways in which information is disseminated to consumers through social media. These commenters state that they are not asking the Department to exempt these devices but to recognize the need for a more flexible approach. American Express Global Business Travel also urges the Department to carefully consider the impact of code-share disclosure requirements on mobile device platforms. TripAdvisor believes that the Department should exclude disclosure requirements for mobile devices less than 8 inches diagonally. In support of this position, TripAdvisor states that phones have extremely limited display space and may be further limited by the operating system and applications. In the alternative, TripAdvisor suggests that the Department should consider other disclosure methods for mobile devices such as disclosing on the first screen after a consumer selects a flight. The U.S. Tour Operators Association (USTOA) asserts that the Department's requirement for oral and telephone code-share disclosure would impermissibly exceed the specific obligation imposed by Congress under Section 41712. The American Society of Travel Agents (ASTA) believes that the target of the disclosure requirement should be the purchasers of the air transportation instead of the passengers, as it stands now, because it is not always the purchasers who would be the passengers. ASTA states that the rule should clarify that the obligation of ticket agents is fulfilled when disclosure is made to the ticket purchaser.

DOT Responses: The Department's current regulation on the disclosure of code-sharing and long term wet lease arrangements, 14 CFR 257.5, was designed to ensure that consumers are aware of the identity of the airline actually operating their flight in code-sharing and long-term wet lease arrangements in domestic and international air transportation. Code-share disclosure is important because the identity of the operating carrier is a factor that affects many consumers' purchasing decisions. In that regard, we believe that codifying 49 U.S.C. 41712(c) and strengthening the code-share disclosure requirements is an effective way to prevent potential consumer confusion. The Department has carefully reviewed all relevant comments on the proposed revisions of the code-share disclosure rule in 14 CFR part 257, and has decided to adopt the following revisions.

Section 257.3 Definition: In the definitions section, 14 CFR 257.3(g), we are replacing the term ''Transporting carrier'', which is used throughout section 257.5, with the term ''Operating carrier'' to refer to the carrier in a code-share or wet lease arrangement that has the operational control of a flight but does not market the flight in its own name. As explained in the NPRM, by such an amendment we are trying to achieve consistency with other recently amended consumer protection rules, see, *e.g.*, 14 CFR 259.4(c) (code-share partners' responsibilities in tarmac delay contingency plans) and 14 CFR 399.85(e) (notice of baggage fees for code-share flights). As the definitions in section 257.3 are arranged in alphabetical order, the definition for ''Operating carrier'' now is under section 257.3(f), and the definition for ''Ticket agent'', previously under section 257.3(f), is now under 257.3(g).

Section 257.5(a) Notice in flight itineraries and schedules: In section 257.5(a) with respect to disclosure in flight itinerary and schedule displays, we are codifying the requirement of 49 U.S.C. 41712(c) in the rule text of 14 CFR 257.5 by requiring that Web site itinerary search results provided by carriers and ticket agents must disclose any code-share arrangement on the first display of the Web site following such a search, in a format that is easily visible to a viewer.

We are also adopting our proposed requirement that not only carriers but also all ticket agents doing business in the United States with respect to flights within, to or from the United States will be covered and must provide code-share disclosure. As we stated in the preamble of the NPRM, any ticket agent that markets to consumers in the United States, either from a brick-and-mortar office located in the United States or via an internet Web site that is marketed towards consumers in the United States, would be considered to be ''doing business in the United States.'' The requirement would cover any travel agent or other ticket agent that does not have a physical presence in the United States but has a Web site that is marketed to consumers in the United States and displays schedule, fare or availability information for flights within, to, or from the United States. We

believe this requirement is reasonable and appropriate given the expansion of e-commerce that effectively eliminated, in many cases, the necessity of having a physical presence in a certain country for providing intangible service products such as air travel reservation service to consumers in that country. To determine whether a Web site is marketed to U.S. consumers with respect to code-share disclosure requirements for itinerary display (in section 257.5(a)) and in airfare advertising (in section 257.5(c)) a variety of factors will be considered—for example, whether the Web site is in English, whether the seller of air transportation displays prices in U.S. dollars, whether the seller uses banner advertisements or highlights special deals for flights to or from the United States, whether the seller has an option on its Web site that differentiates sites or pages designed for U.S. and other consumers, and whether the Web site distinguishes between persons with addresses or telephone numbers in the United States and those outside the United States in the sales process. We note that this is consistent with the enforcement policy currently applied in connection with the Department's full fare advertising rule, 14 CFR 399.84.

The second requirement that we adopt here is that, for a code-share disclosure in an itinerary search result Web page to meet the section 41712(c) requirement to be ''in a format that is easily visible to a viewer,'' the disclosure of the operating carrier must be immediately adjacent to the itinerary displaying the flight operated under a code-share arrangement and in a font size that is not smaller than the font size of the flight identified under the marketing carrier's name and/or code in the itinerary display. Under this requirement, it is not sufficient to locate the disclosure elsewhere on the same Web page that displays all search results meeting the search criteria, such as at the very end of the Web page, with an asterisk or some other symbol next to each flight that has a code-share arrangement. In coming to this conclusion, we observed that quite often there are multiple flights that meet the search criteria so having code-share disclosures located elsewhere on the page, such as at the bottom of the page, is visually remote from the itineraries that include a code-share flight and would likely be overlooked by consumers. This is true particularly in the situation where the entire Web page does not fit on the screen display and the viewer must scroll to the bottom of the page to see the disclosure. In that case, we consider the disclosure located at the bottom of the page to not be on the ''first display'' following an itinerary search, as required by the statute. Accordingly, we consider disclosure of the operating carrier directly adjacent to each flight displayed with the marketing carrier's name and/or code to best meet our goal of clearly and prominently identifying all fights that are under a code-share arrangement.

With respect to code-share disclosure in flight itinerary search results and flight schedule displays provided through mobile devices via Web sites specifically designed for mobile devices (mobile Web sites) or applications (apps), we appreciate the commenters' insight that mobile devices have limited screen display space and it is more difficult to fit all the information into one screen display. However, we also recognize that the use of mobile Web sites and apps is becoming more and more popular among consumers and we only expect this trend to continue with the development of technology that brings the convenience and accessibility of mobile devices to many more consumers' daily life. As such, it is important to ensure that displays on mobile devices include code-share disclosure, but it is also important to ensure that code-share disclosure requirements take into account the limitations of mobile Web sites and apps. As a compromise, we are adopting a simplified format for display of code-share disclosures via mobile Web sites and apps. Specifically, instead of disclosing the code-share arrangement as ''flight 123 is operated by Jane Doe Airlines d/b/a QRS Express,'' where ''Jane Doe Airlines'' is the corporate name of the operating carrier and ''QRS Express'' is the brand name of the domestic code-share network (*e.g.*, American Eagle, Delta Connection, United Express), on mobile Web sites and apps, carriers and ticket agents will be permitted to simply disclose the corporate name of the operating carrier, *e.g.*, ''flight 123 operated by Jane Doe Airlines.'' We believe this compromise is appropriate in striking a balance between sufficiently identifying the operating carrier while preserving some space on mobile displays which is more limited than space on computers. Carriers and ticket agents that are already displaying code-share disclosure information in the same manner as they are required to do on the desktop Web site are free to either maintain such a display format or switch to the simplified format as discussed above. The Department will continue to monitor the development of mobile Web sites and apps and consider amendments to this requirement as necessary.

In connection with comments regarding the requirement for airlines to provide code-share information to the GDSs that they use, we acknowledge that the requirement was inadvertently omitted from the proposed rule text in the NPRM. We are adding the language back to the final rule text to make it clear that if an airline provides schedule information to a GDS, it is required to provide code-share information to the GDSs who can in turn provide the information to ticket agents and consumers.

Section 257.5(b) Notice in oral communications with prospective consumers: Section 257.5(b) requires that carriers and ticket agents must identify the actual operator of a code-share flight to a prospective consumer, ''before booking air transportation,'' over the telephone, or through other means of oral communication. In the preamble of the 1999 final rule implementing this requirement, we explained that the phrase ''before booking transportation'' reflects the Department's enforcement policy: During a given encounter (phone call, visit, etc.) the agent or carrier may not wait until after the consumer has decided to make the reservation or purchase the ticket and disclose the code-sharing arrangement only when reading back the flight information. Instead, the disclosure must be made at the time that the schedule information is being provided to the consumer *during the* ''*information*'' *and* ''*decision-making*'' *portion of the conversation.* We then specifically rejected a carrier's suggestion that disclosures should only be required *during the booking process.* See, 64 FR 12838, March 15, 1999 (emphasis added). We acknowledge that under the existing rule, carriers and ticket agents have a period of time starting from the first mention of a flight involving a code-share operation, through further discussion of the flights available until before the conclusion of the information and decision-making portion of the conversation to make the disclosure.

In this final rule, we are clarifying and amending the existing requirement on oral disclosure of code-share arrangements by narrowing the time window carriers and ticket agents are allowed to provide the disclosure. Specifically, instead of having to make the disclosure at any point during the information-gathering and decision-making process, we are now requiring that the code-share information be provided the first time a code-share

flight is offered to a consumer or, if no such offer was made, the first time a consumer inquires about such a flight. In adopting the new standard, we believe that requiring disclosure at a certain point rather than during a window of time provides the regulated entities a clearer threshold for compliance. In addition, a clear rule that requires disclosure during an early stage of the process benefits consumers and aligns with the online display disclosure requirements of the statute.

The Department views the statutory language in section 41712(c)(2) requiring code-share disclosure in internet schedule search to be on the first display as an indication of Congressional intent so such information will benefit consumers searching for airfares to the maximum extent in making purchasing decisions. Accordingly, we are extending this approach to code-share disclosure in oral communications to enhance information provided to consumers purchasing air transportation through telephone or in person.

We reject some commenters' view that requiring disclosure of code-share information the first time a code-share flight is mentioned will impose unreasonable cost on carriers and ticket agents. In our view, the cost is not unreasonable given the importance of the information. Delta commented that each disclosure will add 5 seconds to a telephone reservation call and estimated that complying with the disclosure requirement as proposed will add $1 million annual recurring cost to its reservations department. This assertion is not only unsubstantiated by underlying data, it also fails to consider that disclosing a code-share arrangement for the first time right before the prospective customer confirms the reservation may potentially cost more to carriers and ticket agents because such information disclosed at the last minute may result in some consumers deciding to revisit all the travel arrangements already made and possibly begin the reservation process again to look for flights that are operated by a different carrier. In fact, according to Delta's interpretation of the current rule, a carrier or ticket agent may stay silent about any code-share arrangements included in a number of flights that a consumer can choose from, and only disclose the code-share nature of the one flight the consumer has selected for booking. This approach completely defeats the purpose of the code-share disclosure requirement, which is to provide complete and accurate material information that may affect consumers' decision making. It is the Department's policy determination that disclosing all material information about a flight early in the reservation process, including code-share arrangements, is the most efficient way to fully use the time of the reservation agents and the consumers.

This section currently applies to, and, under this final rule, will continue to apply to, both U.S. and foreign air carriers, as well as ticket agents doing business in the United States, which is interpreted in the same manner as described in the discussion of that phrase in section 257.5(a) above. Consequently, a ticket agent that sells air transportation via a Web site marketed toward U.S. consumers (or that distributes other marketing material in the United States) is covered by section 257.5(b) even if the agent does not have a physical location in the United States, and such an agent must provide the disclosure required by section 259.5(b) during a telephone call placed from the United States even if the agent receives such calls at a foreign location.

Section 257.5(c) Notice in ticket confirmations: We have received no comments on this section and we are adopting the changes to the rule text as proposed in the NPRM. Specifically, we retain the basic requirements listed in 14 CFR 257.5(c)(1) that requires written disclosure of code-share arrangements ''at the time of purchase''; each flight segment involving a code-share arrangement that has its own flight number must be identified individually with the disclosure information immediately adjacent to the flight number; and if a single-flight-number service involves one or more code-share segments, each code-share segment must be identified individually with the disclosure information immediately adjacent to that flight if there are different operating carriers on the segments. We are also deleting the language in 14 CFR 257.5(c)(2), (c)(3), and (c)(4) that contain outdated references to paper tickets. As paper tickets have predominantly been replaced by electronic tickets, the Department considers a universal requirement to provide disclosure at the time of purchase through a notice automatically generated by the reservation systems to be reasonable and not overly burdensome.

Section 257.5(d) Notice in city-pair specific advertisements: Paragraph (d) deals with disclosure requirements in city-pair specific advertisements. We are adopting the proposal in the NPRM to use the phrase ''written advertisement'' to replace the phrase ''printed advertisement,'' which in the current rule text refers to both advertisements printed on paper and advertisements published on the internet. We believe the word ''written'' is more accurate in describing both types of advertisements.

In addition, we are adding a descriptive phrase—''marketed to consumers in the United States''—in an effort to reduce the possibility of misunderstanding by specifying the scope of the disclosure requirements on internet advertisements. This is meant to clarify that the disclosure requirement applies to all internet advertisements for flights within, to or from the United States that are marketed to consumers in the United States. Similar to the scope of the code-share disclosure requirement for flight itinerary and schedule displays, this approach is consistent with the intended scope of other air travel consumer protection rules, and ensures that internet advertisements marketed to consumers in the United States will be covered even if the hosting server for the Web site is located outside of the United States.

We note that this standard will cover all advertisements appearing on a carrier's or a ticket agent's own Web site, as well as advertisements that are presented to U.S. consumers through other paid advertising venues on the internet (such as a news media Web site or a travel blog Web site) and social media Web sites (such as Facebook or Twitter). In the NPRM, we sought comments with regard to whether applying the same standard to advertisements on all of these Web sites is reasonable and technically practical in light of the brevity of these media posting formats and we received no specific comments. Although some social media communication formats impose a character limit on postings, we do not consider at this time that such limit would warrant a more relaxed code-share disclosure rule for city-pair specific advertisements through these social media formats.

Another change proposed in this NPRM concerns the example disclosure statement in the rule text that a seller of air transportation must include in a radio or television broadcasting advertisement. The current sample statement includes the phrase ''[s]ome services are provided by other airlines.'' Because the words ''services'' and ''provided'' cover a wide range of activities, including ground operations, customer service, etc., they do not accurately convey the information we intended to relate, which was regarding the actual operation of a flight. Accordingly, we are changing the

sentence to read ''[s]ome flights are operated by other airlines.''

Finally, we have decided not to adopt in this final rule the suggestion by Travelers United and National Consumers League to require carriers to provide code-share information on passengers' boarding passes. Passengers have access to, and likely retain a copy of their ticket confirmation before and during their travel even if they did not purchase the tickets themselves, and the relevant code-share information is provided in the ticket confirmation as required by the current rule. To add code-share information on boarding passes could enhance code-share disclosure but we are not sure it is necessary and cost effective.

U.S. and foreign air carriers and ticket agents should be meeting these disclosure requirements for code-share arrangements by the effective date of the rule.

(4) Disclosure That Not All Carriers are Marketed

The NPRM: In the NPRM, the Department stated that it was considering requiring large travel agents to disclose whether they display the airfares of all carriers serving any market that can be searched on the travel agents Web site. We stated that many online travel agents provide flight and fare information for a significant number of carriers—but not all carriers—serving a particular city-pair market or, in some markets, online travel agents may not provide information regarding any carrier serving the market. Further, the Department stated that online travel agents do not necessarily identify the carriers whose schedule and fare information is or is not provided in search results. As a result, consumers may believe the search results provide all possible flight options for a particular city-pair market when in fact there may be other options available. As stated in the NPRM, the Advisory Committee for Aviation Consumer Protection recommended that DOT require ticket agents, including online ticket agents, to disclose the fact that they do not offer for sale all airlines' tickets, if that is the case, and to advise consumers that additional airlines may serve the route being searched, so that consumers know they may need to search elsewhere if they want to find all available air travel options. The Department sought comment on whether to create a disclosure requirement for all ticket agents or just large ticket agents, and if so, in what manner. Specifically, the Department asked for comment on whether to require ticket agents to prominently note on their Web sites that not all U.S. air carriers and non-U.S. air carriers serving the United States are displayed on the Web site or marketed by the travel agent or to prominently display a statement in connection with a search of a particular city pair that not all airlines serving those cities are displayed on the Web site or marketed by the travel agent. The Department also sought comment on whether to require online travel agents to specifically identify all of the airlines that it markets.

Comments: Among airline commenters, some support the requirement to identify carriers marketed, while others oppose it. The Arab Air Carriers Organization, and some carriers, including Frontier, JetBlue, Southwest, and Spirit, support the proposal to require disclosure regarding carriers marketed. While A4A does not object to the requirement, it states that the Department should not require ticket agents to list carriers *not* sold. Spirit, in contrast, comments that the Department *should* require ticket agents to identify carriers *not* sold and the requirement should apply to all ticket agents, regardless of size. Spirit further argues that disclosure should be provided on every search page and, in support of its position, asserts that the lack of such a disclosure would disproportionately harm price-sensitive consumers who were not given the opportunity to learn about Spirit fares. Southwest states that consumers would benefit from knowing that search results may not include all possible flight options for a city-pair and notes that the information may prompt consumers to visit Web sites such as Southwest.com. Southwest proposes that all ticket agents, regardless of size, should be required to include a generic statement in search results notifying consumers that the results only include certain carriers with which the ticket agent has an agreement. Frontier comments that some large travel agents create the impression that they market and sell air transportation of all airlines when in fact they do not; consumers are not informed that not all carriers are offered and therefore the fare or service options being presented are limited.

Consumer advocacy organizations were also divided on this issue. Consumers Union and U.S. PIRG support the requirement and state that ticket agents should disclose all airlines that serve a particular route, and which of those airlines are included in the ticket agent's marketing. Travelers United and National Consumers League (NCL) oppose the requirement, stating that the requirement would not result in a consumer net benefit, citing Web site clutter, among other things.

Ticket agents and their associations generally oppose requiring ticket agents to disclose carriers marketed. Travel Tech comments that no consumer harm that resulted from the lack of such a disclosure requirement has been shown. Travel Tech states that ''consumers are sophisticated enough to realize that not all carriers may be displayed'' and points out that, for example, Southwest advertises extensively that its fares are available only on its own Web site. Meanwhile, the Department's Office of Aviation Enforcement and Proceedings (Enforcement Office) has issued guidance (August 19, 2013, Display of Search Results on Ticket Agent Web sites) stating that Online Travel Agents (OTAs) should not use terms in search results suggesting that no flights exist that match the criteria provided by the consumer to search for and compare flight options from multiple carriers when flights may be available on carriers that the OTA does not market, so according to Travel Tech no new requirement is necessary. Travel Tech members Sabre and Travelport each filed separate comments opposing a requirement to disclose that not all carriers are marketed. Sabre states that such a requirement is unwarranted and unjustified while Travelport states that there is no evidence that the requirement will cure any particular harm and that consumers are already aware that not all carriers distribute through online travel agencies.

ASTA also opposes the requirement, stating that there was no evidence of consumer confusion. Several individual travel agents oppose the requirement for the same reason and note that airlines are not required to disclose to consumers that travel agents may offer a greater variety of airlines and destinations from which to choose. ASTA further comments that if implemented, the requirement should be a generalized statement indicating that some carriers' services may not appear in search results.

USTOA states that the requirement is unnecessary as the issue has been addressed through enforcement policy; however, if a regulation will replace the enforcement policy, USTOA states that it would support a requirement to include a statement on ticket agents' Web site displays stating that the displayed schedules ''may not reflect all carriers in the market.'' BCD Travel comments that it is unnecessary for corporate travel companies to disclose which carriers they market because these agents are incentivized to meet corporate clients' needs. Orbitz objects

to a requirement that applies only to large travel agents instead of all ticket agents and states that the Department's concern that consumers may mistakenly believe that they are provided with all possible flight options is not supported by the evidence. Orbitz further states that maintaining an accurate list of all of the hundreds of airlines it markets would require regular updates and would not be useful to consumers as most of the airlines listed would not serve the city-pair the consumer is searching. Skyscanner comments that it would not be feasible to display full lists of carriers that are featured on a particular flight search tool because markets are changing regularly and any list would quickly become out of date or inaccurate. According to Skyscanner, such a requirement would likely result in the display of inaccurate information to consumers, ''despite the best efforts and intention'' of the site displaying the information. Priceline comments that the requirement might make sense for ''consumer-facing'' Web sites but should not apply to corporate travel Web sites. Carlson Wagonlit Travel states that if such a requirement is implemented, it should apply to all ticket agents, regardless of size, and should be limited to a list on the ticket agent's Web site for consumers and should not apply to corporate travel. American Express Global Business Travel echoes Travel Tech's comments, stating that no specific consumer harm has been shown and ''consumers certainly are sophisticated enough to recognize that some carriers' services may not be available through a particular ticket agent distribution channel.''

DOT Response: The Department has carefully considered all of the comments and has decided not to adopt a requirement that ticket agents provide disclosure on their Web sites that not all carriers are marketed on their site, if that is the case. The Department recognizes that some sophisticated consumers may realize that not all airlines are marketed on all online travel agents without disclosure by the travel agents, but not all consumers have the same level of sophistication regarding the marketing of air travel. The Department maintains the view that the information is important and should be provided to consumers by ticket agents. However, we are persuaded by commenters that a disclosure requirement resembling any of the alternatives on which we sought comment is not appropriate at this time. We are concerned that a general disclosure that not all carriers are marketed on a particular Web site may be confusing to consumers. For example, a general disclosure may result in wasted search time for some consumers whose particular search results do in fact include all carriers and flights that service a particular route/city-pair, but who continue searching because the disclosure indicates that not all carriers are marketed. In addition, by the time the consumer decides to purchase a flight option that was displayed in the initial search, that particular fare or flight option may no longer be available.

Regarding a more specific disclosure for each individual city-pair searched, the Department is concerned that this requirement may be overly burdensome for ticket agents. Ticket agents often market the flights of several hundred carriers serving the United States. A ticket agent may not have all flight information for a particular carrier and the information could change without notice. For example, a carrier may begin serving a destination or exit a particular market without notifying ticket agents; may provide service only seasonally; or may temporarily stop serving a particular city. Accordingly, the Department has determined that it will continue to review this issue and may address it in a future rulemaking if appropriate. In addition, the Department will consider appropriate consumer outreach and education. For example, the Department's Enforcement Office may provide information to consumers that not all carriers are marketed on travel agent Web sites through its consumer publications like ''Fly Rights'' or consumer forums. These Department actions may be in addition to or instead of engaging in a rulemaking to impose a requirement on ticket agents to disclose airlines that they market.

(5) Prohibition on Undisclosed Airfare Display Bias by Ticket Agents and Carriers

The NPRM: An electronic airline information system (EAIS) is defined in the NPRM as a system that combines air carrier or foreign air carrier schedule, fare, rule, or availability information for transmission or display via the internet or other communications system to air carriers or foreign air carriers, ticket agents, other business entities, or consumers. In the NPRM, the Department proposed prohibiting any undisclosed bias in any EAIS display of multiple carriers' schedules, fares, rules, or availability. The regulation would require any carrier or ticket agent that provides electronic display of airfare information to provide unbiased displays or disclose the biases in the display. It would apply to all electronic displays of multiple carriers' fare and schedule information, whether the display is available on an unrestricted basis, *e.g.,* to the general public, or is only available to travel agents who sell to the public. The requirement to provide unbiased displays or disclose biases in the display would also apply to electronic displays used for corporate travel unless a corporation agrees by contract to biases in the display used by its employees for business travel. The requirements would apply to displays provided in response to airfare inquiries made by a consumer for a particular itinerary or airfare inquires made by a travel agent or other intermediary in the sale of air transportation for a particular itinerary. Although the regulation would require carriers and ticket agents that provide airfare information electronically to display the lowest generally available airfares and most direct routings that meet the parameters of the airfare search request, it would not prohibit displays that included biases selected by the consumer or the user of the display, such as a preferred carrier. The only prohibition would be on *undisclosed* biases. We sought comment on whether the prohibition on undisclosed display bias should be limited to airfare and routings and on the costs and benefits of such a prohibition.

In addition to the proposal regarding undisclosed display bias, the Department requested comment on whether to require any ticket agent that decides to bias its displays and disclose the existence of bias to also disclose any incentive payments it is receiving for engaging in such a display bias. We sought comment on how such disclosure should be provided and what kind of disclosure of the existence of incentive payments would be most helpful for consumers.

Existing Guidance: On February 1, 2011, and March 4, 2011, the Department's Enforcement Office issued guidance that stated that undisclosed display bias in search results for airline service would be considered by that office as an unfair and deceptive practice because it prevents consumers and travel agents who advise consumers from obtaining accurate and complete information on schedules and fares. Although the guidance was not mentioned in the NPRM, several commenters referred to it in their comments. The guidance provided that the manner of displaying itinerary information including carrier, lowest fares, departure times, arrival times, trip duration, or airports, must not favor or disfavor a particular carrier unless the bias is clearly and conspicuously

disclosed. The guidance was sent to ticket agent trade associations, major online travel agents, and the GDSs that provide fare, schedule, and availability information to ticket agents that market or sell air transportation to consumers. The guidance was also posted and remains available on the Enforcement Office Web site.

Comments Regarding Disclosure of Bias: Consumer advocacy groups Consumers Union, US PIRG, and FlyersRights.org all support the Department's proposal to prohibit undisclosed display bias in search result displays. Consumers Union and US PIRG state that consumers should know ''whether the scales are being artificially tilted in favor of certain carriers.'' Farelogix, a third party technology provider to the airlines, also supports the prohibition, arguing that bias can cause significant economic damage to an airline and block third parties from creating innovative solutions for the industry. Farelogix comments that it has experienced the negative impact of undisclosed biasing directly. A4A supports the proposal as it applies to ticket agents but states it should not apply to carrier Web sites, commenting that in the past, for example, in the Computer Reservations System (CRS) rulemaking, the Department assumed the public was aware that a carrier would favor its own services on its own Web site over other carriers' services.

Several airlines also support the proposal, including Frontier, JetBlue, and Spirit. Frontier states that it supports the display bias rule because if ticket agents bias they do so in favor of large legacy airlines that have greater bargaining power than smaller carriers and are able to pay for display bias, and that this creates an unfair disadvantage to smaller carriers and to consumers. Spirit comments that undisclosed bias distorts the air travel market and subjects consumers to unfair and misleading information when travel agents and consumers are not made aware that their search results are often tailored to favor certain carriers due to undisclosed contract arrangements or payments. Spirit states that if a carrier is not shown or incentives are provided to the ticket agent for more prominently displaying a particular carrier, disclosure is important to allow consumers and travel agents to make informed decisions. United does not support or oppose the proposal but states that the rule text does not clearly reflect the Department's intent as stated in the preamble of the NPRM regarding disclosure of biasing on corporate travel Web sites, *i.e.* that disclosure is only required to the extent the bias is not agreed to by contract regarding corporate travel. Lufthansa urges the Department to exclude from this proposed rule airline and airline-alliance Web sites, as well as direct connections between ticket agents and airlines' internal reservations systems. Lufthansa argues that ''consumers and ticket agents intuitively understand that an airline 'biases' its Web site and internal reservations systems to prioritize and promote its own services and those of its code-share and alliance partner airlines. Consumers and ticket agents instinctively know that they will not be able to access fares and schedules of other airlines that compete against or are not aligned with the airline whose Web site (and, in the case of ticket agents, internal reservations systems) they access.'' Further, according to Lufthansa, there is no need for DOT to implement and apply anti-biasing rules for corporate travel arrangements that are contractually entered into by sophisticated entities that are well aware that the fares and schedules offered through their business travel programs are limited to certain airlines and do not provide the full range of available fares and schedules offered by other airlines that do not participate in a particular program.

Delta also supports requiring disclosure of any bias in a ticket agent's display to the general public. However, Delta opposes regulations that would change existing business practices in the display algorithms used by agents, including GDSs, that do not bias based on carrier identity. Delta also opposes biasing restrictions on individual carrier Web sites. According to Delta, a customer shopping for tickets on delta.com ''knows and expects that Delta is marketing Delta flights in a manner advantageous to Delta over other carriers, but that otherwise best meets the customer's needs and search parameters.''

Several commenters, including ticket agents and ticket agent associations, oppose the proposed regulation prohibiting undisclosed display bias. American Express Global Business Travel states that there is no need for rules prohibiting undisclosed display bias because the guidance issued in 2011 is sufficient, and that if any prohibition is adopted it should not cover corporate travel. USTOA also opposes the proposed regulation, stating that the existing guidance is sufficient and new regulation is not necessary, and noting that the Department decided against such a regulation in the CRS rulemaking. BCD travel also opposes the regulation, stating that it is not needed and should not apply to corporate travel arrangements where display bias is included in contractual arrangements. Carlson Wagonlit Travel also opposes the proposed regulation, noting that displaying information in a particular order is one of the services travel agents offer, and it inherently involves bias, which may be beneficial, and should be permitted, particularly in corporate travel which involves preferred vendors and other similar corporate programs.

Travel Tech states that imposing such a disclosure requirement would ''micromanage airfare displays, constituting regulatory overkill that cannot be justified in the absence of any evidence of a significant problem warranting such market intrusion.'' Travel Tech states that the existing guidance is sufficient to adequately ensure transparency in the disclosure of carrier preferences in ticket agent displays, and it would not object to a simple rule applicable to any ticket agent that would require appropriate disclosure of the use of carrier identity as a ranking factor in ordering displays. Travel Tech identifies several specific concerns with the proposed rule text itself. Regarding ranking flights, the organization asserts that as drafted, the requirement to identify the lowest airfare including all mandatory fees but not including fees for optional services would not allow for sequential listings or ranking options by total cost including fees for optional services. As such, according to Travel Tech, significantly less desirable flights may be the first flights displayed, even if they involve circuitous routings, very long layovers, or two separate tickets which prevent checking through bags, or other drawbacks. Travel Tech's comments also indicate it is unclear how the rule would apply to queries for schedule and availability that don't seek fare information.

Regarding the ordering criteria for identifying flights, Travel Tech states that the same ordering criteria should not be required for all markets because different criteria may identify flights that meet consumer needs in different markets (*e.g.,* international, U.S. short haul, U.S. long haul). Regarding differentiating carriers, Travel Tech objects to the requirement to treat ''listed carriers'' that have no contractual relationship with the GDS or OTA creating the display the same as ''participating carriers'' that enter into a contract with a GDS or OTA. Travel Tech notes that a GDS or OTA may list schedules and fares (but not availability) of some carriers that are not participating carriers as a service to their users, even though the GDS or OTA does not sell the listed carriers'

services. Travel Tech also comments that the proposed rule text seems to create a violation in the event of an inadvertent but inevitable data error if a GDS or OTA does not include in its system all information provided by a carrier or inadvertently publishes inaccurate information, subjecting it to the risk of a penalty. In response to the question of whether any rule regarding display bias should be limited to airfare and routings, Travel Tech states that such limitation is appropriate.

Finally, Travel Tech argues that there is no basis for applying a prohibition on undisclosed display bias to corporate booking tools. Amadeus also opposes this provision, commenting that the undisclosed display bias prohibition is not needed. According to Amadeus, the guidance on this matter issued by the Department's Enforcement Office in 2011 is sufficient. Amadeus further states that if undisclosed bias is prohibited, the rule should follow the 2011 guidance instead of the elaborate proposed rule that creates excessive regulatory intrusion into the market. As an example, Amadeus states that if it followed the proposed rule, flights with excessive connections or layovers would be displayed but the vast majority of consumers would find them unreasonable or unattractive. Travelport also opposes the prohibition, stating that the Department has not proven the inadequacy of the existing Enforcement Office guidance. Travelport states that the Department should ''outline the problem to be solved by additional regulation and allow the industry to examine the evidence.''

Skyscanner argues that a display bias prohibition is not beneficial to consumers, because it is incorrect to assume that ''all consumers are interested in is price.'' To illustrate its point, Skyscanner compares flight search tools to other shopping search tools available on the internet that allow consumers to sort display results in a variety of ways. Skyscanner states that ''[s]ome display bias is essential for metasearch sites to ensure that served content is relevant to consumers.'' For example, Skyscanner points out that a consumer searching for a flight may be interested in criteria such as the travel duration, the number of transfers, the number of complaints against a carrier, whether the carrier can process a booking on the device being used by the consumer, and whether the route or carrier has been popular with other travelers. Skyscanner argues that metasearch algorithms are designed to provide the user with a high-quality snapshot of the products available, taking their chosen criteria into account. Skyscanner explains that bias describes the technical processes that allow consumers to benefit from combining a large data pool with their own preferences and notes that if price was consumers' only concern, metasearch entities would not spend time, money, and expertise developing what they find to be effective ways to provide search results. The Mercatus Center at George Mason University (Mercatus) also opposes the proposed requirement for similar reasons, stating that travel agencies compete by offering their best judgment to consumers but the proposed rule may limit travel agencies' ability to continue to provide such judgement. Mercatus concedes that consumers may be harmed if they believe a particular site provides unbiased information on all of the options that are available but states that ''most consumers shop several sites for airfare.''

Comments Regarding Disclosure of Incentives: Consumer advocacy groups Consumers Union and US PIRG favor disclosing incentive payments. Spirit Airlines also comments that disclosure of all companies providing incentives and a summary of the incentives should be required. However, many commenters oppose requiring disclosure of incentive payments. ASTA comments that any language at all regarding incentive payments would create a negative impression to consumers and would brand travel agents as untrustworthy. Travel Tech also opposes requiring disclosure of travel agency incentives received from airlines. Amadeus comments that a requirement to disclose incentive payments should not include GDS payments to ticket agents because the information is of no value to consumers and has little or no relationship to any biasing. BCD Travel acknowledges that it receives incentives and states it would be detrimental to industry to disclose specifics. Carlson Wagonlit Travel comments that disclosure of incentives would provide no clear benefit and would confuse and distract consumers. USTOA acknowledges that tour operators receive incentives that may influence the information they provide but states it would be detrimental to industry to disclose specifics and proposes that if there is any disclosure requirement, it should be general and not provide details of the incentives. Several smaller travel agencies also oppose the proposed requirement, arguing that a travel agent's first priority is its clients and that incentives always serve the interest of the clients by allowing an agent to provide cheaper service for a flight on a given airline, so to force disclosure of incentive payments would only serve to demonize what is otherwise a positive thing for consumers, agents, and airlines.

DOT Response on Undisclosed Biasing: After reviewing and carefully considering the comments, the Department has decided to prohibit certain undisclosed bias in electronic displays that include combinations of multiple carriers' schedules, fares, or availability information, if the display is marketed to U.S. consumers or to ticket agents that market to U.S. consumers. In response to comments regarding the alleged overly prescriptive nature of the proposed rule and potential unintended consequences of adopting the rule as proposed, the Department has revised the rule text to clarify that entities still have flexibility to provide the type of routings consumers are interested in when purchasing air transportation. The rule only applies to undisclosed display bias by ticket agents or carriers, not bias requested by the users of the system. For example, if a user filters for a particular carrier, schedule, or other criteria, and certain airlines do not provide any flight options that meet that criteria, and are consequently not displayed in search results, the Department does not consider that to be a bias that must be disclosed. Only biasing by ticket agents or carriers based on carrier identity must be disclosed—*i.e.,* a system presents flight options that favor or disfavor individual carriers.

As discussed in greater detail below, we have decided to prohibit any undisclosed display bias favoring particular carriers over others in search results because we agree with commenters noting that undisclosed bias distorts the air travel market and potentially harms consumers that are not aware of the biasing. This rule will apply not only to ticket agents' Web sites but also to airline and airline alliance Web sites. Our rule also applies to corporate booking tools as well as displays available to the general public, but is limited to undisclosed bias that is not based on contractual arrangements.

Undisclosed display bias prevents consumers and travel agents who advise consumers from realizing that they are not receiving neutral information on schedules and fares and recognizing that they may have to look elsewhere, or take additional steps on the Web site, to find more accurate or complete information. Undisclosed display bias in flight search results may mislead consumers who rely on that flight search tool for neutral, complete and correct information, and result in their not looking on different Web sites or not taking additional steps

on the Web site to find flight options that better meet their preferences. Undisclosed display bias by a GDS may mislead travel agents who rely on the information provided by GDSs, which in turn causes misleading information on available service options being passed on to a significant number of consumers who rely on their travel agents. Undisclosed display bias on an airline or airline alliance Web site may lead a consumer to book on that Web site when a flight on, for example, a code-share partner's Web site, may better suit the consumer's needs. For example, an airline might bias its displays to favor flights that it operates over flights operated by a code-share partner even though the flights operated by the code-share partner may have a lower price or schedule that better suits the consumer. When travel agents or consumers are unaware that information they thought was neutral is, in fact, biased, they may decide to book relatively inferior flights when other flights might better meet those travelers' needs, for example, in terms of price or scheduling.

In connection with biasing that results from business arrangements or business disputes, we recognize that commercial harm to airlines resulting from biasing may be a business matter but it also harms consumers if it is not disclosed. Further, to the extent undisclosed biasing is used to hinder competition in the distribution market, it potentially stifles innovation that would provide consumer benefits. Accordingly, the rule generally requires entities that operate systems displaying fare, schedule or availability information for multiple carriers to display the information for each carrier equitably with that of all other carriers marketed on that system. In the alternative, entities that wish to alter their displays to favor or disfavor any particular carrier are free to do so if the fact that a carrier is favored or disfavored is disclosed and there is no misrepresentation that the information is being displayed in a neutral manner.

To the extent a carrier or ticket agent operating an EAIS engages in display bias based on carrier identity, it must clearly and conspicuously disclose that fact. This applies to both ticket agents and carriers. For example, if a ticket agent favors or disfavors a particular carrier, that bias must be disclosed. Similarly, in connection with systems operated by carriers or carrier alliances, if carrier-identity is a factor in how flights are displayed, that must be disclosed. The notice about display bias may not be in an obscure location as that would not provide sufficient notice to avoid consumer harm. Accordingly, if there is carrier identity bias, we require that the notice appear prominently at the top of the first search result display presented to the user in response to the user-selected search criteria. The notice must specifically state that the order of flights is not neutral with respect to carrier identity.

Response to Display Issues Identified in the Comments: Some commenters identified rule text that appeared to impose requirements that would result in unintended consequences. For example, concerns were expressed that the proposed rule text would require an EAIS to display the lowest generally available airfare without allowing screening out of certain flight options based on unreasonably lengthy or circuitous routings or similar undesirable characteristics. Concerns were also expressed that the requirement to rank flights by the lowest airfare may not be the best ranking method for consumers as it may be more beneficial to rank by total cost which would include not only mandatory fees but also fees for optional services. We found these comments to be persuasive and have made changes to the final rule. This final rule does not contain a requirement for an EAIS to rank by the lowest generally available airfare, or any other specific parameter. Instead, it requires that each EAIS display information in an objective manner, based either on search criteria selected by the user (*e.g.,* lowest fare, lowest cost, date and time of travel, class of service, stopovers, total elapsed time or duration of travel, number of stops, limitations on carriers to be used, particular airport(s), number of passengers, etc.) or default criteria established by the carrier or agent.

Ranking Flight Options and Innovation in Displays: Regarding the ranking of flights, the rule requires systems to identify the flight options that meet the parameters set by the user of the system without ranking based on any undisclosed bias based on carrier identity. However, systems are not precluded from setting default display parameters that are not deceptive or offering users the option to choose a variety of display methods within those parameters. Just as systems already offer consumers many options, such as displaying only non-stop flights in search results, or ranking flights by cost, or elapsed time, or departure time, systems are not precluded from offering additional options for displaying search results. Similarly, as stated above, if a consumer specifies a particular carrier or carriers in search parameters, displaying responsive search results would not be considered undisclosed bias. Many commenters on the various proposals in this rulemaking have emphasized the importance of allowing innovation in the display of airfare and ancillary service fee information. We agree that innovation is beneficial to consumers and encourage systems to offer a variety of options for search result displays. Based on comments in this rulemaking and on public statements from a variety of industry participants, we understand that many airlines and ticket agents are already working on providing more options for consumers to choose in displaying search results. We anticipate in the future that systems will continue to add more sorting mechanisms that allow consumers to choose flight ranking options based on their specific need, for example, fare plus cost of specific ancillary services chosen by the consumer.

We agree with Skyscanner that consumers will benefit from innovations that allow different entities to improve and expand on how to respond to consumer searches and to display search results. We encourage such innovation and note that the requirement to disclose any biases that are built into the system does not preclude creativity in designing displays. For example, existing flight search tools are already providing various display formats and sorting mechanisms that allow consumers to choose how they want their flight options prioritized.

This is also relevant to Skyscanner's comment that consumers may be interested in a variety of factors when selecting a flight and that flight search tools offer a ''snapshot'' of options. We agree that consumers consider a variety of factors when searching for a flight and anticipate that flight search tools will continue to evolve, offering more and more information and ways to sort flight options. However, metasearch entities do not market flight search tools as offering a ''snapshot,'' they market themselves as a neutral source of as much flight information as is available on the internet. Consumers should know about the factors that may impact or limit what flight information is displayed and how it is displayed.

Ordering Criteria; Listed and Participating Carriers: Travel Tech's comments also state that the proposed rule text appears to require the same ordering criteria for identifying flights regardless of the market (*e.g.,* international, U.S. short haul, U.S. long haul). We agree that as long as the criteria are not based on carrier identity, different criteria may better identify

flights that meet consumers' specific needs depending on the market. Accordingly, we are not requiring that the same ordering criteria be used for every market. Rather, the search results should match the user-selected criteria and disclose any bias based on carrier identity. Regarding differentiating carriers, Travel Tech objects to the requirement to treat ''listed carriers'' (carriers that have no contractual relationship with the GDS or OTA) the same as ''participating carriers'' (carriers that enter into a contract with a GDS or OTA). Travel Tech suggests that if an OTA or GDS chooses to provide a ''listed'' carrier's fare and schedule information then there should be no requirement to display that carrier's flight information equitably with the information of participating carriers. We agree that there is no requirement to display a non-participating carrier's flight information. However, if an agent chooses to display a non-participating carrier's flight information, then it must display it equitably or disclose that the information is not being displayed equitably because otherwise consumers could be misled or deceived into thinking that the information is being displayed in a neutral manner. Travel Tech also noted that in many cases the OTA or GDS does not have availability information for carriers that are only listed and not participating. To the extent ticket agents provide fare and schedule information without availability information, this rule requires that, absent disclosure about bias, the information must be provided in a manner that does not favor or disfavor a particular carrier. Finally, Travel Tech commented that ''[i]f adopted as proposed, the rule could encourage GDSs and OTAs to simply remove all information about non-participating carriers from their systems, another perverse result that would clearly not benefit consumers.'' It is our understanding that GDSs and OTAs make a business decision to provide consumers with non-participating carrier flight information even though those carriers do not provide all fare, schedule, and availability information and do not pay the same fees to GDSs or OTAs as participating carriers. To the extent that entities such as those represented by Travel Tech determine that they have a greater interest in not providing non-participating carriers' information rather than disclosing it in an unbiased manner or disclosing that the information is not provided in an unbiased manner, that is a business decision that must be made by each entity. However, we are not persuaded that this is sufficient reason to allow a GDS or OTA to bias displays in a manner that ranks differently those carriers that do not ''participate,'' or pay fees to the GDS or OTA, without disclosing that information to consumers.

Biasing Based on Carrier-Identity on Airline and Airline Alliance Web sites: Regarding airline and airline alliance Web sites' displays that incorporate the flights of more than one carrier, we also believe consumers are entitled to be informed of any biasing that occurs in those displays. We note that most, if not all, alliance and carrier Web sites that display flight options for alliance or code-share flights already provide information regarding the carriers that are marketed on the Web site. The additional disclosure that would be necessary would be a statement regarding the manner in which the display favors or disfavors particular carriers. For example, if an alliance Web site marketed to U.S. consumers biases its displays to favor carriers that operate flights to and from the United States over carriers that only market flights to and from the United States that are operated by another carrier under the code of the marketing carrier, then that fact should be disclosed to consumers.

Corporate Booking Tools: We disagree with the comments that there is no basis for applying a prohibition on undisclosed display bias to corporate booking tools. To the extent that bias is built into corporate booking tool displays pursuant to a contractual agreement that makes clear the parameters of the displays, we would not consider such bias to be biasing that must be disclosed to users of the system and agree that there is no need to disclose that information on every display of search results. However, if changes to a corporate booking tool display were made by the operator of the system so that flight options were biased based on carrier identity, we would consider that to be a violation of the rule and an unfair or deceptive practice unless the bias based on carrier identity was disclosed as required by the rule. For example, if an entity operates a corporate booking tool under a contract with a corporation, and the entity operating the tool is having a business dispute with a particular carrier, that entity may not remove the carrier's flights from search results or place them in a less favorable location in the search results, independent of any contractual terms to favor or disfavor particular carriers in that particular corporate booking tool, without providing disclosure to the users of the booking tool in the manner required by this rule. Business entities benefit from the requirement for biases to be disclosed as they may have policies that require selection of best available fare, or other financial, recordkeeping, or auditing requirements. Further, a business entity that does not have contracts providing benefits or discounts on a particular carrier may still rely on corporate management tools to book business travel as well as to integrate cost and booking data for its travel into its own systems. Those entities are also entitled to be informed if the flight options being displayed reflect bias based on carrier-identity.

Incentives: We have decided not to require the disclosure of information regarding incentives. We have determined that the prohibition on undisclosed biasing is sufficient to protect consumers without mandating the disclosure of specific information about incentive payments. Regardless of the reasons for the biasing, whether due to undisclosed contract arrangements, commercial disputes, or financial incentives, consumers should be made aware when a display is not neutral with respect to carrier identity. Being informed that carrier identity is a factor in the display of flight options, regardless of underlying reason, likely would be useful to consumers. However, we do not see a benefit to requiring disclosure of incentives such as specific commercial arrangements or dollar amounts when there are a variety of other reasons, in addition to incentive payments, that may lead an entity to bias its display. We believe providing information on incentives might result in consumer confusion regarding the significance of the information and not necessarily provide information that would be helpful in making decisions about air travel purchases. We also agree with commenters that it would be difficult to define how and what types of incentives should be disclosed. Further, we acknowledge that disclosure may touch on sensitive commercial information. As such, this final rule does not require the disclosure of incentive payments but simply prohibits undisclosed biasing based on carrier identify.

(6) Amendments/Corrections to Second Enhancing Airline Passenger Protections Rule and Certain Other Provisions

a. Standard Applicable to Reportable Tarmac Delays Under Part 244

In 14 CFR part 244, the Department requires U.S. and foreign air carriers to file Form 244 ''Tarmac Delay Report'' with the Department with respect to any

covered flight that experienced a lengthy departure or arrival delay on the tarmac at a large, medium, small, or non-hub U.S. airport. A ''lengthy'' tarmac delay for purposes of this report is defined in part 244 as any tarmac delay that lasts ''three hours or more.'' This standard is inconsistent with the standard applicable to the tarmac delay contingency plan requirements under 14 CFR part 259 and the existing reporting requirements of BTS, both of which refer to any tarmac delay of ''more than three hours.'' In a Frequently Asked Questions document issued by the Department following the issuance of the final rule for part 244, we acknowledged this discrepancy and stated that we intend to correct it in a future rulemaking. In the NPRM for the instant proceeding, we proposed to amend the rule text of part 244 and to adopt the ''more than three hours'' standard so this part would be consistent with other parts of our rules. Under this action, any tarmac delay that lasts exactly three hours would not be covered under the requirements of part 244. We received no comments on this proposal and are adopting it as proposed.

b. Civil Penalty for Tarmac Delay Violations

In the NPRM, we proposed to amend the tarmac delay rule to clarify that the Department may impose penalties for tarmac delay violations on a per-passenger basis. We received numerous comments opposing this proposal, primarily from carriers and carrier associations stating that the Department lacks statutory authority to impose such a civil penalty on a per-passenger basis.

Since the tarmac delay rule became effective in 2011, the Department's Enforcement Office has maintained that even if all of the violations took place on a single flight, it is not limited to a single civil penalty per flight for tarmac delay violations. It has consistently exercised its discretion and assessed civil penalties for tarmac delay violations on a per-passenger basis, through consent orders that have become actions of the Department. The Enforcement Office has taken the position that the Department has the authority to assess a civil penalty on a per-passenger basis, based on 49 U.S.C. 41712, which prohibits unfair or deceptive practices, and 49 U.S.C. 42301, which requires that carriers adhere to their tarmac delay contingency plans.

Nonetheless, the Department has decided not to amend the tarmac delay rule as we had proposed on this particular issue. Instead, the Enforcement Office will continue to exercise its discretion to enforce the tarmac delay rule as appropriate, on a case-by-case basis.

c. Required Oral Disclosure of Material Restrictions on Travel Vouchers Offered to Potential Volunteers in Oversale Situations Under Part 250

The second Enhancing Airline Passenger Protections rule amended the Department's Oversales rule (14 CFR part 250) in a number of ways. One of the issues was requiring oral disclosure of any material restrictions on travel vouchers offered to both voluntarily and involuntarily bumped passengers. The preamble discussed extensively the reasons for adopting this new provision. But inadvertently, the rule text in part 250 only requires oral disclosures to passengers who are involuntarily denied boarding. The rule text, as it currently stands, allows carriers to provide such disclosure solely by written notice to passengers who are orally solicited to be volunteers in exchange for travel vouchers. We proposed in the NPRM to require carriers to provide oral notification of restrictions to these passengers who are solicited to volunteer.

Travelers United and National Consumers League submitted joint comments in support of this proposal but urge the Department to go further by requiring gate agents to verbally disclose to passengers who are involuntarily denied boarding that they are eligible to receive the maximum amounts of denied boarding compensation in cash for domestic and international flights. The commenters state that such disclosure would put consumers in an educated position when dealing with denied boarding situations. The commenters further state that basic consumer rights involving compensation should be explained in writing by airlines on ticket itineraries and computer generated boarding passes to include compensation for lost luggage, denied boarding and flight delays from Europe to the United States and within Europe.

Spirit Airlines opposes the Department's proposal to require gate attendants to provide a verbal explanation of the terms of vouchers given to volunteers in an overbooking situation. Spirit states that the Department lacks any demonstrable evidence that consumers are harmed by receiving only written disclosures. Spirit states that it would first ask the passengers being solicited to volunteer to read the terms of the vouchers and check a box to state that they agree to the terms and conditions. Spirit asserts that it is completely impractical to require a gate agent to give a private presentation of the material restriction applicable to the travel voucher to each potential volunteer.

The Department continues to believe that oral notification of material restrictions of vouchers is necessary especially when passengers being solicited to volunteer their seats are constrained by time pressure to make a quick decision as to whether to volunteer. We further believe that the written notice that is often embedded in the printed contents of the travel voucher is hard for passenger to review and comprehend in a short time before he or she commits to the acceptance of the voucher. By adopting this requirement, we note that a brief oral summary of the material restrictions applicable to the travel vouchers delivered through the gate PA system following the announcement of a request for volunteers would not place an unreasonable burden on carriers and would benefit consumers by offering them a clear and precise summary description of what they are receiving in exchange for giving up their seats. Such verbal disclosure is not required to be provided individually to each potential volunteer. We expect such disclosure would reduce the likelihood of consumer confusion that in turn would reduce complaints filed with carriers and the cost associated with carriers' handling of these complaints. With respect to the suggestion of Travelers United and National Consumers League to require verbal disclosure of maximum denied boarding compensation amounts to passengers denied boarding involuntarily, and the suggestions to include compensation amounts on boarding passes, we decline to address these proposals in this final rule because they are beyond the scope of our Notice of Proposed Rulemaking.

d. Limitation of Flight Status Notification Requirement of 14 CFR 259.8

Guidance in the *Frequently Asked Questions* that accompanied the second Enhancing Airline Passenger Protections final rule limits the flight status notification requirement in 14 CFR 259.8 to any qualified flight status changes that occur within seven calendar days prior to the scheduled date of the operation. In the NPRM for the instant proceeding, we proposed to codify this standard in the rule. We received no comments on this proposal. We adopt the ''seven-calendar-day'' timeframe in this final rule as we recognize that the closer to the date of the scheduled operations, the more

important it is for carriers to provide notice of a flight status change promptly. Limiting the flights for which carriers are required to comply with section 259.8 according their departure timeframe will also reduce carriers' burdens and ensure that their primary focus is on those flights where the status change would have the most significant impact on consumers. We emphasize, however, that notifications of changes that occur earlier than the seven-day threshold are still required to be delivered to the passengers ''in a timely manner'' by the carriers as provided by 14 CFR 259.5(b)(10).

We are also adopting some proposed editorial changes to section 259.8 to clarify that flight status change notifications required in this section should be provided not only to passengers, but also to any member of the public who may be affected by the changes and who subscribes or attempts to subscribe to a flight status notification system, including persons meeting passengers at airports or escorting them to or from airports. In this regard, we are changing the word ''passengers'' to ''consumers'' in the title of section 259.8, changing the first instance of the word ''passengers'' in subsection 259.8(a)(1) to the phrase ''passengers and other interested persons,'' and changing the second instance of that word to ''subscribers.''

e. Removing the Rebating Provision in Section 399.80(h)

14 CFR 399.80(h) of DOT's Statements of General Policy states that it is an unfair or deceptive practice or unfair method of competition for a ticket agent to advertise or sell air transportation at less than the rates specified in the tariff of the air carrier, or offer rebates or concessions, or permit persons to obtain air transportation at less than the lawful fares and rates. In the NPRM for this proceeding, we proposed to remove this provision. It is a vestige of the period before deregulation of the airline industry. Domestic air fares were deregulated effective 1983, and in most cases international air fares to and from the United States are no longer included in tariffs that specify ''lawful'' fares. In those markets where international fares are still subject to regulation, carriers that do not comply with their tariff are potentially subject to enforcement action under 49 U.S.C. 41510 concerning adherence to tariffs or 49 U.S.C. 41712 concerning unfair or deceptive practices and unfair methods of competition (the statutory basis for section 399.80(h)). The Department's Enforcement Office has said that it will pursue enforcement action against a carrier that does not comply with its tariff when there is clear evidence of a pattern of direct fraud against consumers or deception, invidious discrimination, or violations of the antitrust laws. It has been the longstanding policy of that office to decline to prosecute instances of noncompliance with tariff obligations that result in benefits to consumers absent clear evidence of such fraud, deception, discrimination or antitrust violations. (See the Frequently Asked Questions for ''Rule #2'' of the Enhancing Airline Passenger Protections regulation, *www.transportation.gov/individuals/air-consumer/aviation-rules,* section X, question 38a, footnote 1.) There have been no enforcement actions solely for tariff compliance for over 20 years, and should such action become appropriate in the future, it can proceed under the authority of sections 41510 or 41712.

The American Society of Travel Agents supported the proposal to remove this provision. There were no other comments on this issue. As indicated above, 14 CFR 399.80(h) is not necessary and consequently we are removing this provision.

f. Removing Part 255 Pursuant to Its Sunset Provision

We are removing the rule text of 14 CFR part 255 pursuant to section 255.8 that provides that part 255 shall terminate on July 31, 2004, unless extended by a document published in the **Federal Register**. We are replacing the text of part 255 with ''Reserved.''

Regulatory Analyses and Notices

A. Executive Order 12866 (Regulatory Planning and Review) and DOT Regulatory Policies and Procedures

This action has been determined to be significant under Executive Order 12866 and the Department of Transportation's Regulatory Policies and Procedures. It has been reviewed by the Office of Management and Budget under that Executive Order and Executive Order 13563. This section contains a summary of costs and benefits associated with this final rule. More detail on the economic impact of this final rule can be found in the Regulatory Impact Analysis (RIA), which is available in the docket.

The RIA provides information on the benefits and costs associated with the Final Rule. The rule is not economically significant, as the costs which were able to be quantified, which relate only to the requirements that expand the definition of ''reporting carrier'' and the reporting requirements for reporting carriers, totaled $7.74 over a ten-year period, or an annualized cost of $0.96 million, when discounted using a seven percent rate. Any potential additional costs which could not be quantified are expected to be minimal. The benefits could not be quantified and monetized with reasonable accuracy for the Rule and thus, were evaluated qualitatively.

Provision 1: Expand ''Reporting Carrier'' Pool and Provision 2: Expand Reporting Requirements for Reporting Carriers

Provision 1 expands the ''reporting carrier'' threshold to include more carriers by lowering the threshold for ''reporting carrier'' to 0.50 percent of domestic scheduled passenger revenues. Provision 2 expands the information that each reporting carrier is required to submit to USDOT to include an additional set of performance data for the carrier's domestic code-share flight segments operated by a partner.

Reporting carriers are required to submit the following flight performance data regularly:

- BTS Form 234 ''On-Time Performance Report'' on a *monthly* basis;
- Report baggage mishandling, statistics *monthly;*
- BTS Form 251 regarding denied boarding/oversales on a *quarterly* basis; and
- Lengthy tarmac delays and incidents relating to transport of animals, when/if they occur.

In addition, reporting carriers are currently required to post on-time performance data on their Web sites for each flight they operate and for each flight their U.S. code-share partners operate.

Provisions 1 and 2 will lead to additional performance data reported to the BTS, and in turn made available to consumers through publication in the Air Travel Consumer Report. In addition, new reporting carriers that market directly to consumers will now post on-time performance data on their Web sites for each flight they operate and for each flight its U.S. code-share partners operate. Several larger regional carriers and some of the smaller national carriers will provide a great deal of information regarding their performance to BTS. The public will now be able to compare the performance of these newly reporting carriers across a range of critical performance indicators (*e.g.* on-time performance, rate of mishandled baggage, etc.).

The costs to carriers are calculated by multiplying the number of impacted carriers by the one-time programming cost to collect and report data and on-going costs to process and report data to

the Department. Additional costs associated with training for data gathering and for carriers to report performance data of code-share partners were identified but not quantified or monetized, but are not expected to be very significant.

TABLE 1—ESTIMATED COSTS FOR PROVISION 1 AND 2

	2017 (first year—set-up costs)	2018 (second year—ongoing costs)	2017–2026 (ten years)
Reporting Threshold 0.50%			
Reporting Carriers to Provide Data for Code-Share Flights			
Number of newly reporting carriers who market flights	1		
One-time set-up cost per carrier to post flight delay information to consumers, $/carrier	$441,914		
Total one-time set-up costs for newly reporting carriers who market flights to post on-time performance information to consumers, $_____	$441,914		$441,914
One-time set-up cost per carrier to be able to collect/report performance data for USDOT, $/carrier	$106,173		
Number of newly reporting carriers	7		
Total one-time set-up costs for all newly reporting carriers to collect/report performance data to USDOT, $_____	$743,213		$743,213
Per carrier one-time set-up costs for newly reporting carriers and code-share partners to set up system for revised reporting mishandled baggage rates	$8,000		
Number of newly reporting carriers	7		
Number of code share partnerings, for newly reporting carriers only and their domestic code-share segments	8		
Total one-time set-up costs for newly reporting carriers and code-share partners to set up system for revised reporting mishandled baggage rates	$120,000		$120,000
One-time setup cost to create a link between reporting carriers and code-share partners to share code-share performance data	$106,173		
Total links established between reporting carriers and code-share partners	17		
Total one-time set-up costs for reporting carriers and code-share partners to establish links to transmit data, $_____	$1,804,947		$1,804,947
Hours per carrier for filling performance data Form 234 (on-time performance), Hrs/carrier		240	
Hours per carrier for filling performance data Form 251 (denied boarding/oversales), Hrs/carrier		16	
Hourly labor costs of reporting, $/Hr		$94.57	
Total ongoing labor costs for newly reporting carriers to collect and report data on their own flights, $_____		$169,464	$1,600,470
Number of current or newly reporting carriers who have at least one code-share partner		9	
Additional hours per reporting carrier to report performance data if filing separate reports for code-share partners and main carriers, Hrs/carrier		384	
Total ongoing labor costs for reporting carriers to collect and report data on their code-share flights, $_____		$544,70	$5,144,368
Annual cost of Report Preparation for mishandled baggage		$2,969	
Number of newly reporting carriers		7	
Total costs for newly reporting carriers to prepare annual reports for mishandled baggage		$20,783	$187,047
Number of passengers on newly reporting carriers (0.5%)		64,122,957	
Passengers of newly reporting carriers with checked wheelchairs and scooters,		705,353	
additional cost per item/passenger for the airlines to enter data re wheelchairs and scooters		$0.036	
Total ongoing data entry costs for newly reporting carriers to enter data re wheelchairs and scooters		$25,393	$251,795
Total Component Costs (millions): Undiscounted costs	$3.11	$0.76	$10.29
Discounted costs (7%)	$2.91	$0.66	$7.74

*The hourly labor cost for reporting is an average of hourly rates presented in *Enhancing Airline Passenger Protections Final Rule* of April 25, 2011 RIA and 2003 hourly rates for this specific technical work provided by a reporting carrier which shared this confidential data under agreement that they would not be named publically. The hourly labor cost for reporting includes benefits and supervisory review time. It is adjusted in years going forward by 1.6 percent annually during the study period. Refer to the RIA for detailed information.

Provision 3: Disclosure of Code-Share Segments in Schedules, Advertisements and Communications With Consumers

This provision of the Rule clarifies the Department's code-share disclosure regulation to ensure that carriers and ticket agents disclose any code-share arrangements in schedules, advertisements and communications with consumers. It amends the Department's code-share disclosure regulation to codify the statutory requirement that carriers and ticket agents must disclose any code-share arrangements on their Web sites, including mobile Web sites and applications; clarifies the format in which that information must be displayed; and adds a requirement that verbal codeshare disclosures be made the first time a flight involving a code-share arrangement is offered to consumers or inquired about by consumers during telephone or in person conversations. The provision is very similar to that presented in the NPRM, on which the public provided comments.

Much of the substance of Provision 3 is already in effect, as existing statute (49 U.S.C. 41712(c)) already requires that carriers and ticket agents disclose their code-shared segments, and therefore all carriers and ticket agencies should already be complying with most of this requirement. The aspect of this provision which is new is the specification of *when* during the booking process a carrier or ticket agent must disclose the code-share information. The existing rule requires airlines and ticket agents to disclose code-share information to the consumer ''before booking transportation'' which the Department has explained means at any point during the information-gathering and decision-making process; the new rule's provision stipulates that the disclosure must be made at the first time a flight involving a code-share arrangement is mentioned or offered to consumers. Benefits from this provision will arise from the requirement that verbal code-share disclosures should be made the first time a flight involving a code-share arrangement is mentioned or offered to consumers and will include some time savings for a small number of consumers during ticket reservations and purchase. Since this provision mostly codifies and clarifies existing statute, there are few costs associated with it. Some costs will arise, though, as some carriers may have longer reservation calls and increased training costs. The most notable additional costs would be borne by those carriers and ticket agents that currently do not present code-share information at the first mention of a flight during a reservation call or in-person booking. These carriers and ticket agents may have slightly longer reservation calls and longer in-person bookings.

Provision 4: Prohibition on Undisclosed Biasing Based on Carrier Identity

The Department is aware of instances in which GDSs and large OTAs have manipulated flight search results and provided biased or filtered flight and fare information that disfavored the flights of the airline that was the target of the biasing. These incidents occurred in the course of business disputes when certain GDSs and OTAs influenced and threatened to influence itinerary search results to disfavor particular carriers' flights or not display certain flights in search results. The display bias was not disclosed to consumers or ticket agents that market to consumers. Thus, the fifth provision of the rule prohibits undisclosed biasing by carriers and ticket agents in any online displays of the fare, schedule or availability information of multiple carriers. This provision applies to online travel agencies, corporate booking tools, and carrier and carrier alliance Web sites and is substantially the same as presented in the NPRM.

Undisclosed bias in the display of flight search results can distort the air travel market and potentially harm consumers that are not aware of the biasing. If consumers assume that search results contain no bias and that flights are ranked by lowest fare (or other factors which they can select) they may not fully examine all the results, potentially missing some flights which are either cheaper or a better match for their criteria but are ranked lower. Ensuring that online ticket agents disclose whether they use criteria besides those chosen by the consumer for presenting search results will alert consumers to any potential bias. It would still be the consumers' responsibility to review the results carefully, but there will be greater transparency in the search results, decreasing chances of a misinformed consumer.

Additional costs to carriers and travel agents of this provision should be minimal. The only additional costs of instituting this provision would be small programming costs to add a disclosure specifying what factors or biases, if any, beyond price and those which can be specified by the consumer are used to display search results. Since these disclosures should be relatively simple statements and are not expected to change frequently, these per entity programming costs should be small. Additionally, these costs would not be incurred by all carriers and ticket agents, only by those which use biases or other non-consumer specified factors when organizing flight search results.

Alternatives Considered

The Department considered multiple alternatives to individual provisions of this Final Rule. Costs could only be quantitatively estimated for one of these alternatives—that of lowering the reporting threshold from 1.0 percent of domestic passenger revenue to 0.25 percent, instead of to 0.5 percent as adopted in the final rule. Costs under this alternative increased from $7.74 million over ten years to $9.44 million (both discounted at 7 percent); or higher annualized costs of $1.18 million versus $0.96 million.

B. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires an agency to review regulations to assess their impact on small entities unless the agency determines that a rule is not expected to have a significant economic impact on a substantial number of small entities. This rule will impact a substantial number of small entities, but the economic impact will not be significant.

The provisions of this rule are:

1. Expand the pool of carriers that report on-time performance, mishandled baggage, and oversales data to the Department (often called ''reporting carriers'') from carriers which account for at least 1.0 percent of domestic scheduled passenger revenues (as currently required) to those carriers which account for at least 0.5 percent of domestic scheduled passenger revenues;

2. Expand reporting requirements for covered carriers that market code-share flights to include an additional set of reports for the on-time performance, mishandled baggage, and oversales data of their domestic code-share flights operated by partners;

3. Ensure the disclosure of code-share arrangements in all marketing carriers' schedules, advertisements and communications with consumers; and

4. Prohibit undisclosed display bias by airlines and ticket agents.

This Rule will impact small carriers and small ticket agents that market air transportation. For purposes of rules promulgated by the Office of the Secretary of Transportation regarding aviation economic and consumer matters, an airline is a small entity for purposes of the Regulatory Flexibility Act if it provides air transportation only with aircraft having 60 or fewer seats and no more than 18,000 pounds

payload capacity. The Small Business Administration (SBA) size standard for small business for both travel agents and tour operators is $20.5 million in average annual receipts (SBA does not have a size standard for ticket agents as defined by the Department; travel agents and tour operators are most applicable categories which such data was found).

The Department determined that this final rule is not likely to have a significant economic impact, although it will impact a substantial number of small entities. Provisions 1 and 2 of the Rule will only affect one small carrier; the Department estimated that this carrier would experience a cost of $326,520 in the first year and $491,612 over a 10-year period (discounted at a 7 percent discount rate). A substantial number of small travel agencies and tour operators will be directly impacted by this Rule. However, the Department estimates that the costs of compliance will be minimal for each individual travel agency and/or tour operator.

Since the Department could not estimate all of the costs to small entities of this rule, it prepared a FRFA. The Department considered multiple alternatives to individual provisions of this Final Rule. Costs could only be quantitatively estimated for one of the alternatives to Provision 1—that of lowering the reporting threshold from 1.0 percent of domestic passenger revenue to 0.25 percent, instead of to 0.5 percent as adopted in the final rule.

C. Executive Order 13132 (Federalism)

This final rule has been analyzed in accordance with the principles and criteria contained in Executive Order 13132 (''Federalism''). The rule does not contain any provision that (1) has substantial direct effects on the States, the relationship between the national government and the States, or the distribution of power and responsibilities among the various levels of government; (2) imposes substantial direct compliance costs on State and local governments; or (3) preempts State law. States are already preempted from regulating in this area by the Airline Deregulation Act, 49 U.S.C. 41713. Therefore, the consultation and funding requirements of Executive Order 13132 do not apply.

D. Executive Order 13084

This final rule has been analyzed in accordance with the principles and criteria contained in Executive Order 13084 (''Consultation and Coordination with Indian Tribal Governments''). Because none of the provisions in the final rule significantly or uniquely affect the communities of the Indian tribal governments or impose substantial direct compliance costs on them, the funding and consultation requirements of Executive Order 13084 do not apply.

E. Paperwork Reduction Act

As required by the Paperwork Reduction Act of 1995, the Department has submitted the Information Collection Request (ICR) abstracted below to the Office of Management and Budget (OMB). Before OMB decides whether to approve those proposed collections of information that are part of this final rule and issue a control number, the public must be provided 30 days to comment. Organizations and individuals desiring to submit comments on the information collection requirements should direct them to the Office of Management and Budget, Attention: Desk Officer for the Office of the Secretary of Transportation, Office of Information and Regulatory Affairs, Washington, DC 20503, and should also send a copy of their comments to: Department of Transportation, Office of Aviation Enforcement and Proceedings, Office of the General Counsel, 1200 New Jersey Avenue SE., Washington, DC 20590. OMB is required to make a decision concerning the collection of information requirements contained in this rule between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment to OMB is best assured of having its full effect if OMB receives it within 30 days of publication.

We will respond to any OMB or public comments on the information collection requirements contained in this rule. The Department may not impose a penalty on persons for violating information collection requirements which do not display a current OMB control number, if required. The Department intends to renew the OMB control number for the information collection requirements resulting from this rulemaking action. The OMB control number, when renewed, will be announced by separate notice in the **Federal Register**.

The ICR was previously published in the **Federal Register** as part of the NPRM. *See* 79 FR 29995. The Department invited interested persons to submit comments on any aspect of each of these two information collections: The first collection of information is a requirement that more carriers report on-time performance, mishandled baggage, and oversales data to the Department (*i.e.,* expansion of reporting carriers from any U.S. airline that accounts for at least one percent of annual domestic scheduled passenger revenue to any U.S. airline that accounts for at least 0.5 percent of annual domestic scheduled-passenger revenues). The second information collection is a requirement that mainline carriers provide enhanced reporting for flights operated by their domestic code-share partners including requiring reporting carriers to separately report on-time performance, mishandled baggage, and oversales data for all domestic scheduled passenger flights marketed by the reporting carriers but operated by domestic code-share partners.

The final rule modifies the information collection titled ''Reporting on-time performance/Reporting baggage-handling'' (OMB No. 2138–0041), the information collection titled ''Reporting oversales'' (OMB No. 2138–0018), and the information collection titled ''Posting on-time performance data on carrier's Web site'' (OMB No. 2105–0561). The first collection of information contained in the final rule is a requirement that U.S. carriers that account for at least 0.5 percent but less than one percent of the domestic scheduled passenger revenue to report to the Department the on-time performance, mishandled baggage, and oversales information for the flights they operate. As discussed above, this requirement expands the reporting requirement from one percent of domestic scheduled passenger revenue to 0.5 percent, and therefore expanding the number of reporting carriers from 12 to 19 carriers, an increase of 7 carriers. The second collection of information requires reporting carriers that market codeshare flights operated by another carrier to file separate reports for on-time performance, mishandled baggage, and oversales for those flights. Seven of the 19 reporting carriers will be subject to this requirement. The third information collection is a requirement that U.S. carriers that account for at least 0.5 percent but less than one percent of the domestic scheduled passenger revenue to post on-time performance records on its Web site, if the carrier has a Web site marketing flights to the consumers. One carrier will be subject to this requirement because of this final rule.

First Information Collection

Title: Reports by Carriers on On-time Performance and Mishandled Baggage Data for Flights Operated by Themselves and for Code-share Flights Operated by Another Carrier.

OMB Control Number: 2138–0041.

Type of Request: Modification of Information Collection Request.

Respondents: U.S. carriers operate scheduled passenger service that

account for at least 0.5 percent and less than 1.0 percent of domestic scheduled passenger revenue will be required to report on-time performance and mishandled baggage data for flights that they operate. U.S. carriers operate scheduled passenger service and account for at least 0.5 percent of total domestic scheduled passenger service revenue that market code-share flights only carrying the carrier's code will be required to report separately on-time performance and mishandled baggage data for these code-share flights.

Frequency: For each respondent, one information set each month for on-time performance for flights they operate and one information set each month for mishandled baggage for flights they operate; for each respondent that market code-share flight, one information set each month for on-time performance for code-share flights they market and one information set for mishandled baggage for code-share flights they market.

Estimated Annual Burden on Respondents: Estimated Initial Set-up Cost in the First Year: The 7 non-marketing newly reporting carriers will incur an initial cost of 1,123 hours per carrier for setting up the reporting systems needed to collect data needed for on-time performance reporting and oversales (this figure is calculated from the estimated one-time cost of $106,173 per carrier to be able to collect/report performance data for USDOT and divided by an hourly labor cost of $94.57, derived from which was derived from hourly labor cost estimates from a reporting carrier and research conducted for the Regulatory Evaluation in support of Consumer Rulemaking: Enhancing Airline Passenger Protections II]). The total for all newly reporting carriers will be 7,859 hours. Using an hourly labor rate of $94.57 (derived from which was derived from hourly labor cost estimates from a reporting carrier and research conducted for the Regulatory Evaluation in support of Consumer Rulemaking: Enhancing Airline Passenger Protections II), the 7,859 hours will translate into a total of $743,213.

All reporting carriers which have code-share partnerships will have set-up costs associated with establishing links to their partners for the necessary data reporting. The costs are estimated to be approximately $106,173 per link, and there will be 17 such links among all the reporting carriers. The total cost will be $1,804,947, or approximately 19,086 for all 15 reporting carriers with code-share partners.

An additional $120,000 set-up costs for previously reporting carriers to create links to their code-share partners for mishandled baggage data, and for the seven newly reporting carriers to submit for mishandled baggage data to USDOT will total $120,000 in the first year, or approximately 1,269 hours. Thus, the total hour burden for this all carriers will total 28,215 hours, or $ $2,668,160 for first year set up costs.

Annual on-going burden will total 5,624 hours per year, which includes 240 hours per carrier for the 7 newly marketing carriers to complete form 234 for their own operated flights, an estimated 488 per carrier in ongoing data entry costs for newly reporting carriers to enter data regarding wheelchairs and scooters; and a total of 3,456 for all carriers with code-share partners (varies by carrier based on number of code-share) for reporting on-time performance and mishandled baggage data, which is filed monthly. Using an hourly labor rate of $94.57 (derived from which was derived from hourly labor cost estimates from a reporting carrier and research conducted for the Regulatory Evaluation in support of Consumer Rulemaking: Enhancing Airline Passenger Protections II), the 5,624 will translate into a total of $531,871 first year set-up costs.

Second Information Collection

Title: Reports by Carriers on Oversales Data for Flights Operated by Themselves and for Code-share Flights Operated by Another Carrier.

OMB Control Number: 2138–0018.

Type of Request: Modification of Information Collection Request.

Respondents: U.S. carriers operate scheduled passenger service that account for at least 0.5 percent and less than 1.0 percent of domestic scheduled passenger revenue will be required to report oversales data for flights that they operate. U.S. carriers operate scheduled passenger service and account for at least 0.5 percent of total domestic scheduled passenger service revenue that market code-share flights only carrying the carrier's code will be required to report separately oversales data for these code-share flights.

Frequency: For each respondent, one information set each quarter for oversales for flights they operate; for each respondent that market code-share flight, one information set each quarter for oversales for code-share flights they market.

Estimated Annual Burden on Respondents: The set-up costs for newly reporting carriers to put into place systems for reporting oversales data are included in the set-up costs for reporting performance data, since they are no separate systems. The annual on-going burden will be approximately 16 hours per carrier per year, or 592 hours for all 8 carriers, to report oversales data, which is filed quarterly. The 592 hours translates into $56,000 per years when using an hourly labor cost of $94.57 (see above).

Third Information Collection

Title: Posting on-time performance data on carriers' Web sites.

OMB Control Number: 2105–0561.

Type of Request: Modification of Information Collection Request.

Respondents: U.S. carriers operate scheduled passenger service that account for at least 0.5 percent and less than 1.0 percent of domestic scheduled passenger revenue and marketing flight directly to consumers via a Web site will be required to post on-time performance records for the flights it markets on its Web site.

Frequency: For each respondent, updating on-time performance records once a month on its Web site.

Estimated Annual Burden on Respondents: The 1 newly reporting carrier which markets to consumers will incur approximately 4,673 hours to set up the Web site to post online the on-time performance records for flights marketed on their Web sites. (The estimate of 4,673 is calculated from the estimated one-time cost of posting delay information online of $400,000 in 2009, from U.S. DOT Final RIA Enhanced Airline Passenger Protections [*http://www.dot.gov/sites/dot.gov/files/docs/Final_Rule_on_Enhancing_Airline_Passenger_Protections.pdf* and brought forward to 2015 and divided by an hourly labor cost of $94.57, which was derived from hourly labor cost estimates from a reporting carrier and research conducted for the Regulatory Evaluation in support of Consumer Rulemaking: Enhancing Airline Passenger Protections II]). Ongoing costs for updating the Web site are assumed to be minimal once the systems are in place and the carrier is reporting its on-time performance to BTS as required elsewhere.

F. Unfunded Mandates Reform Act

The Department has determined that the requirements of Title II of the Unfunded Mandates Reform Act of 1995 do not apply to this final rule.

G. National Environmental Policy Act

The Department has analyzed the environmental impacts of this final rule pursuant to the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321 *et seq.*) and has determined that it is categorically excluded pursuant to DOT Order 5610.1C, Procedures for Considering Environmental Impacts (44 FR 56420, Oct. 1, 1979). Categorical

exclusions are actions identified in an agency's NEPA implementing procedures that do not normally have a significant impact on the environment and therefore do not require either an environmental assessment (EA) or environmental impact statement (EIS). *See* 40 CFR 1508.4. In analyzing the applicability of a categorical exclusion, the agency must also consider whether extraordinary circumstances are present that would warrant the preparation of an EA or EIS. *Id.* Paragraph 3.c.6.i of DOT Order 5610.1C categorically excludes ''[a]ctions relating to consumer protection, including regulations.'' The purpose of this rulemaking is to enhance protections for air travelers and to improve the air travel environment. The Department does not anticipate any environmental impacts, and there are no extraordinary circumstances present in connection with this rulemaking.

List of Subjects

14 CFR Part 234

Air carriers, Consumer protection, Reporting and recordkeeping requirements.

14 CFR Part 244

Air carriers, Consumer protection, Reporting and recordkeeping requirements.

14 CFR Part 250

Air carriers, Consumer protection, Reporting and recordkeeping requirements.

14 CFR Part 255

Air carriers, Antitrust.

14 CFR Part 256

Air carriers, Air rates and fares, Antitrust.

14 CFR Part 257

Air carriers, Air rates and fares, Consumer protection, Reporting and recordkeeping requirements.

14 CFR Part 259

Air carriers, Air rates and fares, Consumer protection.

14 CFR Part 399

Administrative practice and procedure, Air carriers, Air rates and fares, Air taxis, Consumer protection, Small businesses.

Issued this 18th day of October 2016, in Washington, DC.

Anthony R. Foxx,

Secretary of Transportation.

Accordingly, 14 CFR chapter II is amended as follows:

PART 234—[AMENDED]

■ 1. The authority citation for part 234 continues to read as follows:

Authority: 49 U.S.C. 329 and Sections 41708 and 41709.

■ 2. The definitions of ''reportable flight'' and ''reporting carrier'' in § 234.2 are revised to read as follows:

§ 234.2 Definitions.

* * * * *

Reportable flight. (1) Reportable flight for air transportation taking place before January 1, 2018 means any nonstop flight, including a mechanically delayed flight, to or from any airport within the contiguous 48 states that accounts for at least 1 percent of domestic scheduled-passenger enplanements in the previous calendar year, as reported to the Department pursuant to part 241 of this title. Qualifying airports will be specified periodically in accounting and reporting directives issued by the Office of Airline Information.

(2) Reportable flight for air transportation taking place on or after January 1, 2018 means any domestic nonstop scheduled passenger flight, including a mechanically delayed flight, held out to the public under the reporting carrier's code, to or from any U.S. large, medium, small, or non-hub airport as defined in 49 U.S.C. 47102. Qualifying airports will be specified periodically in accounting and reporting directives issued by the Office of Airline Information.

Reporting carrier. (1) Reporting carrier for air transportation taking place before January 1, 2018 means an air carrier certificated under 49 U.S.C. 41102 that accounted for at least 1 percent of domestic scheduled-passenger revenues in the most recently reported 12-month period as defined by the Department's Office of Airline Information, and as reported to the Department pursuant to part 241 of this title. Reporting carriers will be identified periodically in accounting and reporting directives issued by the Office of Airline Information.

(2) Reporting carrier for air transportation taking place on or after January 1, 2018 means an air carrier certificated under 49 U.S.C. 41102 that accounted for at least 0.5 percent of domestic scheduled-passenger revenues in the most recently reported 12-month period as defined by the Department's Office of Airline Information, and as reported to the Department pursuant to part 241 of this chapter. Reporting carriers will be identified periodically in accounting and reporting directives issued by the Office of Airline Information.

* * * * *

■ 3. Section 234.3 is revised to read as follows:

§ 234.3 Applicability.

For air transportation taking place before January 1, 2018, this part applies to reportable flights as defined in § 234.2 that are held out to the public by certificated air carriers that account for at least 1 percent of domestic scheduled passenger revenues. As stated in § 234.7, certain provisions also apply to voluntary reporting of on-time performance by carriers. For air transportation taking place on or after January 1, 2018, this part applies to reportable flights as defined in § 234.2 that are held out to the public by certificated air carriers that account for at least 0.5 percent of domestic scheduled passenger revenues. As stated in § 234.7, certain provisions also apply to voluntary reporting of on-time performance by carriers.

■ 4. Section 234.4 is amended by revising paragraph (a) introductory text and adding paragraph (k) to read as follows:

§ 234.4 Reporting of on-time performance.

(a) Each reporting carrier shall file BTS Form 234 ''On-Time Flight Performance Report'' with the Office of Airline Information of the Department's Bureau of Transportation Statistics on a monthly basis, setting forth the information for each of its reportable flights operated by the reporting carrier and held out to the public on the reporting carrier's Web site and the Web sites of major online travel agencies, or in other generally recognized sources of schedule information. (See also paragraph (k) of this section.) The reportable flights include, but are not limited to, cancelled flights, mechanically cancelled flights, diverted flights, new flights and wet-leased flights. The report shall be made in the form and manner set forth in accounting and reporting directives issued by the Director, Office of Airline Statistics, and shall contain the following information:

* * * * *

(k) For air transportation taking place on or after January 1, 2018, each reporting carrier shall also file a separate BTS Form 234 ''On-Time Flight Performance Report'' with the Office of Airline Information on a monthly basis, setting forth the information for each of its reportable flights held out with only the reporting carrier's airline designator code on the reporting carrier's Web site, on the Web sites of major online travel

agencies, or in other generally recognized sources of schedule information, and operated by any code-share partner that is a certificated air carrier or commuter air carrier. If the operating carrier of the flight is not a reporting carrier, the non-operating reporting carrier must file a BTS Form 234 ''On-time Flight Performance Report'' with the Office of Airline Information on a monthly basis, setting forth the information regarding those flights in a form and manner consistent with the requirements set forth in paragraph (a) through (j) of this section. If the operating carrier of the flight is a reporting carrier, the non-operating reporting carrier must file a simplified BTS Form 234 ''On-Time Flight Performance Report'' with the Office of Airline Information on a monthly basis, setting forth the information regarding those flights in a form and manner consistent with the requirements set forth in paragraph (a)(1) through (a)(4) and paragraph (a)(10) of this section, and in accordance with the requirements set forth in accounting and reporting directives issued by the Office of Airline Information.

■ 5. Section 234.6 is amended by revising paragraph (b) to read as follows:

§ 234.6 Baggage-handling statistics.

* * * * *

(b) For air transportation taking place on or after January 1, 2018, each reporting carrier shall report monthly to the Department on a domestic system basis, excluding charter flights:

(1) The total number of checked bags enplaned, including gate checked baggage, ''valet bags,'' interlined bags, and wheelchairs and scooters enplaned in the aircraft cargo compartment for the reportable flights operated by the reporting carrier and separately for the reportable flights held out with only the reporting carrier's airline designator code and operated by any code-share partner that is a certificated air carrier or commuter air carrier,

(2) The total number of wheelchairs and scooters that were enplaned in the aircraft cargo compartment for the reportable flights operated by the reporting carrier and separately for the reportable flights held out with only the reporting carrier's airline designator code and operated by any code-share partner that is a certificated air carrier or commuter air carrier,

(3) The number of mishandled checked bags, including gate-checked baggage, ''valet bags,'' interlined bags and wheelchairs and scooters that were enplaned in the aircraft cargo compartment for the reportable flights operated by the reporting carrier and separately for the reportable flights held out with only the reporting carrier's airline designator code and operated by any code-share partner that is a certificated air carrier or commuter air carrier, and

(4) The number of mishandled wheelchairs and scooters that were enplaned in the aircraft cargo compartment for the reportable flights operated by the reporting carrier and separately for the reportable flights held out with only the reporting carrier's airline designator code and operated by any code-share partner that is a certificated air carrier or commuter air carrier.

PART 244—[AMENDED]

■ 6. The authority citation for part 244 continues to read as follows:

Authority: 49 U.S.C. 40101(a)(4), 40101(a)(9), 40113(a), 41702, and 41712.

■ 7. Section 244.2 is amended by revising the last sentence of paragraph (a) to read as follows:

§ 244.2 Applicability.

(a) * * * Covered carriers must report all passenger operations that experience a tarmac time of more than 3 hours at a U.S. airport.

* * * * *

■ 8. Section 244.3 is amended by revising paragraph (a) introductory text to read as follows:

§ 244.3 Reporting of tarmac delay data.

(a) Each covered carrier shall file BTS Form 244 ''Tarmac Delay Report'' with the Office of Airline Information of the Department's Bureau of Transportation Statistics setting forth the information for each of its covered flights that experienced a tarmac delay of more than 3 hours, including diverted flights and cancelled flights on which the passengers were boarded and then deplaned before the cancellation. The reports are due within 15 days after the end of any month during which the carrier experienced any reportable tarmac delay of more than 3 hours at a U.S. airport. The reports shall be made in the form and manner set forth in accounting and reporting directives issued by the Director, Office of Airline Information, and shall contain the following information:

* * * * *

PART 250—[AMENDED]

■ 9. The authority citation for part 250 continues to read as follows:

Authority: 49 U.S.C. 329 and chapters 41102, 41301, 41708, 41709, and 41712.

■ 10. Section 250.2b is amended by revising paragraph (c) to read as follows:

§ 250.2b Carriers to request volunteers for denied boarding.

* * * * *

(c) If a carrier offers free or reduced rate air transportation as compensation to volunteers, the carrier must disclose all material restrictions, including but not limited to administrative fees, advance purchase or capacity restrictions, and blackout dates applicable to the offer before the passenger decides whether to give up his or her confirmed reserved space on the flight in exchange for the free or reduced rate transportation. If the free or reduced rate air transportation is offered orally to potential volunteers, the carrier shall also orally provide a brief description of the material restrictions on that transportation at the same time that the offer is made.

■ 11. Section 250.5 is amended by adding a sentence at the end of paragraph (c)(3) to read as follows:

§ 250.5 Amount of denied boarding compensation for passengers denied boarding involuntarily.

* * * * *

(c) * * *

(3) * * * (See also § 250.9(c)).

* * * * *

■ 12. Section 250.10 is revised to read as follows:

§ 250.10 Report of passengers denied confirmed space.

(a) Each reporting carrier as defined in § 234.2 of this chapter and any carrier that voluntarily submits data pursuant to § 234.7 of this chapter shall file, on a quarterly basis, the information specified in BTS Form 251. The reporting basis shall be flight segments originating in the United States operated by the reporting carrier. The reports must be submitted within 30 days after the end of the quarter covered by the report. The calendar quarters end March 31, June 30, September 30 and December 31. ''Total Boardings'' on Line 7 of Form 251 shall include only passengers on flights for which confirmed reservations are offered. Data shall not be included for inbound international flights.

(b) For air transportation taking place on or after January 1, 2018, each reporting carrier and voluntary reporting carrier shall file a separate BTS Form 251 for all flight segments originating in the United States marketed under only the reporting carrier's code, and operated by a code-share partner that is a certificated air carrier or commuter air carrier using

aircraft that have a designed passenger capacity of 30 or more seats.

PART 255—[REMOVED AND RESERVED]

■ 13. Under the authority of 49 U.S.C. 40101, 40102, 40105, 40113, and 41712, part 255, is removed and reserved.

■ 14. Part 256 is added to read as follows:

PART 256—ELECTRONIC AIRLINE INFORMATION SYSTEMS

Sec.

Authority: 49 U.S.C. 40101 and 41712.

§ 256.1 Purpose.

(a) The purpose of this part is to set forth requirements for the display of flight options by electronic airline information systems that provide air carrier or foreign air carrier schedule, fare, or availability information, including, but not limited to, global distribution systems (GDSs), corporate booking tools, and internet flight search tools, for use by consumers, carriers, ticket agents, and other business entities so as to prevent unfair or deceptive practices in the distribution and sale of air transportation.

(b) Nothing in this part exempts any person from the operation of the antitrust laws set forth in subsection (a) of the first section of the Clayton Act (15 U.S.C. 12).

§ 256.2 Applicability.

(a) This part applies to any air carrier, foreign air carrier, or ticket agent that operates an electronic airline information system, *e.g.,* GDS, corporate booking tool, or internet flight search tool, that combines the schedules, fares or availability information of more than one air carrier or foreign air carrier for the distribution or sale in the United States of interstate or foreign air transportation.

(b) This part applies only if the electronic airline information system is displayed on a Web site marketed to consumers in the United States or on a proprietary display available to travel agents, business entities, or a limited segment of consumers of air transportation in the United States.

§ 256.3 Definitions.

For purposes of this part:

Availability means information provided in displays with respect to the ability to make a reservation on a particular flight.

Display means the presentation of air carrier or foreign air carrier schedules, fares, or availability to a consumer or agent or other individual involved in arranging air travel for a consumer by means of a computer or mobile electronic device.

Electronic airline information system or EAIS means a system that combines air carrier or foreign air carrier schedule, fare, or availability information for transmission or display to air carriers or foreign air carriers, ticket agents, other business entities, or consumers.

Integrated display means any display that includes the schedules, fares or availability of more than one listed carrier.

§ 256.4 Prohibition on undisclosed display bias.

Each air carrier, foreign air carrier, and ticket agent that operates an EAIS must comply with the requirements of this section.

(a) Each EAIS that uses any factor, not based on user selection or corporate contract travel arrangement, directly or indirectly relating to carrier identity in ordering the information contained in an integrated display must clearly disclose as provided for in § 256.5 that the identity of the carrier is a factor in the order in which information is displayed.

(b) An EAIS's integrated display must not give any carrier's flights a system-imposed preference over any other carrier's flights in that market based on carrier identity unless the preference is prominently disclosed as provided for in § 256.5.

(c) Each EAIS must display information in an objective manner based on search criteria selected by the user (*e.g.,* lowest fare, lowest total cost, date and time of travel, class of service, stopovers, total elapsed time or duration of travel, number of stops, limitations on carriers to be used, particular airport(s), number of passengers, etc.) When providing information in response to a search by a user of the EAIS, the EAIS must order the information provided so that the flight options that best satisfy the parameters of the user-selected search criteria are displayed conspicuously and no less prominently (*e.g.,* in the same or larger font size and the same or more noticeable font color) than any other flight option displayed. Flight options may be presented in sequence, matrix, or other formats, but the flight options that best satisfy the parameters of the user-selected search criteria must be ranked in lists above other flight options, or identified more prominently than other flight options in a matrix or other format. This does not preclude systems from setting default display parameters that are not deceptive or offering users the option to choose a variety of display methods within those parameters.

§ 256.5 Minimum disclosure requirements for biased displays.

To the extent an EAIS engages in display bias based on carrier identity, it must clearly and conspicuously disclose that fact at the top of each search result display presented to the user in response to the user-selected search criteria. The notice must state that the flights are not displayed in neutral order and that certain airlines' fare, schedule or availability information is given preferential treatment in how it is displayed.

§ 256.6 No requirement to provide access to systems.

Nothing in this section requires an air carrier, foreign air carrier, or ticket agent to allow a system to access its internal computer reservation system or to permit ''screen scraping'' or ''content scraping'' of its Web site; nor does it require an air carrier or foreign air carrier to permit the marketing or sale of the carrier's services through any ticket agent or other carrier's system. ''Screen scraping'' as used in this paragraph refers to a process whereby a company uses computer software techniques to extract information from other companies' Web sites without permission from the company operating the targeted Web site.

PART 257—[AMENDED]

■ 15. The authority citation for part 257 continues to read as follows:

Authority: 49 U.S.C. 40113(a) and 41712.

§ 257.3 [Amended]

■ 16. Section 257.3 is amended by removing the term ''Transporting carrier'' and adding ''Operating carrier'' in its place, removing the paragraph designations [(a) through (g)] from the definitions in this section, and placing the definition of ''Operating carrier'' in alphabetical order after the definition of ''Long-term wet lease.''

■ 17. Section 257.5 is revised to read as follows:

§ 257.5 Notice requirement.

(a) *Notice in flight itineraries and schedules.* Each air carrier, foreign air carrier, or ticket agent providing flight

itineraries and/or schedules for scheduled passenger air transportation to the public in the United States and to the Official Airline Guides and comparable publications, and, where applicable, computer reservation systems, shall ensure that each flight on which the designator code is not that of the operating carrier is clearly and prominently identified and contains the following disclosures. If there is more than one operating carrier for a particular flight (*e.g.,* change of gauge), the required disclosures shall be made for each flight segment where the designator code is not that of the operating carrier.

(1) In flight schedule information provided by an air carrier, foreign air carrier, or ticket agent to U.S. consumers on desktop browser-based Web sites or applications in response to any requested itinerary search, for each flight in scheduled passenger air transportation that is operated by a carrier other than the one listed for that flight, the corporate name of the transporting carrier and any other name under which the service is held out to the public must appear prominently in text format, with font size not smaller than the font size of the flight itinerary itself, on the first display following the input of a search query, immediately adjacent to each code-share flight in that search-results list. Roll-over, pop-up and linked disclosures do not comply with this paragraph.

(2) In flight schedule information provided by an air carrier, foreign air carrier, or ticket agent to U.S. consumers on mobile browser-based Web sites or applications in response to any requested itinerary search, for each flight in scheduled passenger air transportation that is operated by a carrier other than the one listed for that flight, the corporate name of the transporting carrier must appear prominently in text format, with font size not smaller than the font size of the flight itinerary itself, on the first display following the input of a search query, immediately adjacent to each code-share flight in that search-results list. Roll-over, pop-up and linked disclosures do not comply with this paragraph.

(3) For static written schedules, each flight in scheduled passenger air transportation that is operated by a carrier other than the one listed for that flight shall be identified by an asterisk or other easily identifiable mark that leads to disclosure of the corporate name of the operating carrier and any other name under which that service is held out to the public.

(4) Each air carrier and foreign air carrier that provides flight schedule information to any computer reservation system or global distribution system that receives and distributes the U.S. or foreign carrier's fare, schedule, or availability information shall ensure that each flight on which the designator code is not that of the operating carrier is clearly and prominently identified and the corporate name of the transporting carrier and any other name under which the service is held out to the public appears prominently in text format, with font size that is not smaller than the font size of the flight itinerary itself, immediately adjacent to each code-share flight in that search-results list.

(b) *Notice in oral communications with prospective consumers.* In any direct oral communication in the United States with a prospective consumer, and in any telephone call placed from the United States by a prospective consumer, concerning a flight within, to, or from the United States that is part of a code-sharing arrangement or long-term wet lease, a ticket agent doing business in the United States or a carrier shall inform the consumer, the first time that such a flight is offered to the consumer, or, if no such offer was made, the first time a consumer inquires about such a flight, that the operating carrier is not the carrier whose name or designator code will appear on the ticket and shall identify the transporting carrier by its corporate name and any other name under which that service is held out to the public.

(c) *Notice in ticket confirmations.* At the time of purchase, each selling carrier or ticket agent shall provide written disclosure of the actual operator of the flight to each consumer of scheduled passenger air transportation sold in the United States that involves a code-sharing arrangement or long-term wet lease. For any flight on which the designator code is not that of the operating carrier the notice shall state ''Operated by'' followed by the corporate name of the transporting carrier and any other name in which that service is held out to the public. The following form of statement will satisfy the requirement of this paragraph:

Important Notice: Service between XYZ City and ABC City will be operated by Jane Doe Airlines d/b/a QRS Express. At the purchaser's request, the notice required by this part may be delivered in person, or by fax, electronic mail, or any other reliable method of transmitting written material.

(d) In any written advertisement distributed in or mailed to or from the United States (including those that appear on an internet Web site that is marketed to consumers in the United States) for service in a city-pair market that is provided under a code-sharing arrangement or long-term wet lease, the advertisement shall prominently disclose that the advertised service may involve travel on another carrier and clearly indicate the nature of the service in reasonably sized type and shall identify all potential operating carriers involved in the markets being advertised by corporate name and by any other name under which that service is held out to the public. In any radio or television advertisement broadcast in the United States for service in a city-pair market that is provided under a code-sharing or long-term wet lease, the advertisement shall include at least a generic disclosure statement, such as ''Some flights are operated by other airlines.''

PART 259—[AMENDED]

■ 18. The authority citation for part 259 continues to read as follows:

Authority: 49 U.S.C. 40101(a)(4), 40101(a)(9), 40113(a), 41702, and 41712.

■ 19. Section 259.8 is amended by revising the second sentence in paragraph (a) introductory text, and paragraph (a)(1), to read as follows:

§ 259.8 Notify consumers of known delays, cancellations, and diversions.

(a) * * * A change in the status of a flight means, at a minimum, a cancellation, diversion or delay of 30 minutes or more in the planned operation of a flight that occurs within seven calendar days of the scheduled date of the planned operation. * * *

(1) With respect to any U.S. air carrier or foreign air carrier that permits passengers and other interested persons to subscribe to flight status notification services, the carrier must deliver such notification to such subscribers, by whatever means the carrier offers that the subscriber chooses.

* * * * *

PART 399—[AMENDED]

■ 20. The authority citation for part 399 continues to read as follows:

Authority: 49 U.S.C. 41712.

■ 21. Section 399.80 is amended by removing and reserving paragraph (h) to read as follows:

§ 399.80 Unfair and deceptive practices of ticket agents.

* * * * *

(h) [Reserved]

* * * * *

[FR Doc. 2016–26178 Filed 11–2–16; 8:45 am]

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FEDERAL REGISTER

Vol. 81 Thursday,
No. 213 November 3, 2016

Part IV

The President

Federal Register
Vol. 81, No. 213
Thursday, November 3, 2016

Presidential Documents

Title 3—

The President

Proclamation 9533 of October 31, 2016

Critical Infrastructure Security and Resilience Month, 2016

By the President of the United States of America

A Proclamation

From the energy that powers our homes to the systems that allow us to communicate with one another, our critical infrastructure is essential to the stability and strength of our national security, economy, and public health. The assets, networks, and systems that enable us to innovate and prosper are necessary for sustaining and supporting the well-being of our Nation, and our increasing dependence on them makes securing and protecting them a top priority. This month, we recognize the importance of our critical infrastructure and resolve to safeguard these vital systems so they remain strong and resilient.

Our critical infrastructure spans a wide array of structures and systems we rely on to meet our day-to-day needs. It includes government facilities, the electric grid, transportation and water systems, information technology, and financial systems—all which play an equally important role in maintaining our way of life. These complex systems work together to keep us safe and healthy, and although they are among the most advanced and secure in the world, we must remain vigilant and ensure their resilience by mitigating the threats and stresses that can weaken them.

Securing our complex critical infrastructure systems requires cooperation and sustained commitment from everyone, which is why my Administration is working with businesses, infrastructure owners, and officials at all levels of government to protect them. We must take necessary steps to modernize our roads, bridges, pipes, and ports to ensure they remain resilient and strong—especially as climate change becomes an increasing risk, causing more extreme weather events that threaten our infrastructure. In addition to physical threats and hazards, cybersecurity risks pose another significant challenge to our Nation. We must ensure that addressing threats to the security of our data and our digital networks remains a priority. By partnering with the private sector, and with the help of the American people, we can prepare our critical infrastructure to withstand and respond to cyber threats, terrorist attacks, acts of nature including space weather events, and other threats and hazards.

Three years ago, I issued a Presidential Policy Directive to strengthen and maintain secure and resilient critical infrastructure. Today, we are continuing to carry out this vision for how Government and the private sector can work together to reduce risks and increase the stability and security of our infrastructure. And because our world has never been more interconnected, we know that keeping our critical infrastructure functioning will require collaboration with international partners. That is why we are working to promote global critical infrastructure security and resilience through information sharing with partners around the world.

As our population grows and our technology advances, the demands of our critical infrastructure become increasingly significant. During Critical Infrastructure Security and Resilience Month, we recommit to reducing risks to these important systems and preparing to adapt and respond to any incident that may occur. To ensure more Americans can thrive in a future of greater safety, stability, and prosperity, we must protect and enhance

these essential elements of our cyber and physical infrastructure for generations to come.

NOW, THEREFORE, I, BARACK OBAMA, President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim November 2016 as Critical Infrastructure Security and Resilience Month. I call upon the people of the United States to recognize the importance of protecting our Nation's infrastructure and to observe this month with appropriate events and training to enhance our national security and resilience.

IN WITNESS WHEREOF, I have hereunto set my hand this thirty-first day of October, in the year of our Lord two thousand sixteen, and of the Independence of the United States of America the two hundred and forty-first.

[FR Doc. 2016–26800
Filed 11–2–16; 11:15 am]
Billing code 3295–F7–P

Presidential Documents

Proclamation 9534 of October 31, 2016

National Alzheimer's Disease Awareness Month, 2016

By the President of the United States of America

A Proclamation

A heartbreaking disease present in more than 5 million Americans, Alzheimer's is the most common form of dementia and causes people to lose many of the critical abilities they need to live independently. Too often, those suffering from Alzheimer's cannot recognize their loved ones or remember how to perform daily tasks, struggling physically and mentally with things that once came naturally. Although we have long known Alzheimer's to be irreversible and fatal, we maintain hope that by advancing research and treatment options we can work to change these outcomes and ensure brighter prospects for all those who face this disease. During National Alzheimer's Disease Awareness Month, we resolve to continue working toward this brighter future as we stand with every person battling, Alzheimer's and their loved ones.

Alzheimer's disease is more likely to affect Americans as they grow older—although genetics can also play a role, age is the most significant risk factor. But Alzheimer's touches many more individuals than simply those who are diagnosed. Dedicated caregivers—whether professionals, family members, or friends—are also emotionally, physically, and financially affected by Alzheimer's disease, giving of themselves to ensure those who face it are not alone. And because these individuals need access to information and resources in order to provide this essential care, we launched www.Alzheimers.gov to give them a place to find help.

Through the National Plan to Address Alzheimer's Disease, my Administration has been working to meet a goal of being able to prevent and effectively treat this illness by 2025. Over the past year we have taken a number of actions to reach this vision, including developing a training curriculum that gives health care workers the necessary skills to care for dementia patients and better detect and diagnose dementia. We have also helped family caregivers look after their own health, in addition to addressing the needs of people with dementia, and launched a campaign to increase awareness of changes in the brain as people age so that older adults feel more comfortable having open conversations with family members and health care providers.

In addition to ensuring anyone with Alzheimer's can access proper care, we must harness the innovative ideas of the scientific community and work to prevent this disease. To ramp up research and development aimed at uncovering the answers to diseases like Alzheimer's, I have increased funding for research dedicated to understanding, preventing, and curing Alzheimer's and related dementias. I also introduced the Brain Research through Advancing Innovative Neurotechnologies Initiative, which will enhance our understanding of brain function and give scientists the tools they need to better understand and discover new ways to treat, cure, and prevent brain disorders. And through a bold new research effort that seeks to deliver personalized care through patient-centered research and collaboration, my Precision Medicine Initiative is working to revolutionize our understanding of diseases like Alzheimer's.

From researchers and advocates who are bringing us closer to preventing this disease to family members who devotedly look after their loved ones, people across our country are doing their part to support those touched by Alzheimer's. This month, let us honor those we have lost too soon and renew our efforts to ensure more Americans can live their lives with health and happiness.

NOW, THEREFORE, I, BARACK OBAMA, President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim November 2016 as National Alzheimer's Disease Awareness Month. I call upon the people of the United States to learn more about Alzheimer's disease and support the individuals living with this disease and their caregivers.

IN WITNESS WHEREOF, I have hereunto set my hand this thirty-first day of October, in the year of our Lord two thousand sixteen, and of the Independence of the United States of America the two hundred and forty-first.

[FR Doc. 2016–26801
Filed 11–2–16; 11:15 am]
Billing code 3295–F7–P

Presidential Documents

Proclamation 9535 of October 31, 2016

National Entrepreneurship Month, 2016

By the President of the United States of America

A Proclamation

Entrepreneurs in America have long lent their talents and passions to solving problems, generating growth and prosperity, and turning dreams into new goods and services for people across our Nation and around the world. During National Entrepreneurship Month, we celebrate the entrepreneurs who serve their communities and bolster our economy, and we pledge our support for them in their pursuit of the ideas and innovations of tomorrow.

Through their intrepid sense of possibility and resilience, and their unwillingness to give in or give up, entrepreneurs from every walk of life make invaluable contributions to the American experience—turning bold ideas into real progress. My Administration has made it a priority from day one to support those who take a risk and put in the hard work required to get a new venture off the ground. In 2010, I signed the Affordable Care Act, which gives Americans greater opportunities to start businesses by offering portable and affordable health insurance plans through the Health Insurance Marketplace. I signed 18 tax breaks for small businesses in my first term, including tax credits for those who hire unemployed workers and veterans, and I launched the Nation of Makers initiative to advance innovation and encourage making, including homegrown technologies and startups. In 2013, I signed an Executive Order to make Government data more accessible to the public, and my Administration has opened up nearly 200,000 datasets on www.Data.gov to fuel economic growth, innovation, and entrepreneurship. And earlier this year, I announced the Computer Science for All Initiative—a plan to give all students in America the chance to learn computer science in school, which will equip our future entrepreneurs, including those from underrepresented backgrounds, with the computational thinking skills they need to succeed.

In the 21st-century economy—where business does not stop at a country's border and where technological advancements have changed the ways we engage in commerce and with one another—it is more important than ever that we give our Nation's entrepreneurs the tools and resources they need to compete on the international stage. This past summer, I signed an Executive Order that encourages entrepreneurship in the United States and around the world, including through the Presidential Ambassadors for Global Entrepreneurship Program, to promote the sharing of knowledge and experience with the entrepreneurs of tomorrow. Additionally, as I attended the Global Entrepreneurship Summit in California in June, companies across America came together to sign the Tech Inclusion Pledge: a commitment to making their technology workforces more representative of the American people. My Administration also used this Summit as an opportunity to announce an expansion of the National Science Foundation's Innovation Corps training program for entrepreneurial scientists and engineers, as well as the Small Business Administration's *Startup in a Day* initiative, with nearly 100 cities and communities across our Nation committed to streamlining licensing, permitting, and other requirements necessary for anyone to start a business. At the end of last year, I signed a bipartisan budget deal that made permanent critical tax incentives to help bolster investment in small businesses and

research and experimentation, including by startups and other innovative companies. And thanks to another bipartisan bill I signed, entrepreneurs can raise small-dollar investments from community members, customers, and other individuals through new and regulated online crowdfunding platforms—because access to capital should be available to every aspiring entrepreneur no matter who they are or where they are from.

My Administration has also striven to expand opportunity to those seeking to utilize their entrepreneurial talents abroad. Following the beginning of our process to normalize relations with our neighbors 90 miles to the south in Cuba, we made it easier for Cuban entrepreneurs to import and export. Entrepreneurs flourish when they are surrounded by an environment that encourages their success—that is true here at home and around the world. My Administration remains committed to implementing the Trans-Pacific Partnership, a trade agreement that will have a profound effect on our efforts to support online entrepreneurs and enable American entrepreneurs to sell ''Made in America'' products all over the world. And through our proposed International Entrepreneur Rule, we are working to ensure the world's best and brightest entrepreneurs can launch companies and create jobs in the United States.

As we celebrate National Entrepreneurship Month and Global Entrepreneurship Week, let us resolve to support those budding entrepreneurs looking to use their ideas and expertise to build a better life for themselves and their families—and let us tap into the diverse skills and talents across our country so that entrepreneurs from all backgrounds can continue creating the businesses of the 21st century. Entrepreneurship is about the opportunity to forge one's own future, and an investment in that future can start as something small and turn into something great. That is the legacy shaped by generations of American entrepreneurs who, through ingenuity, passion, and self-determination, have always striven to achieve the next big, unknown thing.

NOW, THEREFORE, I, BARACK OBAMA, President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim November 2016 as National Entrepreneurship Month. I call upon all Americans to commemorate this month with appropriate programs and activities, and to celebrate November 15, 2016, as National Entrepreneurs' Day.

IN WITNESS WHEREOF, I have hereunto set my hand this thirty-first day of October, in the year of our Lord two thousand sixteen, and of the Independence of the United States of America the two hundred and forty-first.

[FR Doc. 2016–26802
Filed 11–2–16; 11:15 am]
Billing code 3295–F7–P

Presidential Documents

Proclamation 9536 of October 31, 2016

National Family Caregivers Month, 2016

By the President of the United States of America

A Proclamation

Our Nation was founded on the fundamental ideal that we all do better when we look out for one another, and every day, millions of Americans from every walk of life balance their own needs with those of their loved ones as caregivers. During National Family Caregivers Month, we reaffirm our support for those who give of themselves to be there for their family, friends, and neighbors in challenging times, and we pledge to carry forward the progress we have made in our health care system and workplaces to give caregivers the resources and flexibility they need.

Each of us may find ourselves in need of or providing care at some point in our lives. That is why it is imperative that we maintain and expand the Affordable Care Act (ACA). At the time Medicare was created, only a little more than half of all seniors had some form of health insurance. Today, the ACA has given older Americans better care and more access to discounted prescriptions and certain preventive services at no cost. The ACA has also expanded options for home- and community-based services, so that, with the help of devoted, loving caregivers, more Americans are now able to live independently and with dignity. And because looking after an aging family member or a friend with a disability can be challenging, States and local agencies connect individuals with caregiver support groups and respite care. The women and men who put their loved ones before themselves show incredible generosity every day, and we must continue to support them in every task they selflessly carry out.

Many devoted caregivers across our country also attend to members of our Armed Forces when they return home, and my Administration is committed to improving the care and support our veterans and their families receive. For over 5 years, First Lady Michelle Obama and Dr. Jill Biden's *Joining Forces* initiative has worked to ensure those who look after our service members who come home with the wounds of war—whether they are visible or not—have the community and Government support they need to help their siblings and spouses, parents and children, neighbors and friends through one of the greatest battles they may face: the fight to recover and heal.

This month, and every month, let us lift up all those who work to tirelessly advance the health and wellness of those they love. Let us encourage those who choose to be caregivers and look toward a future where our politics and our policies reflect the selflessness and open-hearted empathy they show their loved ones every day.

NOW, THEREFORE, I, BARACK OBAMA, President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim November 2016 as National Family Caregivers Month. I encourage all Americans to pay tribute to those who provide for the health and well-being of their family members, friends, and neighbors.

IN WITNESS WHEREOF, I have hereunto set my hand this thirty-first day of October, in the year of our Lord two thousand sixteen, and of the Independence of the United States of America the two hundred and forty-first.

[FR Doc. 2016–26804
Filed 11–2–16; 11:15 am]
Billing code 3295–F7–P

Presidential Documents

Proclamation 9537 of October 31, 2016

National Native American Heritage Month, 2016

By the President of the United States of America

A Proclamation

As the First Americans, Native Americans have helped shape the future of the United States through every turn of our history. Today, young American Indians and Alaska Natives embrace open-ended possibility and are determining their own destinies. During National Native American Heritage Month, we pledge to maintain the meaningful partnerships we have with tribal nations, and we renew our commitment to our nation-to-nation relationships as we seek to give all our children the future they deserve.

Over our long shared history, there have been too many unfortunate chapters of pain and tragedy, discrimination and injustice. We must acknowledge that history while recognizing that the future is still ours to write. That is why my Administration remains dedicated to strengthening our government-to-government relationships with tribal nations and working to improve the lives of all our people. Three years ago, I issued an Executive Order establishing the White House Council on Native American Affairs to help ensure the Federal Government engages in true and lasting relationships with tribes and promotes the development of prosperous and resilient tribal communities. Last month, I hosted the eighth Tribal Nations Conference and brought tribal leaders together to identify key issues we still face. We have worked to better protect sacred lands and restored many acres of tribal homelands, as well as supported greater representation of indigenous peoples before the United Nations and called for further implementation of the Declaration of the Rights of Indigenous Peoples. And we have taken steps to strengthen tribal sovereignty in criminal justice matters, including through the Tribal Law and Order Act.

Through the Affordable Care Act and permanent reauthorization of the Indian Health Care Improvement Act, we empowered more Native Americans to access the quality health care they need to live full, healthy lives. Throughout their lives, 84 percent of American Indian and Alaska Native women and girls will experience some form of violence, and in 2013, I signed the reauthorization of the Violence Against Women Act, which allows tribes to prosecute non-Native individuals who commit acts of domestic violence in Indian Country. And through the North American Working Group on Violence Against Indigenous Women and Girls, we are strengthening regional coordination on the rights of women and girls from indigenous communities across the continent.

In recognition of the immeasurable contributions that Native Americans have made to our Nation, we continue to advocate for expanding opportunity across Indian Country. We have supported tribal colleges and universities and worked to return control of education to tribal nations—not only to prepare Native youth for the demands of future employment, but also to promote their own tribal languages and cultures. We are investing in job training and clean-energy projects, infrastructure, and high-speed internet that connects Native American communities to the broader economy. We are connecting more young people and fostering a national dialogue to empower the next generation of Native leaders through the Generation Indigenous initiative. Through www.NativeOneStop.gov, we have also worked to

improve coordination and access to Federal services throughout Indian Country. Indian Country still faces many challenges, but we have made significant progress together since I took office, and we must never give up on our pursuit of the ever brighter future that lies ahead.

This month, let us celebrate the traditions, languages, and stories of Native Americans and ensure their rich histories and contributions can thrive with each passing generation. Let us continue to build on the advancements we have made, because enduring progress will depend on our dedication to honoring our trust and treaty responsibilities. With sustained effort and unwavering optimism, we can ensure a vibrant and resilient Indian Country filled with possibility and prosperity.

NOW, THEREFORE, I, BARACK OBAMA, President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim November 2016 as National Native American Heritage Month. I call upon all Americans to commemorate this month with appropriate programs and activities, and to celebrate November 25, 2016, as Native American Heritage Day.

IN WITNESS WHEREOF, I have hereunto set my hand this thirty-first day of October, in the year of our Lord two thousand sixteen, and of the Independence of the United States of America the two hundred and forty-first.

[FR Doc. 2016–26805
Filed 11–2–16; 11:15 am]
Billing code 3295–F7–P

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