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DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 984

[Doc. No. AMS–SC–17–0031; SC17–984–1 IR]

Walnuts Grown in California; Decreased Assessment Rate

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Interim rule with request for comments.

SUMMARY: This rule implements a recommendation from the California Walnut Board (Board) to decrease the assessment rate established for the 2017–18 and subsequent marketing years from $0.0465 to $0.0400 per kernelweight pound of assessable walnuts. The Board is comprised of growers and handlers of walnuts and locally administers the marketing order that regulates the handling of walnuts grown in California. The Board also has a public member who has no financial interest in walnut production or handling. Assessments upon walnut handlers are used by the Board to fund reasonable and necessary expenses of the program. The marketing year begins September 1 and ends August 31. The assessment rate will remain in effect indefinitely unless modified, suspended, or terminated.

DATES: Effective July 24, 2017. Comments received by September 19, 2017 will be considered prior to issuance of a final rule.

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

FOR FURTHER INFORMATION CONTACT: Terry Vawter, Senior Marketing Specialist, or Jeffrey Smutny, Regional Director, California Marketing Field Office, Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA; Telephone: (559) 487–5901, Fax: (559) 487–5906, or Email: *Jeffrey.Smutny@ams.usda.gov* or *Terry.Vawter@ams.usda.gov.*

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

SUPPLEMENTARY INFORMATION: This rule is issued under Marketing Order No. 984, as amended (7 CFR part 984), regulating the handling of walnuts grown in California, hereinafter referred to as the ''order.'' The order is effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), hereinafter referred to as the ''Act.''

The Department of Agriculture (USDA) is issuing this rule in conformance with Executive Orders 12866, 13563, and 13175. Additionally, because this rule does not meet the definition of a significant regulatory action, it does not trigger the requirements contained in Executive Order 13771. See the Office of Management and Budget's (OMB) Memorandum titled ''Interim Guidance Implementing Section 2 of the Executive Order of January 30, 2017, titled 'Reducing Regulation and Controlling Regulatory Costs' '' (February 2, 2017).

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. Under the marketing order now in effect, California walnut handlers are subject to assessments. Funds to administer the order are derived from such assessments. It is intended that the assessment rate will be applicable to all assessable walnuts beginning on September 1, 2017, and continue until amended, suspended, or terminated.

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

This rule decreases the assessment rate established for the Board for the 2017–18 and subsequent marketing years from $0.0465 to $0.0400 per kernelweight pound of assessable walnuts.

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

For the 2016–17 and subsequent marketing years, the Board recommended, and USDA approved, an assessment rate of $0.0465 per kernelweight pound of assessable walnuts that would continue in effect from year to year unless modified, suspended, or terminated by USDA upon recommendation and information

submitted by the Board or other information available to USDA.

The Board met on May 31, 2017, and unanimously recommended 2017–18 expenditures of $24,140,000 and a decreased assessment rate of $0.0400 per kernelweight pound of assessable walnuts. In comparison, last year's budgeted expenditures were $23,143,050. The assessment rate of $0.0400 is $0.0065 per pound lower than the rate currently in effect. The quantity of assessable walnuts for the 2017–18 marketing year is estimated at a three-year average of 615,000 tons (inshell) or 553,500,000 kernelweight pounds, which is 62,000 tons more than the 553,000 tons assessed during the 2016–17 marketing year. At the recommended lower assessment rate of $0.0400 per kernelweight pound, the Board should collect approximately $22,140,000 in assessment income, which, when augmented with funds from the Board's monetary reserve, would be adequate to cover its 2017–18 budgeted expenses of $24,140,000.

The following table compares major budget expenditures recommended by the Board for the 2016–17 and 2017–18 marketing years:

Budget expense categories	2016–17	2017–18
Employee Expenses	$2,292,000	$1,787,000
Travel/Board Expenses/Annual Audit	206,000	192,000
Office Expenses	262,000	265,000
Program Expenses, Including Research:		
Controlled Purchases	10,000	10,000
Crop Acreage Survey	0	103,000
Crop Estimate	130,000	146,000
Production Research Director	175,000	98,000
Production Research	1,800,000	2,000,000
Sustainability Project	75,000	0
Grades and Standards Research	800,000	825,000
Domestic Market Development	18,398,040	19,447,830
Reserve for Contingency	59,010	47,170

The assessment rate recommended by the Board was derived by dividing anticipated expenses by expected volumes of California walnuts certified as merchantable. The 615,000-ton (inshell) estimate for merchantable walnut receipts is an average of the three prior years' shipments.

Section 984.69 of the order authorizes the Board to carry over excess funds into subsequent marketing years as a reserve, provided that funds already in the reserve do not exceed approximately two years' budgeted expenses. The reserve is estimated to be $14,909,800 at the end of the marketing year, well within the authorized reserve amount.

The Board met on May 31, 2017, and unanimously approved using a three prior years' average walnut production volume to formulate the 2017–18 crop estimate. Pursuant to § 984.51(b) of the order, this figure is converted to a merchantable kernelweight basis using a factor of 0.45 (615,000 tons × 2,000 pounds per ton × 0.45), which yields 553,500,000 kernelweight pounds. At $0.0400 per pound, the new assessment rate should generate $22,140,000 in assessment income. The assessment income, plus $2,000,000 from the Board's reserve, will be adequate to cover its budgeted expenses.

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

Although this assessment rate is effective for an indefinite period, the Board will continue to meet prior to or during each marketing year to recommend a budget of expenses and consider recommendations for modification of the assessment rate. The dates and times of Board meetings are available from the Board or USDA. Board meetings are open to the public, and interested persons are encouraged to express their views at these meetings. USDA will evaluate Board recommendations and other available information to determine whether modification of the assessment rate is needed. Further rulemaking will be undertaken as necessary. The Board's 2017–18 budget and those for subsequent marketing years will be reviewed and, as appropriate, approved by USDA.

Initial Regulatory Flexibility Analysis

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

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

There are approximately 5,700 growers of California walnuts in the production area and approximately 90 handlers subject to regulation under the marketing order. Small agricultural growers are defined by the Small Business Administration (SBA) as those whose annual receipts are less than $750,000, and small agricultural service firms are defined as those whose annual receipts are less than $7,500,000 (13 CFR 121.201).

According to USDA's National Agricultural Statistics Service's (NASS) 2012 Census of Agriculture, approximately 86 percent of California's walnut farms were smaller than 100 acres. Further, NASS reports that the average yield for 2015 was 2.01 tons per acre, and the average price received for 2015 was $1,620 per ton. A 100-acre farm with an average yield of 2.01 tons per acre would, therefore, have been expected to produce about 201 tons of walnuts. At $1,620 per ton, that farm's production would have had an approximate value of $325,620. This is well below the SBA threshold of $750,000; thus, it may be concluded that the majority of California's walnut growers are considered small growers according to SBA's definition.

According to information supplied by the industry, approximately two-thirds of California's walnut handlers shipped merchantable walnuts valued under $7,500,000 during the 2016–17 marketing year and would, therefore, be

considered small handlers according to the SBA definition.

This rule decreases the assessment rate established for the Board and collected from handlers for the 2017–18 and subsequent marketing years from $0.0465 to $0.0400 per kernelweight pound of assessable walnuts. The Board unanimously recommended 2017–18 expenditures of $24,140,000 and an assessment rate of $0.0400 per kernelweight pound of assessable walnuts, which is $0.0065 lower than the assessment rate currently in effect. The quantity of assessable walnuts for the 2017–18 marketing year is estimated to be 615,000 tons, 62,000 tons greater than the quantity estimated for the 2016–17 marketing year. Therefore, even at the reduced assessment rate, the Board should collect approximately $22,140,000 in assessment income, which, when combined with $2,000,000 from its reserves, should be adequate to cover its budgeted expenses.

The following table compares major budget expenditures recommended by the Board for the 2016–17 and 2017–18 marketing years:

Budget Expense Categories	2016–17	2017–18
Employee Expenses	$2,292,000	$1,787,000
Travel/Board Expenses/Annual Audit	206,000	192,000
Office Expenses	262,000	265,000
Program Expenses, Including Research:.		
Controlled Purchases	10,000	10,000
Crop Acreage Survey	0	103,000
Crop Estimate	130,000	146,000
Production Research Director	175,000	98,000
Production Research	1,800,000	2,000,000
Sustainability Project	75,000	0
Grades and Standards Research	800,000	825,000
Domestic Market Development	18,398,040	19,447,830
Reserve for Contingency	59,010	47,170

The Board reviewed and unanimously recommended 2017–18 expenditures of $24,140,000. Prior to arriving at this budget, the Board considered alternative expenditure and assessment levels, as well as a recommendation from the Budget and Personnel Committee (Committee). The Committee considered the estimated income and expenses, given the requests from other committees, such as the Production Research, Market Development, and Grades and Standards Committees. The other committees each deliberated, formulated their own budgets of expenses, and made their recommendations to the Committee. The Committee also considered the recommendations and various assessment rates and expenses, then made a recommendation to the Board. The Board ultimately determined that the recommended levels were reasonable and necessary to properly administer the order.

The assessment rate of $0.0400 per kernelweight pound of assessable walnuts was derived by dividing anticipated expenses of $24,140,000 by expected 2017–18 volumes of California walnuts certified as merchantable. Merchantable walnuts certified for the year are estimated at 553,500,000 kernelweight pounds, which should provide $22,140,000 in assessment income. Assessment income, coupled with $2,000,000 from the Board's reserve funds, should allow the Board to cover its expenses. Unexpended funds may be retained in a financial reserve, provided that funds in the financial reserve do not exceed approximately two years' budgeted expenses. The anticipated reserve should be $14,909,800, which is well within the order's requirement.

According to NASS, the season average grower price for 2015 was $1,620 per ton. Dividing this average grower price by 2,000 pounds per ton provides an inshell price per pound of $0.81. Dividing this inshell price per pound by the 0.45 conversion factor (inshell to kernelweight) established in the order yields a potential 2017–18 price of about $1.80 per kernelweight pound of assessable walnuts.

To calculate the percentage of grower revenue represented by the assessment rate, the assessment rate of $0.0400 per kernelweight pound is divided by the price. The estimated assessment revenue for the 2017–18 marketing year, stated as a percentage of total grower revenue, would be approximately 2 percent.

This action decreases the assessment obligation imposed on handlers. Assessments are applied uniformly on all handlers, and some of the costs may be passed on to growers. However, decreasing the assessment rate reduces the burden on handlers and may reduce the burden on growers.

In addition, the Board's meeting was widely publicized throughout the California walnut industry, and all interested persons were invited to attend the meeting and encouraged to participate in Board deliberations on all issues. Like all Board meetings, the May 31, 2017, meeting was a public meeting, and all entities, both large and small, were able to express their views on this issue. Finally, interested persons are invited to submit comments on this interim rule, including the regulatory and informational impacts of this action on small businesses.

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the order information collection requirements have been previously reviewed by OMB and assigned OMB No.: 0581–0178 (Walnuts Grown in California). No changes in those requirements as a result of this action are necessary. Should any changes become necessary, they would be submitted to OMB for approval.

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

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

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

A small business guide on complying with fruit, vegetable, and specialty crop marketing agreements and orders may be viewed at: *http://www.ams.usda.gov/rules-regulations/moa/small-businesses.* Any questions about the compliance guide should be sent to Richard Lower

at the previously mentioned address in the **FOR FURTHER INFORMATION CONTACT** section.

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

Pursuant to 5 U.S.C. 553, it is also found and determined upon good cause that it is impracticable and contrary to the public interest to give preliminary notice prior to putting this rule into effect and that good cause exists for not postponing the effective date of this rule until 30 days after publication in the **Federal Register** because: (1) The action decreases the assessment rate for merchantable walnuts; (2) handlers are aware of this action, which was unanimously recommended by the Board at a public meeting and is similar to other assessment rate actions issued in past years; and (3) this interim rule provides a 60-day comment period, and all comments timely received will be considered prior to finalization of this rule.

List of Subjects in 7 CFR Part 984

Marketing agreements, Nuts, Reporting and recordkeeping requirements, Walnuts.

For the reasons set forth in the preamble, 7 CFR part 984 is amended as follows:

PART 984—WALNUTS GROWN IN CALIFORNIA

■ 1. The authority citation for part 984 continues to read as follows:

Authority: 7 U.S.C. 601–674.

■ 2. Section 984.347 is revised to read as follows:

§ 984.347 Assessment rate.

On and after September 1, 2017, an assessment rate of $0.0400 per kernelweight pound is established for California merchantable walnuts.

Dated: July 17, 2017.

Bruce Summers,

Acting Administrator, Agricultural Marketing Service.

[FR Doc. 2017–15304 Filed 7–20–17; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2016–6968; Directorate Identifier 2015–SW–020–AD; Amendment 39–18950; AD 2017–14–06]

RIN 2120–AA64

Airworthiness Directives; Sikorsky Aircraft Corporation Helicopters (Type Certificate Previously Held by Schweizer Aircraft Corporation)

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: We are superseding airworthiness directive (AD) 93–17–13 for Schweizer Aircraft Corporation and Hughes Helicopters, Inc. (now Sikorsky Aircraft Corporation) (Sikorsky) Model TH55A, 269A, 269A–1, 269B, and 269C helicopters. AD 93–17–13 required installing tachometer markings and inspecting the lower coupling driveshaft (driveshaft). This new AD requires repetitive inspections of the driveshaft and expands the applicability to include Model 269C–1 helicopters. This AD is prompted by reports of accidents because of driveshaft failures. The actions of this AD are intended to prevent the unsafe condition on these products.

DATES: This AD is effective August 25, 2017.

The Director of the Federal Register approved the incorporation by reference of certain documents listed in this AD as of August 25, 2017.

The Director of the Federal Register approved the incorporation by reference of a certain other publication listed in this AD as of October 20, 1993 (58 FR 51770, October 5, 1993).

ADDRESSES: For Schweizer or Sikorsky service information identified in this final rule, contact Sikorsky Aircraft Corporation, Customer Service Engineering, 124 Quarry Road, Trumbull, CT 06611; telephone 1–800–Winged–S or 203–416–4299; email *wcs_cust_service_eng.gr-sik@lmco.com.* You may review a copy of the referenced service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177. It is also available on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–6968.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–6968; or in person at the Docket Operations Office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, any incorporated-by-reference service information, the economic evaluation, any comments received, and other information. The street address for the Docket Operations Office (phone: 800–647–5527) is U.S. Department of Transportation, Docket Operations Office, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Blaine Williams, Aerospace Engineer, Boston Aircraft Certification Office, Engine & Propeller Directorate, 1200 District Avenue, Burlington, Massachusetts 01803; telephone (781) 238–7161; email *blaine.williams@faa.gov.*

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to remove AD 93–17–13, Amendment 39–8684 (58 FR 51770, October 5, 1993) and add a new AD. AD 93–17–13 applied to Schweizer Aircraft Corporation and Hughes Helicopters, Inc. (now Sikorsky) Model TH55A, 269A, 269A–1, 269B, and 269C helicopters. AD 93–17–13 required within 30 days or 100 hours time-in-service (TIS), whichever occurs first and thereafter every 300 hours TIS, visually inspecting for cracks, machining steps, manufacturing tool marks, surface defects, and lack of cleanup during the production grinding operation. AD 93–17–13 also required installing engine and rotor tachometer markings and replacing any unairworthy driveshaft before further flight.

The NPRM published in the **Federal Register** on January 5, 2017 (82 FR 1267) and was prompted by a safety analysis by Sikorsky that determined the initial and recurrent inspection intervals and inspection method required by AD 93–17–13 were not adequate to detect all corrosion, pits, nicks, scratches, dents, and cracks. Accidents due to driveshaft failures continued to occur after AD 93–17–13 was issued. Therefore, the NPRM proposed to require, within 25 hours TIS and thereafter at intervals not to exceed 150 hours TIS, visually inspecting the driveshaft. If there are no cracks, corrosion, or other damage, the NPRM proposed performing a magnetic particle inspection. If there is a crack or

other damage, the NPRM proposed to require replacing the driveshaft before further flight. The NPRM also proposed adding tachometer markings if not previously performed. Expanding the applicability to include Model 269C–1 helicopters was also proposed because these helicopters were not manufactured when AD 93–17–13 was issued but have the applicable driveshafts installed. Finally, the NPRM proposed to include specific part-numbered driveshafts to the applicability because Sikorsky is developing a new driveshaft that we do not expect to be subject to this AD.

Comments

We gave the public the opportunity to participate in developing this AD, but we received no comments on the NPRM.

FAA's Determination

We have reviewed the relevant information and determined that an unsafe condition exists and is likely to exist or develop on other products of these same type designs and that air safety and the public interest require adopting the AD requirements as proposed.

Interim Action

We consider this AD to be an interim action. The design approval holder is developing a replacement driveshaft that will address the unsafe condition identified in this AD. Once the replacement driveshaft is developed, approved, and available, we might consider additional rulemaking.

Related Service Information Under 1 CFR Part 51

We reviewed Sikorsky 269C Helicopter Alert Service Bulletin B–307, Basic Issue, dated December 18, 2014, and Sikorsky 269C–1 Helicopter Alert Service Bulletin C1B–043, Basic Issue, dated December 18, 2014 (ASBs). The ASBs call for a one-time visual and magnetic particle inspection of the driveshaft and driveshaft assembly for damage. The ASBs advise that the driveshaft be sent to Sikorsky and replaced if damaged. The inspection is to be accomplished within 25 hours TIS or within 180 days from the ASBs' issue date, whichever comes first. Sikorsky has since revised its maintenance manual to incorporate these inspections every 150 hours TIS.

We also reviewed Schweizer Aircraft Service Bulletin B–257.1, dated May 21, 1993 (ASB B–257.1). ASB B–257.1 calls for a one-time inspection to look for drive-shaft defects; installing declutched limit markings on the engine/rotor tachometer to reinforce operating limits; and prohibiting engine declutched operations above 1600 RPM.

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.

Differences Between This AD and the Service Information

The Sikorsky service information calls for the initial inspection to be completed within 180 days or 25 hours TIS. This AD requires that the initial inspection to be completed within 25 hours TIS only. The service information requires contacting Sikorsky if a certain part-numbered driveshaft is installed, emailing information to Sikorsky, and returning damaged parts to Sikorsky; this AD does not.

Costs of Compliance

We estimate that this AD affects 619 helicopters of U.S. Registry and that labor costs average $85 per work hour. Based on these estimates, we expect the following costs:

- We estimate that the visual and magnetic particle inspections of the driveshaft requires 11 work hours for a cost of $935 per helicopter and $578,765 for the U.S. fleet per inspection cycle.
- Replacing the driveshaft, if needed, costs about $4,574 for parts. No additional labor costs are necessary.
- Installing engine and rotor tachometer markings requires 0.5 work-hour for a labor cost of about $43. The cost of parts is minimal.

Interim Action

We consider this AD to be an interim action. The design approval holder is developing a replacement driveshaft that will address the unsafe condition identified in this AD. Once the replacement driveshaft is developed, approved and available, we might consider additional rulemaking.

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

This AD will not have federalism implications under Executive Order 13132. This AD will 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 this AD:

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

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

(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.

We prepared an economic evaluation of the estimated costs to comply with this AD and placed it in the AD docket.

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 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) 93–17–13, Amendment 39–8684 (58 FR 51770, October 5, 1993) and adding the following new AD:

2017–14–06 Sikorsky Aircraft Corporation (Type Certificate Previously Held By Schweizer Aircraft Corporation): Amendment 39–18950; Docket No. FAA–2016–6968; Directorate Identifier 2015–SW–020–AD.

(a) Applicability

This AD applies to Model TH55A, 269A, 269A–1, 269B, 269C and 269C–1 helicopters,

with a lower coupling driveshaft (driveshaft) part number (P/N) 269–5412, 269A5504, 269A5504–003, 269A5504–005, 269A5559, or 269A5559–003 installed, certificated in any category.

(b) Unsafe Condition

This AD defines the unsafe condition as failure of a driveshaft. This condition could result in loss of power to the rotor system and subsequent loss of helicopter control.

(c) Affected ADs

This AD supersedes AD 93–17–13, Amendment 39–8684 (58 FR 51770, October 5, 1993).

(d) Effective Date

This AD becomes effective August 25, 2017.

(e) Compliance

You are responsible for performing each action required by this AD within the specified compliance time unless it has already been accomplished prior to that time.

(f) Required Actions

(1) Within 25 hours time-in-service (TIS), install engine and rotor tachometer markings in accordance with Part II of Schweizer Aircraft Service Bulletin B–257.1, dated May 21, 1993.

(2) Within 25 hours TIS and thereafter at intervals not to exceed 150 hours TIS:

(i) Visually inspect the driveshaft for corrosion, a pit, a nick, a scratch, a dent, and a crack in accordance with the Accomplishment Instructions, paragraph 3.B.(1) through 3.B.(6) of Sikorsky 269C Helicopter Alert Service Bulletin B–307, Basic Issue, dated December 18, 2014 (269C ASB), or Sikorsky 269C–1 Helicopter Alert Service Bulletin C1B–043, Basic Issue, dated December 18, 2014 (269C–1 ASB), whichever is applicable for your model helicopter, except we do not require that you use a Sikorsky recommended vendor list. If there is any corrosion, a pit, a nick, a scratch, a dent, or a crack, replace the driveshaft before further flight.

(ii) If there is no corrosion and no pits, nicks, scratches, dents, and cracks, magnetic particle inspect the driveshaft for a crack in accordance with paragraph 3.C.(1) of the 269C ASB or 269C–1 ASB, whichever is applicable for your model helicopter. This magnetic particle inspection must be performed by a Level II or higher technician with the National Aerospace Standard 410 or equivalent certification who has performed a magnetic particle inspection within the last 12 months. If there is a crack, replace the driveshaft before further flight.

(g) Credit for Actions Previously Completed

Compliance with paragraph (a)(1) of AD 93–17–13, Amendment 39–8684 (58 FR 51770, October 5, 1993) before the effective date of this AD is considered acceptable for compliance with the actions specified in paragraph (f)(1) of this AD.

(h) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Boston Aircraft Certification Office, FAA, may approve AMOCs for this AD. Send your proposal to: Blaine Williams, Aerospace Engineer, Boston Aircraft Certification Office, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, Massachusetts 01803; telephone (781) 238–7161; email *blaine.williams@faa.gov.*

(2) For operations conducted under a 14 CFR part 119 operating certificate or under 14 CFR part 91, subpart K, we suggest that you notify your principal inspector, or lacking a principal inspector, the manager of the local flight standards district office or certificate holding district office before operating any aircraft complying with this AD through an AMOC.

(i) Additional Information

For Schweizer or Sikorsky service information identified in this AD, contact Sikorsky Aircraft Corporation, Customer Service Engineering, 124 Quarry Road, Trumbull, CT 06611; telephone 1–800–Winged–S or 203–416–4299; email *wcs_cust_service_eng.gr-sik@lmco.com.* You may review a copy of information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177.

(j) Subject

Joint Aircraft Service Component (JASC) Code: 6300, Main Rotor Drive System.

(k) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(3) The following service information was approved for IBR on August 25, 2017.

(i) Sikorsky 269C Helicopter Alert Service Bulletin B–307, Basic Issue, dated December 18, 2014.

(ii) Sikorsky 269C–1 Helicopter Alert Service Bulletin C1B–043, Basic Issue, dated December 18, 2014.

(4) The following service information was approved for IBR on October 20, 1993 (58 FR 51770, October 5, 1993).

(i) Schweizer Aircraft Corporation Service Bulletin B–257.1, dated May 21, 1993.

(ii) Reserved.

(5) For Schweizer or Sikorsky service information identified in this AD, contact Sikorsky Aircraft Corporation, Customer Service Engineering, 124 Quarry Road, Trumbull, CT 06611; telephone 1–800–Winged–S or 203–416–4299; email *wcs_cust_service_eng.gr-sik@lmco.com.*

(6) You may view this service information at FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222–5110.

(7) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call (202) 741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued in Fort Worth, Texas, on July 3, 2017.

Scott A. Horn,

Acting Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 2017–15032 Filed 7–20–17; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2016–5443; Directorate Identifier 2016–SW–021–AD; Amendment 39–18884; AD 2017–10–10]

RIN 2120–AA64

Airworthiness Directives; Sikorsky Aircraft Corporation Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for Sikorsky Aircraft Corporation (Sikorsky) Model S–92A helicopters. This AD requires installing an engine flame detector bracket assembly and harness assembly. This AD was prompted by reports of false fire warnings. The actions of this AD are intended to prevent an unsafe condition on these products.

DATES: This AD is effective August 25, 2017.

The Director of the Federal Register approved the incorporation by reference of certain documents listed in this AD as of August 25, 2017.

ADDRESSES: For service information identified in this final rule, contact Sikorsky Aircraft Corporation, Customer Service Engineering, 124 Quarry Road, Trumbull, CT 06611; telephone 1–800–Winged–S or 203–416–4299; email *wcs_cust_service_eng.gr-sik@lmco.com.* You may review a copy of the referenced service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177. It is also available on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–5443.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–5443; or in person at the Docket

Operations Office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, any incorporated-by-reference service information, the economic evaluation, any comments received, and other information. The street address for the Docket Operations Office (phone: 800–647–5527) is U.S. Department of Transportation, Docket Operations Office, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Kristopher Greer, Aerospace Engineer, Boston Aircraft Certification Office, Engine & Propeller Directorate, 1200 District Avenue, Burlington, Massachusetts 01803; telephone (781) 238–7799; email *kristopher.greer@faa.gov.*

SUPPLEMENTARY INFORMATION:

Discussion

On December 27, 2016, at 81 FR 95066, the **Federal Register** published our notice of proposed rulemaking (NPRM), which proposed to amend 14 CFR part 39 by adding an AD that would apply to Sikorsky Model S–92A helicopters, serial numbers 920006 through 920298. The NPRM proposed to require installing a No. 2 engine outboard flame detector bracket assembly (bracket) and a No. 2 engine flame detector harness assembly (harness), if not already installed or if the bracket was not installed before the harness. The proposed AD was prompted by reports of false fire indications from the No. 2 engine outboard flame detectors. The proposed requirements were intended to prevent a false fire warning, which could result in an unnecessary emergency landing or ditching.

Comments

We gave the public the opportunity to participate in developing this AD, but we received no comments on the NPRM.

FAA's Determination

We have reviewed the relevant information and determined that an unsafe condition exists and is likely to exist or develop on other products of these same type designs and that air safety and the public interest require adopting the AD requirements as proposed.

Related Service Information Under 1 CFR Part 51

We reviewed Sikorsky S–92 Customer Service Notice 92–094, Revision B, dated June 14, 2016, which provides procedures for installing harness part number (P/N) 92310–04201–041.

We also reviewed Sikorsky Special Service Instructions No. 92–107G, Revision G, dated February 25, 2016, (SSI No. 92–107G) which specifies installing new brackets, P/N 92070–30033–011, 92070–30033–014, and 92070–30033–015, to increase the stability of the No. 2 engine outboard flame detector.

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**.

Other Related Service Information

We reviewed Sikorsky S–92 Alert Service Bulletin (ASB) 92–26–006, Basic Issue, dated February 25, 2016. This service information provides instructions for installing a new bracket by complying with SSI No. 92–107G. We also reviewed S–92 ASB 92–26–007, Basic Issue, dated June 14, 2016. This service information specifies installing harness P/N 92310–04201–041 after or concurrently with the new bracket.

Costs of Compliance

We estimate that this AD affects 50 helicopters of U.S. Registry and that labor costs average $85 per work-hour. Based on these estimates, we expect that installing a new bracket and harness requires 15.25 work hours for a labor cost of about $1,296. Parts cost $100 for a total cost of about $1,396 per helicopter and $69,800 for the U.S. fleet.

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

This AD will not have federalism implications under Executive Order 13132. This AD will 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 this AD:

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

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

(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.

We prepared an economic evaluation of the estimated costs to comply with this AD and placed it in the AD docket.

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

2017–10–10 Sikorsky Aircraft Corporation: Amendment 39–18884; Docket No. FAA–2016–5443; Directorate Identifier 2016–SW–021–AD.

(a) Applicability

This AD applies to Sikorsky Aircraft Corporation (Sikorsky) Model S–92A helicopters, serial numbers 920006 through 920298, certificated in any category.

(b) Unsafe Condition

This AD defines the unsafe condition as a false fire warning. This condition could result in an unnecessary emergency landing or ditching.

(c) Effective Date

This AD becomes effective August 25, 2017.

(d) Compliance

You are responsible for performing each action required by this AD within the

specified compliance time unless it has already been accomplished prior to that time.

(e) Required Actions

Within 180 hours time-in-service:

(1) For helicopters with a No. 2 engine outboard flame detector bracket assembly (bracket) (either part number (P/N) 92070–30033–014, or both P/N 92070–30033–011 and 92070–30033–015) installed, and with a No. 2 engine flame detector harness assembly (harness) P/N 92310–04201–041 installed: If the harness was installed before the bracket, replace the harness.

(2) For helicopters with a bracket (either P/N 92070–30033–014, or both P/N 92070–30033–011 and 92070–30033–015) installed, and without a harness P/N 92310–04201–041 installed: Remove the harness and install harness P/N 92310–04201–041 by following the Accomplishment Instructions, section 3.C.1, of Sikorsky S–92 Customer Service Notice 92–094, Revision B, dated June 14, 2016 (CSN 92–094).

(3) For helicopters without a bracket (either P/N 92070–30033–014, or both P/N 92070–30033–011 and 92070–30033–015) installed, and with a harness P/N 92310–04201–041 installed:

(i) Install a bracket P/N 92070–30033–014 by following the Instructions, paragraph D, of Sikorsky Special Service Instructions No. 92–107G, Revision G, dated February 25, 2016 (SSI 92–107G).

(ii) Replace the harness.

(4) For helicopters without a bracket (either P/N 92070–30033–014, or both P/N 92070–30033–011 and 92070–30033–015) installed, and without a harness P/N 92310–04201–041 installed:

(i) Install a bracket P/N 92070–30033–014 by following the Instructions, paragraph D, of SSI 92–107G.

(ii) Remove the harness and install harness P/N 92310–04201–041 by following the Accomplishment Instructions, section 3.C.1, of CSN 92–094.

(f) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Boston Aircraft Certification Office, FAA, may approve AMOCs for this AD. Send your proposal to: Kristopher Greer, Aerospace Engineer, Boston Aircraft Certification Office, Engine & Propeller Directorate, 1200 District Avenue, Burlington, Massachusetts 01803; telephone (781) 238–7799; email *kristopher.greer@faa.gov.*

(2) For operations conducted under a 14 CFR part 119 operating certificate or under 14 CFR part 91, subpart K, we suggest that you notify your principal inspector, or lacking a principal inspector, the manager of the local flight standards district office or certificate holding district office before operating any aircraft complying with this AD through an AMOC.

(g) Additional Information

Sikorsky S–92 Alert Service Bulletin 92–26–006, Basic Issue, dated February 25, 2016, and Sikorsky S–92 Alert Service Bulletin 92–26–007, Basic Issue, dated June 14, 2016, which are not incorporated by reference, contain additional information about the subject of this AD. For service information identified in this AD, contact Sikorsky Aircraft Corporation, Customer Service Engineering, 124 Quarry Road, Trumbull, CT 06611; telephone 1–800–Winged–S or 203–416–4299; email *wcs_cust_service_eng.grsik@lmco.com.* You may review a copy of this service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177.

(h) Subject

Joint Aircraft Service Component (JASC) Code: 2612, Fire Detection.

(i) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(i) Sikorsky S–92 Customer Service Notice 92–094, Revision B, dated June 14, 2016.

(ii) Sikorsky Special Service Instructions No. 92–107G, Revision G, dated February 25, 2016.

(3) For Sikorsky service information identified in this AD, contact Sikorsky Aircraft Corporation, Customer Service Engineering, 124 Quarry Road, Trumbull, CT 06611; telephone 1–800–Winged–S or 203–416–4299; email *wcs_cust_service_eng.grsik@lmco.com.*

(4) You may view this service information at FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkw., Room 6N–321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222–5110.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call (202) 741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued in Fort Worth, Texas, on May 5, 2017.

Scott A. Horn,

Acting Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 2017–15033 Filed 7–20–17; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2016–9501; Directorate Identifier 2016–NM–137–AD; Amendment 39–18961; AD 2017–15–01]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for certain The Boeing Company Model 777 airplanes. This AD was prompted by reports of uncommanded altitude display changes in the mode control panel (MCP) altitude window. This AD requires replacing the existing MCP with a new MCP having a different part number. We are issuing this AD to address the unsafe condition on these products.

DATES:

This AD is effective August 25, 2017.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of August 25, 2017.

ADDRESSES: For service information identified in this final rule, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminster Blvd., MC 110–SK57, Seal Beach, CA 90740–5600; telephone 562–797–1717; Internet *https://www.myboeingfleet.com.* You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221. It is also available on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–9501.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–9501; 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 AD, the regulatory evaluation, any comments received, and other information. The address for the Docket Office (phone: 800–647–5527) is Docket Management Facility, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Frank Carreras, Aerospace Engineer, Systems and Equipment Branch, ANM–130S, FAA, Seattle Aircraft Certification Office (ACO), 1601 Lind Avenue SW., Renton, WA 98057–3356; phone: 425–917–6442; fax: 425–917–6590; email: *frank.carreras@faa.gov.*

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to certain The Boeing Company Model 777 airplanes. The NPRM published in the **Federal Register** on December 20, 2016 (81 FR 92740) (''the NPRM''). The NPRM was prompted by reports of uncommanded altitude display changes in the MCP altitude window. The NPRM proposed to require replacing the existing MCP with a new MCP having a different part number. We are issuing this AD to prevent uncommanded changes to the MCP selected at altitude; such uncommanded changes could result in incorrect spatial separation between airplanes, midair collision, or controlled flight into terrain.

Comments

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

Support for the NPRM

Boeing and FedEx stated that they concur with the contents of the NPRM.

Request To Reduce the Compliance Time

Air Line Pilots Association, International (ALPA), indicated its support for the NPRM but requested that the compliance time in paragraph (g) of the proposed AD be reduced from 60 months to 50 months. The commenter did not provide justification for its request.

We do not agree with the commenter's request to reduce the compliance time. In developing an appropriate compliance time, we considered the safety implications and the availability of required parts. In addition, we also received manufacturer concurrence for the 60-month compliance time. In consideration of all of these factors, we determined that the compliance time, as proposed, represents an appropriate interval in which the MCP parts can be replaced in a timely manner within the fleet, while still maintaining an adequate level of safety. For most ADs, operators are permitted to accomplish the requirements at a time earlier than the specified compliance time; for this AD, an operator may choose to replace the affected MCP at any time up to 60 months after the effective date of this AD. If additional data are presented that would justify a shorter compliance time, we might consider further rulemaking on this issue. We have not changed this AD in this regard.

Request To Revise the Applicability

United Airlines (UAL) requested that the applicability of the proposed AD be limited to only those MCP series parts on which the uncommanded changes in the speed/mach window occurred. The commenter noted that the NPRM did not indicate if the uncommanded changes were reported on all three MCP series parts (MCP–770, MCP–771, and MCP–770C) or only one MCP series part. The commenter suggested that if the uncommanded changes occurred only on one MCP series part, then the applicability of the proposed AD should be limited to that particular MCP series part. The commenter observed that this would reduce the number of MCP parts that need to be replaced or upgraded and reduce the compliance time needs.

We agree that clarification is necessary regarding the affected MCP series parts. Based on the manufacturer's installation review, the unsafe condition has been identified to exist in all three MCP series parts. Therefore, no change to this AD is required regarding this issue.

Request To Review the MCP Design

One commenter, Geoffrey Barrance, noted that the FAA has issued AD 2016–25–01, Amendment 39–18727 (81 FR 94949, December 27, 2016), which addressed uncommanded autopilot engagement before takeoff. The commenter thought that there was a similarity in the root causes (malfunction of the MCP) of the unsafe conditions in AD 2016–25–01 and this final rule. The commenter recommended that the FAA initiate a review of the MCP design, including changes that might have been introduced over the life of these units, to identify if the design was initially susceptible to, or has been subsequently compromised in a way that could result in the unsafe conditions of both ADs.

We infer the commenter may think the unsafe condition associated with AD 2016–25–01 resulted from a similar root cause as the unsafe condition addressed by this AD based on a statement in the Discussion section of the NPRM (80 FR 79735, December 23, 2015) associated with AD 2016–25–01. That statement noted that ''the erroneous autopilot engage request is believed to have come from the mode control panel (MCP) and to have been caused by contamination within the MCP.'' During the public comment period for the NPRM associated with AD 2016–25–01, Boeing stated that this statement was speculative and requested that the FAA remove it and replace it with a statement that possible failures in the autopilot flight director system can cause an uncommanded engagement of the autopilot. We agreed the replacement statement would be less speculative; however, because the Discussion section of an NPRM is not repeated in the final rule, AD 2016–25–01 was not revised.

We do not agree with the commenter's request because we have determined that there is no similarity in the root cause of the unsafe condition of AD 2016–25–01 and this AD. The unsafe condition identified in AD 2016–25–01 is different from the unsafe condition identified in this final rule. AD 2016–25–01 addresses uncommanded autopilot engagement on the ground, potentially resulting in incorrect stabilizer trim adjustment during takeoff. This final rule addresses uncommanded altitude display changes in the MCP while the autopilot is engaged. We have not changed this AD regarding this issue.

Requests To Revise the Estimated Costs of Compliance

Cathay Pacific Airlines asked why operators are being charged for the parts and labor associated with compliance with the proposed AD if the unsafe condition is the result of a design flaw (the problematic MCP–770 part) that could not be detected during flight tests or the design phase. We infer that the commenter is requesting that either the estimated costs of the proposed AD be revised or the manufacturer's warranty coverage.

We do not agree to revise the cost estimates. We do not control the manufacturer's warranty coverage. We have identified an unsafe condition that must be corrected to ensure that airplanes are operated in an airworthy condition, as required by the Federal Aviation Regulations. We have not changed this AD in regard to this issue.

UAL requested a revision to the estimated costs of the proposed AD because the estimated costs provided are too low. UAL stated that only MCP–770C can be upgraded and all other MCP series parts would need to be replaced. UAL observed that its estimated fleet cost would exceed $8,000,000.

We do not agree with the commenter's request. We acknowledge that the cost estimate does not include the cost of a new MCP. The estimated costs in the NPRM were based on data provided in Boeing Special Attention Service Bulletin 777–22–0034, dated March 3, 2016. The cost section of the NPRM indicated that we have received no definitive data regarding the cost of a new MCP. Although UAL provided a

cost estimate for its fleet, we still have not received a definitive cost estimate for a new MCP. We have not changed this AD regarding this issue.

Conclusion

We reviewed the relevant data, considered the comments received, and determined that air safety and the public interest require adopting this AD as proposed except for minor editorial changes. We have determined that these minor changes:

• Are consistent with the intent that was proposed in the NPRM for correcting the unsafe condition; and

• Do not add any additional burden upon the public than was already proposed in the NPRM.

We also determined that these changes will not increase the economic burden on any operator or increase the scope of this AD.

Related Service Information Under 1 CFR Part 51

We reviewed Boeing Special Attention Service Bulletin 777–22–0034, dated March 3, 2016. The service information describes procedures for replacing the existing MCP part with a new MCP part having a different part number, in the glareshield in the flight compartment. 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.

Costs of Compliance

We estimate that this AD affects 203 airplanes of U.S. registry. We estimate the following costs to comply with this AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Replacement	2 work-hours × $85 per hour = $170	Up to $5,800[1]	Up to $5,970	Up to $1,211,910.[1]

[1] Since we have received no definitive data regarding the cost of a new MCP we have provided costs for the upgrade (modified part) only.

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

This AD will not have federalism implications under Executive Order 13132. This AD will 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 this AD:

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

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

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

(4) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

2017–15–01 The Boeing Company: Amendment 39–18961; Docket No. FAA–2016–9501; Directorate Identifier 2016–NM–137–AD.

(a) Effective Date

This AD is effective August 25, 2017.

(b) Affected ADs

None.

(c) Applicability

This AD applies to The Boeing Company Model 777–200, –200LR, –300, –300ER, and 777F series airplanes, certificated in any category, identified in Boeing Special Attention Service Bulletin 777–22–0034, dated March 3, 2016.

(d) Subject

Air Transport Association (ATA) of America Code 22; Auto flight.

(e) Unsafe Condition

This AD was prompted by reports of uncommanded altitude display changes in the mode control panel (MCP) altitude window. We are issuing this AD to prevent uncommanded changes to the MCP selected altitude; such uncommanded changes could result in incorrect spatial separation between airplanes, midair collision, or controlled flight into terrain.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Replacement of MCP

Within 60 months after the effective date of this AD: Replace the existing MCP part with a new MCP part having a different part number, in accordance with the Accomplishment Instructions of Boeing Special Attention Service Bulletin 777–22–0034, dated March 3, 2016.

(h) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Seattle Aircraft Certification Office (ACO), FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the ACO, send it to the attention of the person identified in paragraph (i) of this AD. Information may be emailed to: *9-ANM-Seattle-ACO-AMOC-Requests@faa.gov.*

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

(3) An AMOC that provides an acceptable level of safety may be used for any repair, modification, or alteration required by this AD if it is approved by the Boeing Commercial Airplanes Organization Designation Authorization (ODA) that has been authorized by the Manager, Seattle ACO, to make those findings. To be approved, the repair method, modification deviation, or alteration deviation must meet the certification basis of the airplane, and the approval must specifically refer to this AD.

(4) For service information that contains steps that are labeled as Required for Compliance (RC), the provisions of paragraphs (h)(4)(i) and (h)(4)(ii) of this AD apply.

(i) The steps labeled as RC, including substeps under an RC step and any figures identified in an RC step, must be done to comply with the AD. If a step or substep is labeled ''RC Exempt,'' then the RC requirement is removed from that step or substep. An AMOC is required for any deviations to RC steps, including substeps and identified figures.

(ii) Steps not labeled as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the RC steps, including substeps and identified figures, can still be done as specified, and the airplane can be put back in an airworthy condition.

(i) Related Information

For more information about this AD, contact Frank Carreras, Aerospace Engineer, Systems and Equipment Branch, ANM–130S, FAA, Seattle ACO, 1601 Lind Avenue SW., Renton, WA 98057–3356; phone: 425–917–6442; fax: 425–917–6590; email: *frank.carreras@faa.gov.*

(j) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(i) Boeing Special Attention Service Bulletin 777–22–0034, dated March 3, 2016.

(ii) Reserved.

(3) For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Data & Services Management, P.O. Box 3707, MC 2H–65, Seattle, WA 98124–2207; telephone: 206–544–5000, extension 1; fax: 206–766–5680; Internet: *https://www.myboeingfleet.com.*

(4) You may view this service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued in Renton, Washington, on July 7, 2017.

Dionne Palermo,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2017–14929 Filed 7–20–17; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2016–9516; Directorate Identifier 2016–NM–053–AD; Amendment 39–18964; AD 2017–15–04]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for certain The Boeing Company Model 787–8 and 787–9 airplanes. This AD was prompted by wire harness chafing on the electro-mechanical actuators (EMAs) for certain spoilers due to insufficient separation with adjacent structure. This AD requires replacement of affected EMAs. We are issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective August 25, 2017.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of August 25, 2017.

ADDRESSES: For service information identified in this final rule, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminster Blvd., MC 110–SK57, Seal Beach, CA 90740–5600; telephone 562–797–1717; Internet *https://www.myboeingfleet.com.* You may view this service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221. It is also available on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–9516.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–9516; 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 final rule, the regulatory evaluation, any comments received, and other information. The address for the Docket Office (phone: 800–647–5527) is Docket Management Facility, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Sean Schauer, Aerospace Engineer, Systems and Equipment Branch, ANM–130S, FAA, Seattle Aircraft Certification Office (ACO), 1601 Lind Avenue SW., Renton, WA 98057–3356; phone: 425–917–6479; fax: 425–917–6590; email: *sean.schauer@faa.com.*

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to certain The Boeing Company Model 787–8 and 787–9 airplanes. The NPRM published in the **Federal Register** on December 28, 2016 (81 FR 95536) (''the NPRM''). The NPRM was prompted by wire harness chafing on the EMAs for certain spoilers due to insufficient separation with adjacent structure. The NPRM proposed to require replacement of affected EMAs. We are issuing this AD to prevent chafing and consequent wire damage that could result in a potential source of ignition in the flammable leakage zone and a consequent fire or explosion.

Comments

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

Support for the NPRM

Boeing indicated its support for the intent of the NPRM.

Request To Reduce Compliance Time

The Air Line Pilots Association, International, (ALPA), supported the intent of the NPRM but asked that the compliance time in the proposed AD be reduced from 40 to 20 months. The commenter stated that the NPRM's 40-month compliance time, combined with the release date of Boeing Service Bulletin B787–81205–SB270030–00, Issue 001, dated October 22, 2015, would provide operators in excess of 56

months to comply. ALPA stated that it believes that operators have had sufficient time to schedule the proposed maintenance procedures, and recommended the shorter compliance time, which would provide an overall timeframe of 36 months from the release date of Boeing Service Bulletin B787–81205–SB270030–00, Issue 001, dated October 22, 2015, to resolve the issue.

We do not agree with the commenter's request to reduce the compliance time. In developing an appropriate compliance time for this action, we considered the safety implications, parts availability, and normal maintenance schedules for timely accomplishment of replacement of the EMAs. Further, we arrived at the proposed compliance time with the manufacturer's concurrence. In consideration of all of these factors, we determined that the compliance time, as proposed, represents an appropriate interval in which the EMA can be replaced in a timely manner within the fleet, while still maintaining an adequate level of safety. Most ADs, including this one, permit operators to accomplish the requirements of an AD at a time earlier than the specified compliance time; therefore, an operator may choose to replace the EMA at any time within the 40-month compliance time. If additional data are presented that would justify a shorter compliance time, we may consider further rulemaking on this issue. We have not changed the AD in this regard.

Request To Extend Compliance Time

United Airlines (UA) asked that the compliance time in the proposed AD be extended. UA stated that considering the extensive ground time required for implementing the corrective action, additional time is necessary.

We do not agree with the commenter's request to extend the compliance time. UA did not suggest an alternative compliance time. In developing an appropriate compliance time for this action, we considered the safety implications, parts availability, and normal maintenance schedules for the timely accomplishment of the replacement. In consideration of these items, we have determined that a 40-month compliance time will ensure an acceptable level of safety and allow the replacements to be done during scheduled maintenance intervals for most affected operators. We have not changed the AD in this regard.

Conclusion

We reviewed the relevant data, considered the comments received, and determined that air safety and the public interest require adopting this AD as proposed, except for minor editorial changes. We have determined that these minor changes:

- Are consistent with the intent that was proposed in the NPRM for correcting the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the NPRM.

Related Service Information Under 1 CFR Part 51

We reviewed Boeing Service Bulletin B787–81205–SB270030–00, Issue 001, dated October 22, 2015. The service information describes procedures for replacing affected EMAs with new EMAs. 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.

Costs of Compliance

We estimate that this AD affects 19 airplanes of U.S. registry. We estimate the following costs to comply with this AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
EMA replacement	32 work-hours × $85 per hour = $2,720 per EMA replacement.	[1] $0	$2,720	$51,680

[1] Parts cost is not included in the service information, but Boeing has indicated that existing parts can be modified to become the new parts.

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

This AD will not have federalism implications under Executive Order 13132. This AD will 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 this AD:

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

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

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

(4) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

2017–15–04 The Boeing Company: Amendment 39–18964; Docket No.

FAA–2016–9516; Directorate Identifier 2016–NM–053–AD.

(a) Effective Date

This AD is effective August 25, 2017.

(b) Affected ADs

None.

(c) Applicability

This AD applies to The Boeing Company Model 787–8 and 787–9 airplanes, certificated in any category, as identified in Boeing Service Bulletin B787–81205–SB270030–00, Issue 001, dated October 22, 2015.

(d) Subject

Air Transport Association (ATA) of America Code 27, Flight controls.

(e) Unsafe Condition

This AD was prompted by wire harness chafing on the electro-mechanical actuators (EMAs) for certain spoilers due to insufficient separation with adjacent structure. We are issuing this AD to prevent chafing and consequent wire damage that could result in a potential source of ignition in the flammable leakage zone and a consequent fire or explosion.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) EMA Replacement

Within 40 months after the effective date of this AD, replace the EMAs with new EMAs, in accordance with the Accomplishment Instructions of Boeing Service Bulletin B787–81205–SB270030–00, Issue 001, dated October 22, 2015.

(h) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Seattle Aircraft Certification Office (ACO), FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the ACO, send it to the attention of the person identified in paragraph (i) of this AD. Information may be emailed to: *9-ANM-Seattle-ACO-AMOC-Requests@faa.gov.*

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

(3) An AMOC that provides an acceptable level of safety may be used for any repair, modification, or alteration required by this AD if it is approved by the Boeing Commercial Airplanes Organization Designation Authorization (ODA) that has been authorized by the Manager, Seattle ACO, to make those findings. To be approved, the repair method, modification deviation, or alteration deviation must meet the certification basis of the airplane, and the approval must specifically refer to this AD.

(4) For service information that contains steps that are labeled as Required for Compliance (RC), the provisions of paragraphs (h)(4)(i) and (h)(4)(ii) of this AD apply.

(i) The steps labeled as RC, including substeps under an RC step and any figures identified in an RC step, must be done to comply with the AD. If a step or substep is labeled ''RC Exempt,'' then the RC requirement is removed from that step or substep. An AMOC is required for any deviations to RC steps, including substeps and identified figures.

(ii) Steps not labeled as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the RC steps, including substeps and identified figures, can still be done as specified, and the airplane can be put back in an airworthy condition.

(i) Related Information

For more information about this AD, contact Sean Schauer, Aerospace Engineer, Systems and Equipment Branch, ANM–130S, FAA, Seattle ACO, 1601 Lind Avenue SW., Renton, WA 98057–3356; phone: 425–917–6479; fax: 425–917–6590; email: *sean.schauer@faa.com.*

(j) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(i) Boeing Service Bulletin B787–81205–SB270030–00, Issue 001, dated October 22, 2015.

(ii) Reserved.

(3) For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminster Blvd., MC 110–SK57, Seal Beach, CA 90740–5600; telephone 562–797–1717; Internet *https://www.myboeingfleet.com.*

(4) You may view this service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued in Renton, Washington, on July 12, 2017.

Dionne Palermo,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2017–15121 Filed 7–20–17; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2016–9572; Directorate Identifier 2016–NM–151–AD; Amendment 39–18963; AD 2017–15–03]

RIN 2120–AA64

Airworthiness Directives; Airbus Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: We are superseding Airworthiness Directive (AD) 2014–08–02 which applied to certain Airbus Model A300 B4–600 and A300 B4–600R series airplanes. AD 2014–08–02 required modifying the profile of stringer run-outs of both wings, including a high frequency eddy current (HFEC) inspection of the fastener holes for defects, and repairs if necessary. This new AD retains the actions required by AD 2014–08–02 and revises the compliance times. This AD was prompted by further analysis in the context of widespread fatigue damage (WFD), which concluded that shorter compliance times are necessary to meet specified requirements to address WFD. We are issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective August 25, 2017.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of August 25, 2017.

The Director of the Federal Register approved the incorporation by reference of a certain other publication listed in this AD as of May 21, 2014 (79 FR 21392, April 16, 2014).

ADDRESSES: For service information identified in this final rule, contact Airbus SAS, Airworthiness Office—EAW, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 44 51; email *account.airworth-eas@airbus.com;* Internet *http://www.airbus.com.* You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221. It is also available on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–9572.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–9572; 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 AD, the regulatory evaluation, any comments received, and other information. The address for the Docket Office (telephone 800–647–5527) is Docket Management Facility, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Dan Rodina, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, WA 98057–3356; telephone 425–227–2125; fax 425–227–1149.

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to supersede AD 2014–08–02, Amendment 39–17826 (79 FR 21392, April 16, 2014) (''AD 2014–08–02''). AD 2014–08–02 applied to certain Airbus Model A300 B4–600 and A300 B4–600R series airplanes. The NPRM published in the **Federal Register** on March 13, 2017 (82 FR 13405). The NPRM was prompted by further analysis in the context of WFD, which concluded that a shorter compliance time is necessary to meet specified requirements to address WFD. The NPRM proposed to continue to require modifying the profile of stringer run-outs of both wings, including a high frequency eddy current inspection of the fastener holes for defects, and repairs if necessary. The NPRM also proposed to require a revised compliance time for these actions. We are issuing this AD to prevent cracking in the bottom wing skin stringers, which could result in reduced structural integrity of the wings.

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union, has issued EASA Airworthiness Directive 2016–0174, dated August 30, 2016 (referred to after this as the Mandatory Continuing Airworthiness Information, or ''the MCAI''), to correct an unsafe condition for certain Airbus Model A300 B4–600 and A300 B4–600R series airplanes. The MCAI states:

During full-scale fatigue testing, cracks were detected in the bottom wing skin stringers at Rib 14. In addition, operators have also reported finding cracks in the same area on in-service aeroplanes.

This condition, if not detected and corrected, could impair the structural integrity of the wings.

Additional analysis results showed that the improved design of the stringer run-out was necessary for aeroplanes operating beyond the Extended Service Goal 1.

To address this unsafe condition, Airbus issued Service Bulletin (SB) A300–57–6046 Revision 01 to provide modification instructions, and EASA issued AD 2013–0008 (later revised) [which corresponds to FAA AD 2014–08–02], to require the removal of the stringer end run-out plate at stringer 19 on the bottom wing skin and a re-profiling modification of the stringers 10, 11, 12, 17 and 19.

Since that [EASA] AD was issued, further analysis in the context of Widespread Fatigue Damage (WFD), concluded that a threshold reduction is necessary to meet the WFD requirements. Consequently, Airbus revised SB A300–57–6046 accordingly (now at Revision 03).

For the reasons described above, this [EASA] AD retains the requirements of EASA AD 2013–0008R1, which is superseded, but reduces the modification threshold, and introduces a pre-mod High Frequency Eddy Current (HFEC) inspection.

You may examine the MCAI in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–9572.

Comments

We gave the public the opportunity to participate in developing this AD. We considered the comment received. FedEx Express had no objection to the NPRM.

Conclusion

We reviewed the available data, including the comment received, and determined that air safety and the public interest require adopting this AD as proposed except for minor editorial changes. We have determined that these minor changes:

- Are consistent with the intent that was proposed in the NPRM for correcting the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the NPRM.

Related Service Information Under 1 CFR Part 51

We reviewed Airbus Service Bulletin A300–57–6046, Revision 03, including Appendix 01, dated February 4, 2015. The service information describes procedures to modify the profile of stringer run-outs of both wings, including a HFEC inspection of the fastener holes for defects, and repairs. It also describes new compliance times for completing the modifications. 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.

Costs of Compliance

We estimate that this AD affects 29 airplanes of U.S. registry.

The actions required by AD 2014–08–02, and retained in this AD, take about 63 work-hours per product, at an average labor rate of $85 per work-hour. Required parts cost about $2,360 per product. Based on these figures (accounting for updated work-hour and parts cost estimates), the estimated cost of this AD on U.S. operators is $7,715 per product.

We have received no definitive data that would enable us to provide cost estimates for any on-condition actions specified in this AD. We have no way of determining the number of aircraft that might need these repairs.

Authority for This Rulemaking

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

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

Regulatory Findings

We determined that this AD will not have federalism implications under Executive Order 13132. This AD will 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 this AD:

1. Is not a ''significant regulatory action'' under Executive Order 12866;

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

3. Will not affect intrastate aviation in Alaska; and

4. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 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) 2014–08–02, Amendment 39–17826 (79 FR 21392, April 16, 2014), and adding the following new AD:

2017–15–03 Airbus: Amendment 39–18963; Docket No. FAA–2016–9572; Directorate Identifier 2016–NM–151–AD.

(a) Effective Date

This AD is effective August 25, 2017.

(b) Affected ADs

This AD replaces AD 2014–08–02, Amendment 39–17826 (79 FR 21392, April 16, 2014) (''AD 2014–08–02'').

(c) Applicability

This AD applies to Airbus Model A300–B4–601, B4–603, B4–620, and B4–622 airplanes, and Model A300–B4–605R and B4–622R airplanes, certificated in any category, except airplanes on which Airbus Modification 10324 or 10325 has been embodied in production.

(d) Subject

Air Transport Association (ATA) of America Code 57, Wings.

(e) Reason

This AD was prompted by an evaluation by the design approval holder indicating that certain wing skin stringers are subject to widespread fatigue damage. We are issuing this AD to prevent cracking in the bottom wing skin stringers, which could result in reduced structural integrity of the wings.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Retained Modification of Rib 14, With Revised Compliance Time and Service Information

This paragraph restates the requirements of paragraph (g) of AD 2014–08–02, with revised compliance times and service information. At the time specified in paragraph (g)(1) or (g)(2) of this AD, whichever occurs earlier, modify the profile of stringer run-outs at rib 14 of both wings, including a high frequency eddy current inspection of the fastener holes for defects and all applicable repairs, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A300–57–6046, Revision 02, dated June 21, 2013; or Revision 03, including Appendix 01, dated February 4, 2015; except as required by paragraph (h) of this AD. Do all applicable repairs before further flight. As of the effective date of this AD, only Airbus Service Bulletin A300–57–6046, Revision 03, including Appendix 01, dated February 4, 2015, may be used.

(1) Before the accumulation of 42,500 total flight cycles, or within 2,000 flight cycles after May 21, 2014 (the effective date of AD 2014–08–02), whichever occurs later.

(2) Before the accumulation of 30,000 total flight cycles, or within 2,000 flight cycles after the effective date of this AD, whichever occurs later.

(h) Retained Exception to the Service Information, With Revised Service Information

This paragraph restates the requirements of paragraph (h) of AD 2014–08–02, with revised service information.

(1) Where Airbus Mandatory Service Bulletin A300–57–6046, Revision 02, dated June 21, 2013, specifies to contact Airbus for repair instructions, this AD requires contacting the Manager, ANM–116, International Branch, Transport Airplane Directorate, FAA, or the European Aviation Safety Agency (EASA) (or its delegated agent) for repair instructions and doing those repairs before further flight.

(2) Where Airbus Service Bulletin A300–57–6046, Revision 03, including Appendix 01, dated February 4, 2015, specifies to contact Airbus for appropriate action: Before further flight, accomplish corrective actions in accordance with the procedures specified in paragraph (j)(2) of this AD.

(i) Credit for Previous Actions

This paragraph provides credit for actions required by paragraph (g) of this AD, if those actions were performed before the effective date of this AD using the service information specified in paragraph (i)(1), (i)(2), or (i)(3) of this AD.

(1) Airbus Service Bulletin A300–57–6046, dated January 18, 1994, which is not incorporated by reference in this AD.

(2) Airbus Service Bulletin A300–57–6046, Revision 01, dated April 18, 2011, which is not incorporated by reference in this AD.

(3) Airbus Service Bulletin A300–57–6046, Revision 02, dated June 21, 2013, which was incorporated by reference in AD 2014–08–02.

(j) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the International Branch, send it to the attention of the person identified in paragraph (k)(2) of this AD. Information may be emailed to: *9-ANM-116-AMOC-REQUESTS@faa.gov.* Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(2) *Contacting the Manufacturer:* As of the effective date of this AD, for any requirement in this AD to obtain corrective actions from a manufacturer, the action must be accomplished using a method approved by the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA; or EASA; or Airbus's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(3) *Required for Compliance (RC):* Except as required by paragraph (h) of this AD: If any service information contains procedures or tests that are identified as RC, those procedures and tests must be done to comply with this AD; any procedures or tests that are not identified as RC are recommended. Those procedures and tests that are not identified as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the procedures and tests identified as RC can be done and the airplane can be put back in an airworthy condition. Any substitutions or changes to procedures or tests identified as RC require approval of an AMOC.

(k) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) EASA Airworthiness Directive 2016–0174, dated August 30, 2016, for related information. This MCAI may be found in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–9572.

(2) For more information about this AD, contact Dan Rodina, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, WA 98057–3356; telephone 425–227–2125; fax 425–227–1149.

(3) Service information identified in this AD that is not incorporated by reference is available at the addresses specified in paragraphs (l)(4) and (l)(5) of this AD.

(l) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless this AD specifies otherwise.

(3) The following service information was approved for IBR on August 25, 2017.

(i) Airbus Service Bulletin A300–57–6046, Revision 03, including Appendix 01, dated February 4, 2015.

(ii) Reserved.

(4) For service information identified in this AD, contact Airbus SAS, Airworthiness Office—EAW, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 44 51; email *account.airworth-eas@airbus.com;* Internet *http://www.airbus.com.*

(5) You may view this service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

(6) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued in Renton, Washington, on July 11, 2017.

Dionne Palermo,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2017–15119 Filed 7–20–17; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2016–9480; Airspace Docket No. 16–AEA–13]

Amendment of Class D and Class E Airspace; Morgantown, WV

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action amends Class E airspace designated as an extension to a Class D surface area by removing the Notice to Airmen (NOTAM) part-time status at Morgantown Municipal Airport-Walter L. Bill Hart Field, Morgantown, WV, and updating the airport's geographic coordinates. Also, this action updates the geographic coordinates of the airport listed in Class D airspace, Class E surface area airspace, and Class E 700 foot airspace. This action enhances the safety and management of instrument flight rules (IFR) operations at the airport.

DATES: Effective 0901 UTC, October 12, 2017. The Director of the Federal Register approves this incorporation by reference action under title 1, Code of Federal Regulations, part 51, subject to the annual revision of FAA Order 7400.11 and publication of conforming amendments.

ADDRESSES: FAA Order 7400.11A, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *http://www.faa.gov/air_traffic/publications/.* For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591; telephone: (202) 267–8783. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order 7400.11A at NARA, call (202) 741–6030, or go to *http://www.archives.gov/federal_register/code_of_federal-regulations/ibr_locations.html.*

FAA Order 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

FOR FURTHER INFORMATION CONTACT: John Fornito, Operations Support Group, Eastern Service Center, Federal Aviation Administration, P.O. Box 20636, Atlanta, Georgia 30320; telephone (404) 305–6364.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. 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. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it amends Class D and Class E airspace at Morgantown Municipal Airport-Walter L. Bill Hart Field, Morgantown, WV, in support of IFR operations at the airport.

History

On April 7, 2017, the FAA published in the **Federal Register** (82 FR 16958) Docket No. FAA–2016–9480, a notice of proposed rulemaking (NPRM) to amend Class E airspace designated as an extension to a Class D surface area at Morgantown Municipal Airport-Walter L. Bill Hart Field, Morgantown, WV, by removing the NOTAM part-time status of the Class E airspace designated as an extension to a Class D surface area. Also, the geographic coordinates of the airport would be adjusted in the associated Class D and E airspace. Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. No comments were received.

This action also makes an editorial change to the associated Class D and E airspace legal descriptions removing the words ''(previously called Airport/Facility Directory). Except for this change, the rule is the same as published in the NPRM.

Class D and E airspace designations are published in paragraphs 5000, 6002, 6004, and 6005, respectively, of FAA Order 7400.11A dated August 3, 2016, and effective September 15, 2016, which is incorporated by reference in 14 CFR part 71.1. The Class D and E airspace designations listed in this document will be published subsequently in the Order.

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order 7400.11A, Airspace Designations and Reporting Points, dated August 3, 2016, and effective September 15, 2016. FAA Order 7400.11A is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.11A lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

This amendment to Title 14, Code of Federal Regulations (14 CFR) part 71 amends Class E Airspace designated as an extension to a Class D surface area at Morgantown Municipal Airport-Walter L. Bill Hart Field, Morgantown, WV, by eliminating the NOTAM information from the regulatory text that reads, ''This Class E airspace area is effective during the specific dates and time established in advance by Notice to Airmen. The effective date and time will thereafter be continuously published in the Airport/Facility Directory.'' This action also amends Class D airspace, Class E surface area airspace, and Class E airspace extending upward from 700 feet or more above the surface by updating the geographic coordinates of the airport to be in concert with the FAA's aeronautical database.

Additionally, this action removes the words ''(previously called Airport/Facility Directory)'' from the associated

Class D and E airspace legal descriptions.

Regulatory Notices and Analyses

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

Environmental Review

The FAA has determined that this action qualifies for categorical exclusion under the National Environmental Policy Act in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures,'' paragraph 5–6.5a. This airspace action is not expected to cause any potentially significant environmental impacts, and no extraordinary circumstances exist that warrant preparation of an environmental assessment.

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the FAA amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120, E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.11A, Airspace Designations and Reporting Points, dated August 3, 2016, effective September 15, 2016, is amended as follows:

Paragraph 5000 Class D Airspace.

* * * * *

AEA WV D Morgantown, WV [Amended]

Morgantown Municipal Airport-Walter L. Bill Hart Field, WV
(Lat. 39°38′37″ N., long. 79°55′03″ W.)

That airspace extending upward from the surface to and including 3,700 feet MSL within a 4-mile radius of Morgantown Municipal Airport-Walter L. Bill Hart Field. This Class D airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Chart Supplement.

Paragraph 6002 Class E Surface Area Airspace.

* * * * *

AEA WV E2 Morgantown, WV [Amended]

Morgantown Municipal Airport-Walter L. Bill Hart Field, WV
(Lat. 39°38′37″ N., long. 79°55′03″ W.)

Within a 4-mile radius of Morgantown Municipal Airport-Walter L. Bill Hart Field. This Class E airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Chart Supplement.

Paragraph 6004 Class E Airspace Designated as an Extension to a Class D Surface Area.

* * * * *

AEA WV E4 Morgantown, WV [Amended]

Morgantown Municipal Airport-Walter L. Bill Hart Field, WV
(Lat. 39°38′37″ N., long. 79°55′03″ W.)
Morgantown VORTAC
(Lat. 39°33′24″ N., long. 79°51′37″ W.)

That airspace extending upward from the surface within 1 mile either side of the Morgantown VORTAC 332° radial extending from the 4-mile radius of Morgantown Municipal Airport-Walter L. Bill Hart Field to the Morgantown VORTAC.

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

* * * * *

AEA WV E5 Morgantown, WV [Amended]

Morgantown Municipal Airport-Walter L. Bill Hart Field, WV
(Lat. 39°38′37″ N., long. 79°55′03″ W.)
Morgantown VORTAC
(Lat. 39°33′24″ N., long. 79°51′37″ W.)

That airspace extending upward from 700 feet above the surface within a 6.5-mile radius of Morgantown Municipal Airport-Walter L. Bill Hart Field, and within 3 miles each side of the Morgantown VORTAC 152° radial extending from the 6.5-mile radius to 8.8 miles southeast of the VORTAC, and within 3 miles west of the Morgantown VORTAC 336° radial clockwise to 3 miles east of Morgantown Municipal Airport-Walter L. Bill Hart Field north localizer course extending from the 6.5-mile radius to 15.1 miles north of the airport.

Issued in College Park, Georgia, on July 10, 2017.

Ryan W. Almasy,

Manager, Operations Support Group, Eastern Service Center, Air Traffic Organization.

[FR Doc. 2017–15286 Filed 7–20–17; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2017–0284; Airspace Docket No. 17–ACE–5]

Amendment of Class E Airspace; Orange City, IA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action modifies Class E airspace extending up to 700 feet above the surface at Orange City Municipal Airport, Orange City, IA. Airspace reconfiguration is necessary due to the decommissioning of the Orange City non directional radio beacon (NDB), and cancellation of the NDB approach. This action enhances the safety and management of standard instrument approach procedures for instrument flight rules (IFR) operations at the airport.

DATES: Effective 0901 UTC, September 14, 2017. The Director of the Federal Register approves this incorporation by reference action under Title 1, Code of Federal Regulations, part 51, subject to the annual revision of FAA Order 7400.11 and publication of conforming amendments.

ADDRESSES: FAA Order 7400.11A, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *http://www.faa.gov/air_traffic/publications/.* For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591; telephone: (202) 267–8783. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order 7400.11A at NARA, call (202) 741–6030, or go to *http://www.archives.gov/federal_register/code_of_federal-regulations/ibr_locations.html.* FAA Order 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

FOR FURTHER INFORMATION CONTACT: Walter Tweedy (prepared by Ron

Laster), Federal Aviation Administration, Operations Support Group, Central Service Center, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone (817) 222–5802.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. 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. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it modifies Class E airspace extending up to and including 700 feet above the surface area at Orange City Municipal Airport.

History

The FAA published in the **Federal Register** (82 FR 19194, April 26, 2017) Docket No. FAA–2017–0284 a notice of proposed rulemaking (NPRM) to modify Class E airspace extending upward from 700 feet above the surface at Orange City Municipal Airport, Orange City, IA. Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. No comments were received. Class E airspace designations are published in paragraph 6005 of FAA Order 7400.11A, dated August 3, 2016, and effective September 15, 2016, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in the Order.

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order 7400.11A, Airspace Designations and Reporting Points, dated August 3, 2016, and effective September 15, 2016. FAA Order 7400.11A is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.11A lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

This amendment to Title 14 Code of Federal Regulations (14 CFR) part 71 amends Class E airspace extending upward from 700 feet above the surface within the 6.4-mile radius of Orange City Municipal Airport, Orange City, IA, and within 2 miles each side of the 165° bearing from the airport extending from the 6.4-mile radius to 10.1 miles south of the airport. The segment each side of the 172° bearing from the Orange City NDB extending from the 6.4-mile radius to 7.4 miles south of the airport is removed due to the decommissioning of the NDB, and cancellation of the NDB approach. The airport coordinates are amended to be in concert with the FAA's aeronautical database. This action enhances the safety and management of the standard instrument approach procedures for IFR operations at the airport.

Regulatory Notices and Analyses

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current, is non-controversial and unlikely to result in adverse or negative comments. It, therefore: (1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, does not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

The FAA has determined that this action qualifies for categorical exclusion under the National Environmental Policy Act in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures,'' paragraph 5–6.5.a. This airspace action is not expected to cause any potentially significant environmental impacts, and no extraordinary circumstances exist that warrant preparation of an environmental assessment.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.11A, Airspace Designations and Reporting Points, dated August 3, 2016, and effective September 15, 2016, is amended as follows:

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

* * * * *

ACE IA E5 Orange City, IA [Amended]

Orange City Municipal Airport, IA
(Lat. 42°59′20″ N., long. 96°03′45″ W.)

That airspace extending upward from 700 feet above the surface within a 6.4-mile radius of Orange City Municipal Airport and within 2 miles each side of the 165° bearing from the airport extending from the 6.4-mile radius to 10.1 miles south of the airport.

Issued in Fort Worth, Texas, on July 12, 2017.

Walter Tweedy,

Acting Manager, Operations Support Group, ATO Central Service Center.

[FR Doc. 2017–15273 Filed 7–20–17; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2016–9488; Airspace Docket No. 16–ASO–18]

Amendment of Class E Airspace; Albany, GA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action amends Class E Airspace Designated as an Extension to a Class D Surface Area by eliminating the Notice to Airmen (NOTAM) part time status for Southwest Georgia Regional Airport, Albany, GA. This action corrects differences between the descriptions of Class D airspace and Class E surface areas and their associated Class E surface area extensions. This action enhances the safety and management of Instrument Flight Rules (IFR) operations.

DATES: Effective 0901 UTC, October 12, 2017. The Director of the Federal Register approves this incorporation by reference action under title 1, Code of Federal Regulations, part 51, subject to the annual revision of FAA Order 7400.11 and publication of conforming amendments.

ADDRESSES: FAA Order 7400.11A, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *http://www.faa.gov/air_traffic/publications/*. For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591; telephone: (202) 267–8783. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order 7400.11A at NARA, call (202) 741–6030, or go to *http://www.archives.gov/federal_register/code_of_federal-regulations/ibr_locations.html.*

FAA Order 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

FOR FURTHER INFORMATION CONTACT: John Fornito, Operations Support Group, Eastern Service Center, Federal Aviation Administration, P.O. Box 20636, Atlanta, Georgia 30320; telephone (404) 305–6364.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. 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. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it amends Class E airspace designated as an extension to Class D airspace at Southwest Georgia Regional Airport, Albany, GA.

History

On April 25, 2017, the FAA published in the **Federal Register** a notice of proposed rulemaking (NPRM) (82 FR 19008) Docket No. FAA–2016–9488, to amend Class E Airspace Designated as an Extension to a Class D Surface Area at Southwest Georgia Regional Airport, Albany, GA, by eliminating the NOTAM part-time status information. Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. No comments were received.

Class E airspace designations are published in paragraph 6004 FAA Order 7400.11A dated August 3, 2016, and effective September 15, 2016, which is incorporated by reference in 14 CFR 71.1. The Class D and E airspace designations listed in this document will be published subsequently in the Order.

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order 7400.11A, Airspace Designations and Reporting Points, dated August 3, 2016, and effective September 15, 2016. FAA Order 7400.11A is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.11A lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

This amendment to Title 14, Code of Federal Regulations (14 CFR) part 71 amends Class E Airspace designated as an extension to a Class D surface area at Southwest Georgia Regional Airport, Albany, GA, by eliminating the NOTAM information from the regulatory text that reads, ''This Class E airspace area is effective during the specific dates and time established in advance by Notice to Airmen. The effective date and time will thereafter be continuously published in the Airport/Facility Directory.'' This action brings the airspace description for the airport listed in FAA Order 7400.11A in line with the airspace hours listed in the applicable Chart Supplement.

Regulatory Notices and Analyses

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

Environmental Review

The FAA has determined that this action qualifies for categorical exclusion under the National Environmental Policy Act in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures,'' paragraph 5–6.5a. This airspace action is not expected to cause any potentially significant environmental impacts, and no extraordinary circumstances exist that warrant preparation of an environmental assessment.

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120, E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.11A, Airspace Designations and Reporting Points, dated August 3, 2016, effective September 15, 2016, is amended as follows:

Paragraph 6004 Class E Airspace Designated as an Extension to a Class D Surface Area.

* * * * *

ASO GA E4 Albany-Southwest Georgia Regional Airport, GA [Amended]

Southwest Georgia Regional Airport, GA
(Lat. 31°32′08″ N., long. 84°11′40″ W.)
Pecan VORTAC
(Lat. 31°39′19″ N., long. 84°17′35″ W.)

That airspace extending upward from the surface within 1.3 miles each side of Pecan VORTAC 143° radial, extending from the 4.2-mile radius of Southwest Georgia Regional Airport to 1 mile southeast of the VORTAC.

Issued in College Park, Georgia, on July 13, 2017.

Ryan W. Almasy,

Manager, Operations Support Group, Eastern Service Center, Air Traffic Organization.

[FR Doc. 2017–15289 Filed 7–20–17; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2017–0070; Airspace Docket No. 17–ASO–2]

Amendment of Class E Airspace; Fayetteville, TN

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action amends Class E airspace upward from 700 feet or more above the surface at Fayetteville, TN, as the Kelso non-directional radio beacon (NDB) has been decommissioned, requiring airspace reconfiguration at Fayetteville Municipal Airport. This action enhances the safety and airspace management of instrument flight rules (IFR) operations at the airport. This action also updates the geographic coordinates of the airport.

DATES: Effective 0901 UTC, October 12, 2017. The Director of the Federal Register approves this incorporation by reference action under title 1, Code of Federal Regulations, part 51, subject to the annual revision of FAA Order 7400.11 and publication of conforming amendments.

ADDRESSES: FAA Order 7400.11A, Airspace Designations and Reporting Points, and subsequent amendments can be viewed on-line at *http://www.faa.gov/air_traffic/publications/.* For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591; telephone: 1 (800) 647–8927, or (202) 267–8783. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order 7400.11A at NARA, call (202) 741–6030, or go to *http://www.archives.gov/federal_register/code_of_federal-regulations/ibr_locations.html.*

FAA Order 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

FOR FURTHER INFORMATION CONTACT: John Fornito, Operations Support Group, Eastern Service Center, Federal Aviation Administration, P.O. Box 20636, Atlanta, GA 30320; telephone (404) 305–6364.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. 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. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it amends Class E airspace extending upward from 700 feet above the surface at Fayetteville Municipal Airport, Fayetteville, TN, for the continued safety, and management of IFR operations at the airport.

History

The FAA published a notice of proposed rulemaking (NPRM in the **Federal Register** (82 FR 16957, April 7, 2017) Docket No. FAA–2017–0070 proposing to amend Class E airspace extending upward from 700 feet above the surface at Fayetteville Municipal Airport, Fayetteville, TN, due to the decommissioning of the Kelso NDB and cancellation of the NDB approach. The NPRM also proposed amendment of the airport's geographic coordinates. Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. No comments were received.

Class E airspace designations are published in paragraph 6005 of FAA Order 7400.11A dated August 3, 2016, and effective September 15, 2016, which is incorporated by reference in 14 CFR part 71.1. The Class E airspace designations listed in this document will be published subsequently in the Order.

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order 7400.11A, Airspace Designations and Reporting Points, dated August 3, 2016, and effective September 15, 2016. FAA Order 7400.11A is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.11A lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

This amendment to Title 14, Code of Federal Regulations (14 CFR) part 71 amends Class E airspace extending upward from 700 feet above the surface within a 6.6-mile radius of Fayetteville Municipal Airport, Fayetteville, TN, due to the decommissioning of the Kelso NDB and cancellation of the NDB approach. Therefore, these changes are necessary for continued safety and management of IFR operations at the airport. Also, the geographic coordinates of the airport are amended to coincide with the FAAs aeronautical database.

Regulatory Notices and Analyses

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

Environmental Review

The FAA has determined that this action qualifies for categorical exclusion under the National Environmental Policy Act in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures,'' paragraph 5–6.5a. This airspace action is not expected to cause any potentially significant environmental impacts, and no extraordinary circumstances exist that warrant preparation of an environmental assessment.

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120, E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.11A, Airspace Designations and Reporting Points, dated August 3, 2016, effective September 15, 2016, is amended as follows:

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

* * * * *

ASO TN E5 Fayetteville, TN [Amended]

Fayetteville Municipal Airport, TN
(Lat. 35°03′35″ N., long. 86°33′50″ W.)

That airspace extending upward from 700 feet above the surface within a 6.6-mile radius of Fayetteville Municipal Airport and within 4 miles each side of the 014° bearing from airport, extending from the 6.6-mile radius to 10.1-miles north of the airport.

Issued in College Park, Georgia, on July 11, 2017.

Ryan W. Almasy,

Manager, Operations Support Group, Eastern Service Center, Air Traffic Organization.

[FR Doc. 2017–15284 Filed 7–20–17; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2017–0071; Airspace Docket No. 17–ASO–3]

Amendment of Class E Airspace; Laurel, MS

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action amends Class E airspace at Laurel, MS, as the Tallahala non-directional radio beacon (NDB) has been decommissioned, requiring airspace reconfiguration at Hesler-Noble Field Airport. Controlled airspace is necessary for the safety and management of instrument flight rules (IFR) operations at the airport. This action also updates the geographic coordinates of the airport.

DATES: Effective 0901 UTC, October 12, 2017. The Director of the Federal Register approves this incorporation by reference action under title 1, Code of Federal Regulations, part 51, subject to the annual revision of FAA Order 7400.11 and publication of conforming amendments.

ADDRESSES: FAA Order 7400.11A, Airspace Designations and Reporting Points, and subsequent amendments can be viewed on line at *http://www.faa.gov/air_traffic/publications/.* For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591; telephone: 1 (800) 647–8927, or (202) 267–8783. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order 7400.11A at NARA, call (202) 741–6030, or go to *http://www.archives.gov/federal_register/code_of_federal-regulations/ibr_locations.html.*

FAA Order 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

FOR FURTHER INFORMATION CONTACT: John Fornito, Operations Support Group, Eastern Service Center, Federal Aviation Administration, P.O. Box 20636, Atlanta, GA 30320; telephone (404) 305–6364.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. 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. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it amends Class E airspace extending upward from 700 feet above the surface within an 8.4-mile radius of Hesler-Noble Field Airport, Laurel, MS, in support of IFR operations at the airport.

History

The FAA published a notice of proposed rulemaking (NPRM) in the **Federal Register** (82 FR 16953, April 7, 2017) Docket No. FAA–2017–0071 to amend Class E airspace extending upward from 700 feet above the surface at Hesler-Noble Field Airport, Laurel, MS, due to the decommissioning of the Tallahala NDB and cancellation of the NDB approach, thereby removing the extension airspace. The NPRM also advised of the proposed amendment of the airport's geographic coordinates. Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. No comments were received.

Class E airspace designations are published in paragraph 6005 of FAA Order 7400.11A dated August 3, 2016, and effective September 15, 2016, which is incorporated by reference in 14 CFR part 71.1. The Class E airspace designation listed in this document will be published subsequently in the Order.

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order 7400.11A, Airspace Designations and Reporting Points, dated August 3, 2016, and effective September 15, 2016. FAA Order 7400.11A is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.11A lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

This amendment to Title 14, Code of Federal Regulations (14 CFR) part 71 amends Class E airspace extending upward from 700 feet above the surface within a 8.4-mile (increased from a 7.5-mile) radius of Hesler-Noble Field Airport, Laurel, MS due to the decommissioning of the Tallahala NDB and cancellation of the NDB approach. The Tallahala NDB is removed from the legal description, thereby removing the 5-mile wide segment from the Tallahala NDB extending from the current 7.5-mile radius to 7 miles northwest of the NDB (excluding that airspace within the Hattiesburg, MS Class E airspace area). The geographic coordinates of the airport are amended to coincide with the FAAs aeronautical database. This action ensures the continued safety and management of IFR operations at the airport.

Regulatory Notices and Analyses

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore: (1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that only affects air traffic procedures and air navigation, it is certified that this rule, when promulgated, does not have a significant economic impact on a substantial

number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

The FAA has determined that this action qualifies for categorical exclusion under the National Environmental Policy Act in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures,'' paragraph 5–6.5a. This airspace action is not expected to cause any potentially significant environmental impacts, and no extraordinary circumstances exist that warrant preparation of an environmental assessment.

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120, E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.11A, Airspace Designations and Reporting Points, dated August 3, 2016, effective September 15, 2016, is amended as follows:

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

* * * * *

ASO MS E5 Laurel, MS [Amended]

Laurel, Hesler-Noble Field Airport, MS
(Lat. 31°40′23″ N., long. 89°10′22″ W.)

That airspace extending upward from 700 feet above the surface within an 8.4-mile radius of Hesler-Noble Field Airport.

Issued in College Park, Georgia, on July 11, 2017.

Ryan W. Almasy,

Manager, Operations Support Group, Eastern Service Center, Air Traffic Organization.

[FR Doc. 2017–15274 Filed 7–20–17; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2017–0195; Airspace Docket No. 16–ANM–14]

Amendment of Class E Airspace; Medford, OR

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action modifies Class E airspace designated as an extension to a Class D or E surface area, Class E airspace extending upward from 700 feet above the surface, and removes Class E airspace upward from 1,200 feet above the surface at Rogue Valley International-Medford Airport, Medford, OR. This action is necessary due to the decommissioning of the PUMIE locator outer marker and removal of the Rogue Valley VHF Omnidirectional Range/Tactical Air Navigation (VORTAC) from the airspace description as the FAA transitions from ground-based navigation aids to satellite-based navigation. Also, this action updates the airport's geographic coordinates for the Class D and E airspace areas to reflect the FAA's current aeronautical database.

DATES: Effective 0901 UTC, October 12, 2017. The Director of the Federal Register approves this incorporation by reference action under Title 1, Code of Federal Regulations, part 51, subject to the annual revision of FAA Order 7400.11 and publication of conforming amendments.

ADDRESSES: FAA Order 7400.11A, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *http://www.faa.gov/air_traffic/publications/.* For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591; telephone: (202) 267–8783. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call (202) 741–6030, or go to *http://www.archives.gov/federal_register/code_of_federal-regulations/ibr_locations.html.*

FAA Order 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

FOR FURTHER INFORMATION CONTACT: Tom Clark, Federal Aviation Administration, Operations Support Group, Western Service Center, 1601 Lind Avenue SW., Renton, WA 98057; telephone (425) 203–4511.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. 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. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it modifies Class E airspace at Rogue Valley International-Medford Airport, Medford, OR, in support of the transition from ground-based navigation aids to satellite-based navigation.

History

On April 13, 2017, the FAA published in the **Federal Register** (82 FR 17776) Docket FAA–2017–0195, a notice of proposed rulemaking to modify Class E airspace designated as an extension to a Class D or E surface area, Class E airspace extending upward from 700 feet above the surface, remove Class E airspace extending upward from 1,200 feet above the surface at Rogue Valley International-Medford Airport, Medford, OR, and update the geographic coordinates of the airport. Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. No comments were received.

Also, an editorial change is made to the Class D and Class E surface area airspace legal descriptions replacing Airport/Facility Directory with the term Chart Supplement.

Class D and E airspace designations are published in paragraph 5000, 6002, 6004, and 6005, respectively, of FAA Order 7400.11A, dated August 3, 2016, and effective September 15, 2016, which is incorporated by reference in 14 CFR part 71.1. The Class D and E airspace designations listed in this document will be published subsequently in the Order.

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order 7400.11A, Airspace Designations and Reporting Points, dated August 3, 2016,

and effective September 15, 2016. FAA Order 7400.11A is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.11A lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

The FAA is amending Title 14 Code of Federal Regulations (14 CFR) part 71 by modifying Class E airspace designated as an extension to a Class D or E surface area, modifying Class E airspace extending upward from 700 feet above the surface, removing Class E airspace upward from 1,200 feet above the surface at Rogue Valley International-Medford Airport, Medford, OR, and updating the geographic coordinates of the airport. This action is necessary due to the proposed decommissioning of the PUMIE locator outer marker and for the safety and management of aircraft within the national airspace system as the FAA transitions from ground-based navigation aids to satellite-based navigation.

Class E airspace designated as an extension to Class D or E surface area northeast of the airport is reduced to a 4-mile wide segment (from 5.5 miles wide) extending to 11 miles northwest (from 17.5 miles northwest) of the airport, and the segment to the southeast is reduced to a 5-mile wide segment (from 8 miles), extending to 9 miles (from 19.4 miles) southeast of the airport. This airspace redesign is due to the removal of the Rogue Valley VORTAC navigation aid.

Class E airspace extending upward from 700 feet above the surface is reduced northeast, southeast, and southwest of the airport to only that area necessary to contain IFR departures within 1,500 feet of the surface and IFR departures until reaching 1,200 feet above the surface. Additionally, the Class E airspace area extending upward from 1,200 feet above the surface designated for Rogue Valley International-Medford Airport is removed, as this airspace duplicates the Rogue Valley Class E en route airspace area.

Also, the geographic coordinates of the airport are updated to match the FAA's current aeronautical database. Additionally, this action replaces the outdated term Airport/Facility Directory with the term Chart Supplement in the associated Class D and E airspace legal descriptions.

Regulatory Notices and Analyses

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current, is non-controversial and unlikely to result in adverse or negative comments. It, therefore: (1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that only affects air traffic procedures and air navigation, it is certified that this rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

The FAA has determined that this action qualifies for categorical exclusion under the National Environmental Policy Act in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures,'' paragraph 5–6.5a. This airspace action is not expected to cause any potentially significant environmental impacts, and no extraordinary circumstances exist that warrant preparation of an environmental assessment.

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.11A, Airspace Designations and Reporting Points, dated August 3, 2016, and effective September 15, 2016, is amended as follows:

Paragraph 5000 Class D Airspace.

* * * * *

ANM OR D Medford, OR [Modified]

Rogue Valley International-Medford Airport, OR

(Lat. 42°22′27″ N., long. 122°52′25″ W.)

That airspace extending upward from the surface to and including 3,800 feet MSL within a 4.1-mile radius of Rogue Valley International-Medford Airport. This Class D airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Chart Supplement.

Paragraph 6002 Class E Airspace Designated as Surface Areas.

* * * * *

ANM OR E2 Medford, OR [Modified]

Rogue Valley International-Medford Airport, OR

(Lat. 42°22′27″ N., long. 122°52′25″ W.)

That airspace extending upward from the surface within a 4.1-mile radius of Rogue Valley International-Medford Airport. This Class E airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Chart Supplement.

Paragraph 6004 Class E Airspace Areas Designated as an Extension to a Class D or Class E Surface Area.

* * * * *

ANM OR E4 Medford, OR [Modified]

Rogue Valley International-Medford Airport, OR

(Lat. 42°22′27″ N., long. 122°52′25″ W.)

That airspace extending upward from the surface within 2.5 miles each side of the 159° bearing from the Rogue Valley International-Medford Airport, extending from the 4.1-mile radius of the airport to 9 miles southeast of the airport, and within 2 miles each side of the 339° bearing from the airport extending from the 4.1-mile radius of the airport to 11 miles northwest of the airport.

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

* * * * *

ANM OR E5 Medford, OR [Modified]

Rogue Valley International-Medford Airport, OR

(Lat. 42°22′27″ N., long. 122°52′25″ W.)

That airspace extending upward from 700 feet above the surface within a 9-mile radius of Rogue Valley International-Medford Airport, and within 4 miles each side of the 159° bearing from the airport extending from the 9-mile radius to 18.5 miles southeast of the airport, and within 9 miles west and 5.5 miles east of the 352° bearing from the airport extending from the 9-mile radius of the airport to 26 miles northwest of the airport.

Issued in Seattle, Washington, on July 11, 2017.

Sam S.L. Shrimpton,

Acting Group Manager, Operations Support Group, Western Service Center.

[FR Doc. 2017–15290 Filed 7–20–17; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2013–0442; Airspace Docket No. 13–ASO–12]

Establishment of Class E Airspace; Ashburn, GA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action establishes Class E airspace extending upward from 700 feet above the surface at Ashburn, GA, to accommodate new Area Navigation (RNAV) Global Positioning System (GPS) Standard Instrument Approach Procedures (SIAPs) serving Turner County Airport. Controlled airspace is necessary for the safety and management of instrument flight rules (IFR) operations at the airport.

DATES: Effective 0901 UTC, October 12, 2017. The Director of the Federal Register approves this incorporation by reference action under title 1, Code of Federal Regulations, part 51, subject to the annual revision of FAA Order 7400.11 and publication of conforming amendments.

ADDRESSES: FAA Order 7400.11A, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *http://www.faa.gov/air_traffic/publications/*. For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591; telephone: (202) 267–8783. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order 7400.11A at NARA, call (202) 741–6030, or go to *http://www.archives.gov/federal_register/code_of_federal-regulations/ibr_locations.html.*

FAA Order 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

FOR FURTHER INFORMATION CONTACT: John Fornito, Operations Support Group, Eastern Service Center, Federal Aviation Administration, P.O. Box 20636, Atlanta, Georgia 30320; telephone (404) 305–6364.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. 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. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it amends Class E airspace at Turner County Airport, Ashburn, GA, to support IFR operations under standard instrument approach procedures at the airport.

History

The FAA published a notice of proposed rulemaking (NPRM) in the **Federal Register** (82 FR 24273, May 26, 2017) Docket No. FAA–2013–0442 to establish Class E airspace extending upward from 700 feet above the surface at Turner County Airport, Ashburn, GA, due to the new RNAV (GPS) standard instrument approach procedures for IFR operations at the airport. Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. No comments were received.

Class E airspace designations are published in paragraph 6005 of FAA Order 7400.11A dated August 3, 2016, and effective September 15, 2016, which is incorporated by reference in 14 CFR part 71.1. The Class E airspace designations listed in this document will be published subsequently in the Order.

Availability and Summary of Documents for Incorporation by Reference

This document proposes to amend FAA Order 7400.11A, Airspace Designations and Reporting Points, dated August 3, 2016, and effective September 15, 2016. FAA Order 7400.11A is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.11A lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

This action amends Title 14 Code of Federal Regulations (14 CFR) part 71 by establishing Class E airspace extending upward from 700 feet above the surface within a 6.8-mile radius of Turner County Airport, Ashburn, GA. This action provides the controlled airspace required to support the new RNAV (GPS) standard instrument approach procedures for IFR operations at Turner County Airport.

Regulatory Notices and Analyses

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this regulation: (1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that only affects air traffic procedures and air navigation, it is certified that this rule, when promulgated, does not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

The FAA has determined that this action qualifies for categorical exclusion under the National Environmental Policy Act in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures,'' paragraph 5–6.5a. This airspace action is not expected to cause any potentially significant environmental impacts, and no extraordinary circumstances exist that warrant preparation of an environmental assessment.

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the FAA amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.11A, Airspace Designations and Reporting Points, dated August 3, 2016, effective September 15, 2016, is amended as follows:

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

* * * * *

ASO GA E5 Ashburn, GA [New]

Turner County Airport, GA
(Lat. 31°41′15″ N., long. 83°37′59″ W.)

That airspace extending upward from 700 feet above the surface within a 6.8-mile radius of Turner County Airport.

Issued in College Park, Georgia, on July 11, 2017.

Ryan W. Almasy,

Manager, Operations Support Group, Eastern Service Center, Air Traffic Organization.

[FR Doc. 2017–15276 Filed 7–20–17; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Parts 100, 117, 147, and 165

[USCG–2015–0242]

Quarterly Listings; Safety Zones, Security Zones, Special Local Regulations, Drawbridge Operation Regulations and Regulated Navigation Areas

AGENCY: Coast Guard, DHS.

ACTION: Notice of expired temporary rules issued.

SUMMARY: This document provides notice of substantive rules issued by the Coast Guard that were made temporarily effective but expired before they could be published in the **Federal Register**. This notice lists temporary safety zones, security zones, special local regulations, drawbridge operation regulations and regulated navigation areas, all of limited duration and for which timely publication in the **Federal Register** was not possible.

DATES: This document lists temporary Coast Guard rules that became effective, primarily between August 2014 and September 2015, and were terminated before they could be published in the **Federal Register**.

ADDRESSES: Temporary rules listed in this document may be viewed online, under their respective docket numbers, using the Federal eRulemaking Portal at *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: For questions on this notice contact Yeoman First Class David Hager, Office of Regulations and Administrative Law, telephone (202) 372–3862.

SUPPLEMENTARY INFORMATION: Coast Guard District Commanders and Captains of the Port (COTP) must be immediately responsive to the safety and security needs within their jurisdiction; therefore, District Commanders and COTPs have been delegated the authority to issue certain local regulations. *Safety zones* may be established for safety or environmental purposes. A safety zone may be stationary and described by fixed limits or it may be described as a zone around a vessel in motion. *Security zones* limit access to prevent injury or damage to vessels, ports, or waterfront facilities. *Special local regulations* are issued to enhance the safety of participants and spectators at regattas and other marine events. *Drawbridge operation regulations* authorize changes to drawbridge schedules to accommodate bridge repairs, seasonal vessel traffic, and local public events. *Regulated Navigation Areas* are water areas within a defined boundary, for which regulations for vessels navigating within the area have been established by the regional Coast Guard District Commander.

Timely publication of these rules in the **Federal Register** may be precluded when a rule responds to an emergency, or when an event occurs without sufficient advance notice. The affected public is, however, often informed of these rules through Local Notices to Mariners, press releases, and other means. Moreover, actual notification is provided by Coast Guard patrol vessels enforcing the restrictions imposed by the rule. Because **Federal Register** publication was not possible before the end of the effective period, mariners were personally notified of the contents of these safety zones, security zones, special local regulations, regulated navigation areas or drawbridge operation regulations by Coast Guard officials on-scene prior to any enforcement action. However, the Coast Guard, by law, must publish in the **Federal Register** notice of substantive rules adopted. To meet this obligation without imposing undue expense on the public, the Coast Guard periodically publishes a list of these temporary safety zones, security zones, special local regulations, regulated navigation areas, and drawbridge operation regulations. Permanent rules are not included in this list because they are published in their entirety in the **Federal Register**. Temporary rules are also published in their entirety if sufficient time is available to do so before they are placed in effect or terminated.

The following unpublished rules were placed in effect temporarily during the period between August 2014 and September 2015 unless otherwise indicated. To view copies of these rules, visit *www.regulations.gov* and search by the docket number indicated in the list below.

Docket No.	Location	Type	Effective date
USCG–2014–0963	Pago Pago, American Samoa	Safety Zones (Parts 147 and 165)	11/11/2014
USCG–2014–1027	Sabine, TX	Safety Zones (Parts 147 and 165)	11/28/2014
USCG–2014–1040	Rockwood, IL	Safety Zones (Parts 147 and 165)	12/6/2014
USCG–2014–1049	New Orleans, LA	Safety Zones (Parts 147 and 165)	12/31/2014
USCG–2014–1065	Baton Rouge, LA	Safety Zones (Parts 147 and 165)	12/31/2014
USCG–2014–1064	Gulfport, MS	Safety Zones (Parts 147 and 165)	1/7/2015
USCG–2014–1042	New Orleans, LA	Safety Zones (Parts 147 and 165)	1/8/2015
USCG–2015–0012	Pennington, AL	Safety Zones (Parts 147 and 165)	1/11/2015
USCG–2015–0054	St. Claire County, MI	Safety Zones (Parts 147 and 165)	1/25/2015
USCG–2015–0029	Pascagoula, MS	Safety Zones (Parts 147 and 165)	1/30/2015
USCG–2015–0477	Santa Barbara, CA	Safety Zones (Parts 147 and 165)	5/27/2015
USCG–2015–0263	Sabine, TX	Safety Zones (Parts 147 and 165)	5/27/2015
USCG–2015–0494	St.Louis, MO	Safety Zones (Parts 147 and 165)	5/30/2015
USCG–2015–0495	St. Louis, MO	Safety Zones (Parts 147 and 165)	5/30/2015
USCG–2015–0514	Louis, MO	Safety Zones (Parts 147 and 165)	6/2/2015
USCG–2015–0264	Sabine, TX	Safety Zones (Parts 147 and 165)	6/3/2015
USCG–2015–0535	St. Louis, MO	Safety Zones (Parts 147 and 165)	6/7/2015
USCG–2015–0553	Louisville, KY	Safety Zones (Parts 147 and 165)	6/14/2015

Docket No.	Location	Type	Effective date
USCG–2015–0265	Ports of Beaumont, Port Arthur, Orange, TX and Lake Charles.	Safety Zones (Parts 147 and 165)	6/15/2015
USCG–2015–0125	Wantagh, NY	Special Local Regulations (Part 100)	6/17/2015
USCG–2015–0579	Henry, IL	Safety Zones (Parts 147 and 165)	6/18/2015
USCG–2015–0523	Chester, WV	Safety Zones (Parts 147 and 165)	6/20/2015
USCG–2015–0517	San Francisco, CA	Safety Zones (Parts 147 and 165)	6/20/2015
USCG–2015–0625	City of Aurora, IN	Safety Zones (Parts 147 and 165)	6/27/2015
USCG–2015–0372	Cumberland City, TN	Safety Zones (Parts 147 and 165)	6/27/2015
USCG–2015–0387	Beaver, PA	Safety Zones (Parts 147 and 165)	6/27/2015
USCG–2015–0133	Chattanooga, TN	Special Local Regulations (Part 100)	6/28/2015
USCG–2015–0545	Port Boston Zone	Safety Zones (Parts 147 and 165)	6/28/2015
USCG–2015–0583	Incline Village, NV	Safety Zones (Parts 147 and 165)	6/30/2015
USCG–2015–0233	Lake Tahoe, NV	Safety Zones (Parts 147 and 165)	7/1/2015
USCG–2015–0606	Los Angeles, CA	Safety Zones (Parts 147 and 165)	7/2/2015
USCG–2015–0522	Perth Amboy, NJ	Safety Zones (Parts 147 and 165)	7/2/2015
USCG–2015–0237	Kings Beach, CA	Safety Zones (Parts 147 and 165)	7/3/2015
USCG–2015–0607	Long Beach, CA	Safety Zones (Parts 147 and 165)	7/3/2015
USCG–2015–0608	Santa Catalina Island, CA	Safety Zones (Parts 147 and 165)	7/3/2015
USCG–2015–0589	Richmond Harbor, CA	Safety Zones (Parts 147 and 165)	7/3/2015
USCG–2015–0283	San Francisco, CA	Safety Zones (Parts 147 and 165)	7/3/2015
USCG–2015–0575	Olcott, NY	Safety Zones (Parts 147 and 165)	7/3/2015
USCG–2015–0599	Morris, IL	Safety Zones (Parts 147 and 165)	7/3/2015
USCG–2015–0587	Cornucopia, WI	Safety Zones (Parts 147 and 165)	7/3/2015
USCG–2015–0639	Burlington, VT	Safety Zones (Parts 147 and 165)	7/3/2015
USCG–2015–0538	Laplace, LA	Safety Zones (Parts 147 and 165)	7/3/2015
USCG–2015–0547	New Albany, IN	Safety Zones (Parts 147 and 165)	7/3/2015
USCG–2015–0541	Louisville, KY	Safety Zones (Parts 147 and 165)	7/3/2015
USCG–2015–0440	Charleston, WV	Safety Zones (Parts 147 and 165)	7/3/2015
USCG–2015–0550	Madison, IN	Special Local Regulations (Part 100)	7/3/2015
USCG–2015–0557	Long Island Port Zone	Safety Zones (Parts 147 and 165)	7/3/2015
USCG–2015–0324	Sea Isle City, NJ	Safety Zones (Parts 147 and 165)	7/4/2015
USCG–2015–0239	Glenbrook, NV	Safety Zones (Parts 147 and 165)	7/4/2015
USCG–2015–0588	Madeline Island, WI	Safety Zones (Parts 147 and 165)	7/4/2015
USCG–2015–0546	Miami, FL	Safety Zones (Parts 147 and 165)	7/4/2015
USCG–2015–0327	Dewey Beach, DE	Safety Zones (Parts 147 and 165)	7/4/2015
USCG–2015–0481	Manhattan, NY	Special Local Regulations (Part 100)	7/4/2015
USCG–2015–0426	Oyester Bay, NY	Special Local Regulations (Part 100)	7/4/2015
USCG–2015–0528	7th Coast Guard District	Special Local Regulations (Part 100)	7/4/2015
USCG–2015–0255	Lake Union, WA	Safety Zones (Parts 147 and 165)	7/4/2015
USCG–2015–0254	Friday Harbor, WA	Safety Zones (Parts 147 and 165)	7/4/2015
USCG–2015–0437	Manteo, NC	Safety Zones (Parts 147 and 165)	7/4/2015
USCG–2015–0609	Long Beach, CA	Safety Zones (Parts 147 and 165)	7/4/2015
USCG–2015–0610	Newport Beach, CA	Safety Zones (Parts 147 and 165)	7/4/2015
USCG–2015–0399	Pittsburgh, CA	Safety Zones (Parts 147 and 165)	7/4/2015
USCG–2015–0581	Vallejo, CA	Safety Zones (Parts 147 and 165)	7/4/2015
USCG–2015–0640	Berkeley, CA	Safety Zones (Parts 147 and 165)	7/4/2015
USCG–2015–0585	Duluth, MN	Safety Zones (Parts 147 and 165)	7/4/2015
USCG–2015–0598	Neenah, WI	Safety Zones (Parts 147 and 165)	7/4/2015
USCG–2015–0573	Cleveland, OH	Safety Zones (Parts 147 and 165)	7/4/2015
USCG–2015–0597	Cedar Point, OH	Safety Zones (Parts 147 and 165)	7/4/2015
USCG–2015–0596	Marbledhead, OH	Safety Zones (Parts 147 and 165)	7/4/2015
USCG–2015–0586	Bayfield, WI	Safety Zones (Parts 147 and 165)	7/4/2015
USCG–2015–0577	Buffalo, NY	Safety Zones (Parts 147 and 165)	7/4/2015
USCG–2015–0352	Castine, ME	Safety Zones (Parts 147 and 165)	7/4/2015
USCG–2015–0449	Cincinnati, OH	Safety Zones (Parts 147 and 165)	7/4/2015
USCG–2015–0367	Point Pleasant, WV	Safety Zones (Parts 147 and 165)	7/4/2015
USCG–2015–0560	Owensboro, KY	Safety Zones (Parts 147 and 165)	7/4/2015
USCG–2015–0602	Jefferson City, MO	Safety Zones (Parts 147 and 165)	7/4/2015
USCG–2015–0542	Evansville, IN	Safety Zones (Parts 147 and 165)	7/4/2015
USCG–2015–0364	Greenup, KY	Safety Zones (Parts 147 and 165)	7/4/2015
USCG–2015–0391	Middleport, OH	Safety Zones (Parts 147 and 165)	7/4/2015
USCG–2015–0516	Chester, WV	Safety Zones (Parts 147 and 165)	7/4/2015
USCG–2015–0530	Lake Michigan Zone	Safety Zones (Parts 147 and 165)	7/4/2015
USCG–2015–0444	Paducah, KY	Safety Zones (Parts 147 and 165)	7/4/2015
USCG–2015–0530	Lake Michigan Zone	Safety Zones (Parts 147 and 165)	7/4/2015
USCG–2015–0059	Louisville, KY	Safety Zones (Parts 147 and 165)	7/5/2015
USCG–2015–0600	Palos Heights, IL	Safety Zones (Parts 147 and 165)	7/8/2015
USCG–2015–0638	San Diego, CA	Safety Zones (Parts 147 and 165)	7/10/2015
USCG–2015–0617	Grosse Pointe Shores, MI	Safety Zones (Parts 147 and 165)	7/10/2015
USCG–2015–0219	Cincinnati, OH	Special Local Regulations (Part 100)	7/10/2015
USCG–2015–0620	Oswego, NY	Safety Zones (Parts 147 and 165)	7/11/2015
USCG–2015–0645	Mystic, CT	Special Local Regulations (Part 100)	7/11/2015
USCG–2015–0307	Cincinnati, OH	Safety Zones (Parts 147 and 165)	7/11/2015
USCG–2015–0644	Bellevue, KY	Safety Zones (Parts 147 and 165)	7/11/2015

Docket No.	Location	Type	Effective date
USCG–2015–0664	Wyandotte, MI	Special Local Regulations (Part 100)	7/12/2015
USCG–2015–0010	Florence, AL	Special Local Regulations (Part 100)	7/12/2015
USCG–2015–0680	Philadelphia, PA	Security Zones (Part 165)	7/14/2015
USCG–2015–0353	Castine, ME	Safety Zones (Parts 147 and 165)	7/14/2015
USCG–2015–0605	Augusta, GA	Safety Zones (Parts 147 and 165)	7/16/2015
USCG–2012–1036	Port Long Island Sound Zone	Safety Zones (Parts 147 and 165)	7/17/2015
USCG–2015–0679	Lorain, OH	Safety Zones (Parts 147 and 165)	7/18/2015
USCG–2015–0354	South Bristol, ME	Safety Zones (Parts 147 and 165)	7/18/2015
USCG–2015–0658	Brewerton, NY	Safety Zones (Parts 147 and 165)	7/18/2015
USCG–2015–0675	Brooklyn, NY	Drawbridges (Part 117)	7/18/2015
USCG–2015–0425	Portland, ME	Special Local Regulations (Part 100)	7/18/2015
USCG–2015–0679	Lorain, OH	Safety Zones (Parts 147 and 165)	7/18/2015
USCG–2015–0396	Oakmont, PA	Safety Zones (Parts 147 and 165)	7/18/2015
USCG–2015–0661	Cleveland, OH	Safety Zones (Parts 147 and 165)	7/19/2015
USCG–2015–0702	Galveston, TX	Safety Zones (Parts 147 and 165)	7/20/2015
USCG–2015–0685	Pittsburgh, PA	Security Zones (Part 165)	7/21/2015
USCG–2015–0443	Milwaukee, WI	Safety Zones (Parts 147 and 165)	7/23/2015
USCG–2015–0611	Ogdensburg, NY	Safety Zones (Parts 147 and 165)	7/24/2015
USCG–2015–0700	Grafton, IL	Safety Zones (Parts 147 and 165)	7/24/2015
USCG–2015–0660	Oswego, NY	Safety Zones (Parts 147 and 165)	7/25/2015
USCG–2015–0592	Pacific Grove, CA	Safety Zones (Parts 147 and 165)	7/25/2015
USCG–2015–0302	Nashville, TN	Special Local Regulations (Part 100)	7/26/2015
USCG–2015–0657	Queens, NY	Drawbridges (Part 117)	7/27/2015
USCG–2010–0062	Seattle, WA	Safety Zones (Parts 147 and 165)	7/29/2015
USCG–2015–0377	New Orleans, LA	Safety Zones (Parts 147 and 165)	7/30/2015
USCG–2015–0214	LaPointe, WI	Safety Zones (Parts 147 and 165)	8/1/2015
USCG–2015–0714	Mentor, OH	Safety Zones (Parts 147 and 165)	8/2/2015
USCG–2015–0281	Cincinnati, OH	Special Local Regulations (Part 100)	8/2/2015
USCG–2014–0794	Lakebay, WA	Safety Zones (Parts 147 and 165)	8/4/2015
USCG–2015–0681	National Harbor, MD	Safety Zones (Parts 147 and 165)	8/6/2015
USCG–2015–0761	Chicago, IL	Safety Zones (Parts 147 and 165)	8/6/2015
USCG–2015–0709	San Diego, CA	Safety Zones (Parts 147 and 165)	8/7/2015
USCG–2015–0759	Chicago, IL	Safety Zones (Parts 147 and 165)	8/8/2015
USCG–2015–0721	Port Huron, MI	Special Local Regulations (Part 100)	8/8/2015
USGC–2015–0622	Perry, WA	Safety Zones (Parts 147 and 165)	8/8/2015
USCG–2015–0762	Sylvan Beach, NY	Safety Zones (Parts 147 and 165)	8/9/2015
USCG–2015–0795	Cedar Point, OH	Safety Zones (Parts 147 and 165)	8/13/2015
USCG–2015–0652	Havre de Grace, MD	Safety Zones (Parts 147 and 165)	8/14/2015
USCG–2015–0724	San Diego, CA	Safety Zones (Parts 147 and 165)	8/15/2015
USCG–2015–0530	Algoma, WI	Safety Zones (Parts 147 and 165)	8/16/2015
USCG–2015–0785	Detriot, MI	Special Local Regulations (Part 100)	8/21/2015
USCG–2015–0707	Huntsville, AL	Special Local Regulations (Part 100)	8/23/2015
USCG–2015–0775	South Port, ME	Safety Zones (Parts 147 and 165)	8/28/2015
USCG–2015–0766	Petaluma, CA	Safety Zones (Parts 147 and 165)	9/1/2015
USCG–2015–0525	Virginia Beach, VA	Safety Zones (Parts 147 and 165)	9/1/2015
USCG–2015–0592	South Lake Tahoe, CA	Safety Zones (Parts 147 and 165)	9/4/2015
USCG–2012–1036	Port Long Island Sound Zone	Safety Zones (Parts 147 and 165)	9/5/2015
USGC–2015–0771	Boston Harbor, MA	Safety Zones (Parts 147 and 165)	9/5/2015
USCG–2015–0811	Prince William County, VA	Safety Zones (Parts 147 and 165)	9/5/2015
USCG–2015–0770	Port Boston Zone	Safety Zones (Parts 147 and 165)	9/5/2015
USCG–2015–0821	Miami Beach, FL	Safety Zones (Parts 147 and 165)	9/5/2015
USCG–2015–0842	Hood River, OR	Safety Zones (Parts 147 and 165)	9/7/2015
USCG–2015–0857	Dana Point, CA	Special Local Regulations (Part 100)	9/11/2015
USCG–2014–0876	Port Huron, MI	Special Local Regulations (Part 100)	9/12/2015
USCG–2015–0844	Pasco, WA	Safety Zones (Parts 147 and 165)	9/12/2015
USCG–2015–0834	Buffalo, NY	Safety Zones (Parts 147 and 165)	9/13/2015
USCG–2015–0868	Portland, OR	Drawbridges (Part 117)	9/13/2015
USCG–2015–0816	Long Island Port Zone	Safety Zones (Parts 147 and 165)	9/15/2015
USCG–2015–0890	San Pedro, CA	Safety Zones (Parts 147 and 165)	9/17/2015
USCG–2015–0683	Cocoa Beach, FL	Special Local Regulations (Part 100)	9/18/2015
USCG–2015–0881	San Pedro, CA	Safety Zones (Parts 147 and 165)	9/18/2015
USCG–2015–0561	Miami, FL	Safety Zones (Parts 147 and 165)	9/20/2015
USCG–2015–0843	Portland, OR	Safety Zones (Parts 147 and 165)	9/20/2015
USCG–2015–0897	Point Mugu, CA	Safety Zones (Parts 147 and 165)	9/25/2015
USCG–2015–0845	Portland, OR	Safety Zones (Parts 147 and 165)	9/27/2015

Katia Kroutil,
Chief, Office of Regulations and Administrative Law.

[FR Doc. 2017–15373 Filed 7–20–17; 8:45 am]

BILLING CODE P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2017–0212]

RIN 1625–AA09

Drawbridge Operation Regulation; St. Louis River (Duluth-Superior Harbor), Between the Towns of Duluth, MN and Superior, WI

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: The Coast Guard is modifying the regulations that govern the drawbridges over the St. Louis River at Duluth-Superior Harbor. This waterway borders Minnesota and Wisconsin and is listed under Minnesota as St. Louis River (Duluth-Superior Harbor) and under Wisconsin as Duluth-Superior Harbor (St. Louis River) in the CFR. This rule affects both regulations. The owner of the Burlington Northern Grassy Point Railroad Bridge at mile 5.44 requested the regulation be updated to include permanent winter operating schedule. This rule also aligns river mile numbers with the United States Coast Pilot and deletes bridges from the regulations that were removed from the waterway and makes the regulation easier to read and less confusing to the mariner.

DATES: This rule is effective August 21, 2017.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov,* type [USCG–2017–0212]. In the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rulemaking.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Mr. Lee D. Soule, Bridge Management Specialist, Ninth Coast Guard District; telephone 216–902–6085, email *Lee.D.Soule@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
FR Federal Register
LWD Low Water Datum
NEPA National Environmental Policy Act of 1969
NPRM Notice of proposed rulemaking
RFA Regulatory Flexibility Act of 1980
SNPRM Supplemental notice of proposed rulemaking
Pub. L. Public Law
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

On April 19, 2017, we published a notice of proposed rulemaking (NPRM) entitled, Drawbridge Operation Regulation; St. Louis River (Duluth-Superior Harbor), between the towns of Duluth, MN and Superior, WI, in the **Federal Register** (82 FR 18407). We did not receive any comments on this proposed rule.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under the authority of 33 U.S.C. 499. The current regulations for St. Louis River drawbridges (33 CFR 117.669 and 33 CFR 117.1083) includes the operating schedules for the Burlington Northern Grassy Point Railroad Bridge at mile 5.44, the Grassy Point Bridge at mile 8.0, the Arrow Head Bridge at mile 8.7, and the Duluth, Missabe & Iron Range combined Railroad and Highway Bridge, also known as the Oliver Bridge, at mile 13.91.

IV. Discussion of Comments, Changes and the Final Rule

The Coast Guard provided a 30 day comment period in the **Federal Register** and solicited comments through the Ninth Coast Guard Local Notice to Mariners for the same 30 days and we did not receive any comments.

Title 33 of the Code of Regulations part 117 lists drawbridge regulations by state. The St. Louis River is the border between Minnesota (listed under 33 CFR 117.669) and Wisconsin (listed under 33 CFR 117.1083). The St. Louis River is listed by state separately under both sections of the CFR. This rule will revise 33 CFR 117.1083 (under Wisconsin) to direct readers to 33 CFR 117.669 (under Minnesota) to simplify the rule and make it easier to reference by mariners.

The Coast Guard is modifying the operating schedule of the The Burlington Northern Grassy Point Railroad Bridge at mile 5.44 to include authorized permanent winter hours. Mariners will still be able to request bridge openings with 12-hours advance notice during times of light traffic volume on the river due to ice formation that typically prevents most vessel navigation in the channel from December 15 through March 15 each year.

The bridges listed in the regulations as the Grassy Point Bridge at mile 8.0 and the Arrow Head Bridge at mile 8.7, respectively, have been removed from the waterway and will be removed from the regulations.

The Duluth, Missabe & Iron Range combined Railroad and Highway Bridge, also known as the Oliver Bridge, at mile 13.91, will be renamed the Canadian National Combined Railroad and Highway Bridge to reflect the current owner and use. The authorization to remain in the closed position will continue as before, but the drawbridge must return to operable condition when notified by the District Commander to do so.

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 protesters.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. Executive Order 13771 directs agencies to control regulatory costs through a budgeting process. This 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 (OMB) and pursuant to OMB guidance it is exempt from the requirements of Executive Order 13771.

This regulatory action determination is based on the ability that vessels can still transit the bridge given advanced notice during the winter when ice typically prevents vessels from transiting the waterway and vessel traffic is at its lowest. This rule will also align river mile numbers with the United States Coast Pilot and delete bridges from the regulations that have been removed from the waterway and make the regulation easier to read and less confusing to the mariner.

B. Impact on Small Entities

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

operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard did not receive any comments from the Small Business Administration on this rule. 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 bridge may be small entities, for the reasons stated in section IV.A above this final rule would not have a significant economic impact on any vessel owner or operator because the bridge will open with advance notice.

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**, above.

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

C. Collection of Information

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

D. Federalism and Indian Tribal Government

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this 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.

E. Unfunded Mandates Reform Act

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

F. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guides the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA)(42 U.S.C. 4321–4370f), and have made a determination that this action is one of a category of actions which do not individually or cumulatively have a significant effect on the human environment. This rule simply promulgates the operating regulations or procedures for drawbridges. This action is categorically excluded from further review, under figure 2–1, paragraph (32)(e), of the Instruction. A preliminary Record of Environmental Consideration and a Memorandum for the Record are not required for this rule.

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 117

Bridges.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 117 as follows:

PART 117—DRAWBRIDGE OPERATION REGULATIONS

■ 1. The authority citation for part 117 continues to read as follows:

Authority: 33 U.S.C. 499; 33 CFR 1.05–1; Department of Homeland Security Delegation No. 0170.1.

■ 2. Revise § 117.669 to read as follows:

§ 117.669 St. Louis River (Duluth-Superior Harbor).

(a) The draw of the Burlington Northern Grassy Point railroad Bridge, mile 5.44, shall open on signal except that, from December 15 through March 15 the draw shall open if at least 12-hour notice is given.

(b) The draw of the Canadian National Combined Railroad and Highway Bridge, mile 13.91, need not be opened for the passage of vessels. The owner shall return the draw to operable condition within a reasonable time when notified by the District Commander to do so.

■ 3. Revise § 117.1083 to read as follows:

§ 117.1083 Duluth-Superior Harbor (St. Louis River).

See § 117.669 St. Louis River (Duluth-Superior Harbor), listed under Minnesota.

Dated: June 15, 2017.

N.A. Bartolotta,

Captain, U.S. Coast Guard, Commander, Ninth Coast Guard District, Acting.

[FR Doc. 2017–15371 Filed 7–20–17; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2017–0594]

Safety Zone; Upper Ohio Valley Italian Heritage Festival/Upper Ohio Valley Italian Heritage Festival Fireworks, Wheeling, WV

AGENCY: Coast Guard, DHS.

ACTION: Notice of enforcement of regulation.

SUMMARY: The Coast Guard will enforce a safety zone for the Upper Ohio Valley Italian Heritage Festival/Upper Ohio Valley Italian Heritage Festival Fireworks on the Ohio River mile 90.0 to 90.5. The safety zone is necessary to provide for the safety of life and to protect vessels from the hazards associated with the ''Upper Ohio Valley

Italian Heritage Festival/Upper Ohio Valley Italian Heritage Festival Fireworks'' land-based fireworks display. During the enforcement period, entry into the safety zone is prohibited for all vessels not registered with the sponsor as participants or official patrol vessels, unless specifically authorized by the Captain of the Port Marine Safety Unit Pittsburgh (COTP) or a designated representative.

DATES: The regulations in 33 CFR 165.801, Table 1, line 14, will be enforced from 9 p.m. through 10:30 p.m., on July 22, 2017.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notice of enforcement, call or email MST1 Jennifer Haggins, Marine Safety Unit Pittsburgh, U.S. Coast Guard; telephone 412–221–0807, email *Jennifer.L.Haggins@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the safety zone for the annual ''Upper Ohio Valley Italian Heritage Festival/Upper Ohio Valley Italian Heritage Festival Fireworks'' land based fireworks display, listed in the regulations in 33 CFR 165.801, Table 1, Sector Ohio Valley, line 14 from 9 p.m. through 10:30 p.m., on July 22, 2017. Our Sector Ohio Valley Annual and Recurring Safety Zones, § 165.801, specifies the location of the regulated area for the Ohio River, Mile 90.0 to 90.5. Entry into the safety zone is prohibited unless authorized by the Captain of the Port Marine Safety Unit Pittsburgh (COTP) or a designated representative. Persons or vessels desiring to enter into or passage through the safety zone must request permission from the COTP or a designated representative. If permission is granted, all persons and vessels shall comply with the instructions of the COTP or designated representative.

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

Dated: June 28, 2017.

F. Smith,

Lieutenant Commander, U.S. Coast Guard, Captain of the Port Marine Safety Unit Pittsburgh, Acting.

[FR Doc. 2017–15370 Filed 7–20–17; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

37 CFR Part 2

[Docket No. PTO–T–2017–0025]

RIN 0651–AD22

Miscellaneous Changes to Trademark Trial and Appeal Board Rules of Practice; Clarification

AGENCY: United States Patent and Trademark Office, Commerce.

ACTION: Final rule.

SUMMARY: The United States Patent and Trademark Office (''USPTO'') published in the **Federal Register** on October 7, 2016 a final rule, which became effective on January 14, 2017, revising the Rules of Practice before the Trademark Trial and Appeal Board. This document clarifies certain provisions of the rules of practice regarding the deadlines for filing motions to compel discovery, motions to test the sufficiency of responses or objections to requests for admission, and motions for summary judgment. The clarification promotes clarity and reflects ongoing and current practice, in keeping with the goals of efficiency and predictability in the procedure and process of trial cases.

DATES: This rule is effective on July 21, 2017.

FOR FURTHER INFORMATION CONTACT: Cheryl Butler, Trademark Trial and Appeal Board, by email at *TTABFRNotices@uspto.gov,* or by telephone at (571) 272–4259.

SUPPLEMENTARY INFORMATION: The USPTO issues this final rule to clarify the latest time in an inter partes proceeding that certain motions may be filed. The USPTO's October 7, 2016 final rule revising the Trademark Trial and Appeal Board Rules of Practice (81 FR 69950) (published under RIN 0651–AC35), effective January 14, 2017, required that any motion to compel discovery, § 2.120(f)(1), motion to test the sufficiency of responses or objections to requests for admission, § 2.120(i)(1), or motion for summary judgment, § 2.127(e)(1), be filed prior to the deadline for pretrial disclosures for the first testimony period as set or as reset. The USPTO now amends the rules of practice to make clear that such motions must be filed before the day of the deadline for pretrial disclosures for the first testimony period as originally set or as reset.

The amendments promote clarity in the regulations and further the objectives of the January 14, 2017 final rule. They advance the goals of efficiency of inter partes proceedings by streamlining discovery and pretrial procedure, particularly by signaling that the trial phase of the proceedings commences with the deadline for the first pretrial disclosure, by which juncture all discovery disputes will have been resolved or at least brought to the attention of the Board and all parties.

Discussion of Rule Changes

Discovery

The USPTO is amending the third sentence of § 2.120(f)(1) to indicate that a motion to compel discovery must be filed before the day of the deadline for pretrial disclosures for the first testimony period as originally set or as reset.

The USPTO is amending the first sentence of § 2.120(i)(1) to indicate that a motion to determine and test the sufficiency of an answer or objection to a request for admission must be filed before the day of the deadline for pretrial disclosures for the first testimony period as originally set or as reset.

Motions

The USPTO is amending the second sentence of § 2.127(e)(1) to indicate that a motion for summary judgment must be filed before the day of the deadline for pretrial disclosures for the first testimony period as originally set or as reset.

Rulemaking Considerations

Administrative Procedure Act: The changes in this rulemaking involve rules of agency practice and procedure and/or interpretive rules. *See Nat'l Org. of Veterans' Advocates* v. *Sec'y of Veterans Affairs,* 260 F.3d 1365, 1375 (Fed. Cir. 2001) (Rule that clarifies interpretation of a statute is interpretive.); *Bachow Communications Inc.* v. *FCC,* 237 F.3d 683, 690 (D.C. Cir. 2001) (Rules governing an application process are procedural under the Administrative Procedure Act.); *Inova Alexandria Hosp.* v. *Shalala,* 244 F.3d 342, 350 (4th Cir. 2001) (Rules for handling appeals were procedural where they did not change the substantive standard for reviewing claims.).

Accordingly, prior notice and opportunity for public comment for the rule changes are not required pursuant to 5 U.S.C. 553(b) or (c), or any other law. *See Perez* v. *Mortgage Bankers Ass'n,* 135 S. Ct. 1199, 1206 (2015) (Notice-and-comment procedures are required neither when an agency

''issue[s] an initial interpretive rule'' nor ''when it amends or repeals that interpretive rule.''); *Cooper Techs. Co.* v. *Dudas,* 536 F.3d 1330, 1336–37 (Fed. Cir. 2008) (stating that 5 U.S.C. 553, and thus 35 U.S.C. 2(b)(2), does not require notice and comment rulemaking for ''interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice'' (quoting 5 U.S.C. 553(b)(A))).

Similarly, the 30-day delay in effectiveness is not applicable because this rule is not a substantive rule. 5 U.S.C. 553(d). As discussed above, this rulemaking involves rules of agency practice and procedure, merely consisting of clarifications to the procedure and timing of filing certain motions in inter partes proceedings. These changes are procedural in nature and will have no impact on the substantive evaluation of a trademark application or registration.

Regulatory Flexibility Act: The Deputy General Counsel for General Law of the United States Patent and Trademark Office has certified to the Chief Counsel for Advocacy of the Small Business Administration that this rule will not have a significant economic impact on a substantial number of small entities. *See* Regulatory Flexibility Act, 5 U.S.C. 605(b).

This rulemaking involves changes to a rule of agency practice and procedure in matters before the Trademark Trial and Appeal Board. The changes provide greater clarity as to certain deadlines in Board proceedings. This rule does not alter any substantive criteria used to decide cases.

This rule will apply to all persons appearing before the Board. Applicants for a trademark and other parties to Board proceedings are not industry-specific and may consist of individuals, small businesses, non-profit organizations, and large corporations. The Office does not collect or maintain statistics in Board cases on small- versus large-entity parties, and this information would be required in order to determine the number of small entities that would be affected by this rule.

No additional burden is imposed by this rule change. This rule will benefit all the parties to proceedings by increasing certainty, efficiency and clarity in the process, and streamlining the procedures. Therefore, this action will not have a significant economic impact on a substantial number of small entities.

Executive Order 12866: This rule has been determined not to be significant for purposes of Executive Order 12866.

Executive Order 13563 (Improving Regulation and Regulatory Review): The Office has complied with Executive Order 13563 (Jan. 18, 2011). Specifically, the Office has, to the extent feasible and applicable: (1) Made a reasoned determination that the benefits justify the costs of the rule changes; (2) tailored the rule to impose the least burden on society consistent with obtaining the regulatory objectives; (3) selected a regulatory approach that maximizes net benefits; (4) specified performance objectives; (5) identified and assessed available alternatives; (6) provided the public with a meaningful opportunity to participate in the regulatory process, including soliciting the views of those likely affected prior to issuing a notice of proposed rulemaking, and provided online access to the rulemaking docket; (7) attempted to promote coordination, simplification, and harmonization across government agencies and identified goals designed to promote innovation; (8) considered approaches that reduce burdens and maintain flexibility and freedom of choice for the public; and (9) ensured the objectivity of scientific and technological information and processes, to the extent applicable.

Executive Order 13771 (Reducing Regulation and Controlling Regulatory Costs): This rule is not an Executive Order 13771 regulatory action because this rule is not significant under Executive Order 12866.

Executive Order 13132: This rule does not contain policies with federalism implications sufficient to warrant preparation of a Federalism Assessment under Executive Order 13132 (Aug. 4, 1999).

Congressional Review Act: Under the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*), prior to issuing any final covered rule, the Office will submit a report containing the final rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the Government Accountability Office. The changes in this rule are not expected to result in an annual effect on the economy of 100 million dollars or more, a major increase in costs or prices, or significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises in domestic and export markets. Therefore, this rule change is not covered because it is not expected to result in a major rule as defined in 5 U.S.C. 804(2).

Unfunded Mandate Reform Act of 1995: The Unfunded Mandates Reform Act (2 U.S.C. 1501 *et seq.*) requires that agencies prepare an assessment of anticipated costs and benefits before issuing any rule that may result in expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more (adjusted annually for inflation) in any given year. This rule will have no such effect on State, local, and tribal governments or the private sector.

Paperwork Reduction Act: The Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3549) requires that the Office consider the impact of paperwork and other information collection burdens imposed on the public. This rule involves information collection requirements that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3549). The collections of information involved in this rulemaking have been reviewed and previously approved by OMB under control numbers 0651–0040 and 0651–0054. This rulemaking does not add any additional information requirements or fees for parties before the Board, and therefore, it does not change the information collection burdens approved under the OMB control numbers 0651–0040 and 0651–0054.

Notwithstanding any other provision of law, no person is required to respond to, nor shall any person be subject to, a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a currently valid OMB control number.

List of Subjects in 37 CFR Part 2

Administrative practice and procedure, Trademarks.

For the reasons given in the preamble and under the authority contained in 15 U.S.C. 1113, 15 U.S.C. 1123, and 35 U.S.C. 2, as amended, the Office is amending part 2 of title 37 as follows:

PART 2—RULES OF PRACTICE IN TRADEMARK CASES

■ 1. The authority citation for part 2 continues to read as follows:

Authority: 15 U.S.C. 1113, 15 U.S.C. 1123, 35 U.S.C. 2, Section 10(c) of Pub. L. 112–29, unless otherwise noted.

■ 2. Amend § 2.120 by revising paragraphs (f)(1) and (i)(1) to read as follows:

§ 2.120 Discovery.

* * * * *

(f) * * *

(1) If a party fails to make required initial disclosures or expert testimony disclosure, or fails to designate a person pursuant to Rule 30(b)(6) or Rule 31(a) of the Federal Rules of Civil Procedure, or if a party, or such designated person, or an officer, director or managing agent of a party fails to attend a deposition or fails to answer any question propounded in a discovery deposition, or any interrogatory, or fails to produce and permit the inspection and copying of any document, electronically stored information, or tangible thing, the party entitled to disclosure or seeking discovery may file a motion to compel disclosure, a designation, or attendance at a deposition, or an answer, or production and an opportunity to inspect and copy. A motion to compel initial disclosures must be filed within thirty days after the deadline therefor and include a copy of the disclosure(s), if any, and a motion to compel an expert testimony disclosure must be filed prior to the close of the discovery period. A motion to compel discovery must be filed before the day of the deadline for pretrial disclosures for the first testimony period as originally set or as reset. A motion to compel discovery shall include a copy of the request for designation of a witness or of the relevant portion of the discovery deposition; or a copy of the interrogatory with any answer or objection that was made; or a copy of the request for production, any proffer of production or objection to production in response to the request, and a list and brief description of the documents, electronically stored information, or tangible things that were not produced for inspection and copying. A motion to compel initial disclosures, expert testimony disclosure, or discovery must be supported by a showing from the moving party that such party or the attorney therefor has made a good faith effort, by conference or correspondence, to resolve with the other party or the attorney therefor the issues presented in the motion but the parties were unable to resolve their differences. If issues raised in the motion are subsequently resolved by agreement of the parties, the moving party should inform the Board in writing of the issues in the motion which no longer require adjudication.

* * * * *

(i) * * *

(1) Any motion by a party to determine the sufficiency of an answer or objection, including testing the sufficiency of a general objection on the ground of excessive number, to a request made by that party for an admission must be filed before the day of the deadline for pretrial disclosures for the first testimony period, as originally set or as reset. The motion shall include a copy of the request for admission and any exhibits thereto and of the answer or objection. The motion must be supported by a written statement from the moving party showing that such party or the attorney therefor has made a good faith effort, by conference or correspondence, to resolve with the other party or the attorney therefor the issues presented in the motion and has been unable to reach agreement. If issues raised in the motion are subsequently resolved by agreement of the parties, the moving party should inform the Board in writing of the issues in the motion which no longer require adjudication.

* * * * *

■ 3. Amend § 2.127 by revising paragraph (e)(1) to read as follows:

§ 2.127 Motions.

* * * * *

(e)(1) A party may not file a motion for summary judgment until the party has made its initial disclosures, except for a motion asserting claim or issue preclusion or lack of jurisdiction by the Trademark Trial and Appeal Board. A motion for summary judgment must be filed before the day of the deadline for pretrial disclosures for the first testimony period, as originally set or as reset. A motion under Rule 56(d) of the Federal Rules of Civil Procedure, if filed in response to a motion for summary judgment, shall be filed within thirty days from the date of service of the summary judgment motion. The time for filing a motion under Rule 56(d) will not be extended or reopened. If no motion under Rule 56(d) is filed, a brief in response to the motion for summary judgment shall be filed within thirty days from the date of service of the motion unless the time is extended by stipulation of the parties approved by the Board, or upon motion granted by the Board, or upon order of the Board. If a motion for an extension is denied, the time for responding to the motion for summary judgment may remain as specified under this section. A reply brief, if filed, shall be filed within twenty days from the date of service of the brief in response to the motion. The time for filing a reply brief will not be extended or reopened. The Board will consider no further papers in support of or in opposition to a motion for summary judgment.

* * * * *

Dated: July 17, 2017.

Joseph D. Matal,

Performing the Functions and Duties of the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

[FR Doc. 2017–15346 Filed 7–20–17; 8:45 am]

BILLING CODE 3510–16–P

POSTAL SERVICE

39 CFR Part 447

Rules of Conduct for Postal Employees

AGENCY: Postal Service.

ACTION: Final rule.

SUMMARY: The Postal Service is revising its rules concerning employee conduct to specify the circumstances under which a nonbargaining employee may consume intoxicating beverages at an Officer Approved Event or a Postmaster General Approved event. This revision is intended to ensure that the relevant rules conform to the Postal Service's existing practices regarding this matter.

DATES: *Effective date:* August 21, 2017.

FOR FURTHER INFORMATION CONTACT: David B. Ellis at (202) 268–2981, or *david.b.ellis@usps.gov.*

SUPPLEMENTARY INFORMATION: The Postal Service has determined that it is necessary to revise and update its regulations concerning employee conduct to reflect current practices concerning the possession and consumption of intoxicating beverages at officially-approved Postal Service events. The current rules, set forth at 39 CFR 447.21(e), are couched in general terms that fail to provide sufficient guidance to managers or employees.

As revised, the general prohibition against consuming intoxicating beverages on duty is replaced with a rule that intoxicating beverages may be consumed by non-bargaining employees while on duty only if consumption occurs at certain events known as *Officer Approved Events* and *Postmaster General Approved Events.* This change was made because the current regulations' general prohibition against on-duty consumption is not in accordance with Postal Service practice. The Postal Service permits the consumption of intoxicating beverages by nonbargaining employees at business meetings, sales meetings, and recognition events. At such events, Postal Service nonbargaining employees may be on duty because the event occurs during their normal work hours and their attendance is authorized or required, or because they are hosting or

performing Postal Service responsibilities at a recognition event, meeting with a customer, or otherwise conducting Postal Service business, whether or not the event occurs during the nonbargaining employee's normal work hours. Such events often involve the serving of food and beverages, whether during a meal or as refreshments at the event.

The Postal Service, however, wishes to restrict the consumption of intoxicating beverages by nonbargaining employees at Postal Service events to appropriate situations for which executive approval has been obtained, whether or not the employees are on duty. As a result, any event where intoxicating beverages are served to Postal Service nonbargaining employees, whether they are on duty or off duty, must meet the requirements for an Officer Approved Event or a Postmaster General Approved Event. Among other things, this means that the consumption of intoxicating beverages at the event would require the express approval of a Postal Service Officer or the Postmaster General.

The new regulations will not change the existing prohibitions against beginning work or returning to duty intoxicated. They will, however, impose a specific prohibition against becoming intoxicated at Officer Approved Events or Postmaster General Approved Events.

The new regulations also clarify the conditions under which intoxicating beverages may be possessed or consumed on Postal Service premises. First, beer and wine would be permitted on Postal Service premises if approved by a Postal Service Officer in connection with an Officer Approved Event. Under current regulations, only the Postmaster General may approve the consumption of intoxicating beverages on Postal Service Premises. Second, intoxicating beverages other than beer and wine would never be permitted on Postal Service premises, regardless of whether the event is an Officer Approved Event or a Postmaster General Approved Event. Under current regulations, the Postmaster General may approve the consumption of intoxicating beverages other than beer and wine on Postal Service premises.

List of Subjects in 39 CFR Part 447

Conflict of interests, Employee conduct, Government employees.

For the reasons stated in the preamble, the Postal Service amends 39 CFR part 447 as set forth below:

PART 447—RULES OF CONDUCT FOR POSTAL EMPLOYEES

■ 1. The authority citation for part 447 continues to read as follows:

Authority: 39 U.S.C. 401.

Subpart B—Employee Conduct

■ 2. Revise § 447.21(e) to read as follows:

§ 447.21 Prohibited conduct.

* * * * *

(e)(1) Except as provided in this paragraph, employees must not drink beer, wine, or other intoxicating beverages while on duty; begin work or return to duty intoxicated; or drink intoxicating beverages in a public place while in uniform. Employees found to be violating this policy may be subject to disciplinary action.

(2) A nonbargaining employee may consume beer or wine at an Officer Approved Event. An *Officer Approved Event* means: A meeting of Postal Service employees convened by management, such as a working meal, an employee recognition event, or an employee appreciation event; or an event whose primary purpose is to interact with external individuals or entities, such as an industry conference, a sales meeting, or a supplier meeting; that in all cases is either attended by an Officer of the Postal Service who personally decides that the consumption of beer and wine by employees is appropriate, or with respect to which an Officer of the Postal Service has granted specific, written, and advance approval for the consumption of beer and wine by employees.

(3) A nonbargaining employee may consume beer, wine, or other intoxicating beverages at a Postmaster General Approved Event. A *Postmaster General Approved Event* means any Postal Service-related event with respect to which the Postmaster General personally approves the consumption of beer, wine, or other intoxicating beverages.

(4) No employee may become intoxicated while at an Officer Approved Event or a Postmaster General Approved Event. Except in connection with an Officer Approved Event or a Postmaster General Approved Event occurring at a Postal Service facility or premises, no employee shall have or bring any container of beer or wine into any Postal Service facility or premises, whether the container has been opened or not. Intoxicating beverages other than beer and wine may never be brought into any Postal Service facility or premises under any circumstances.

* * * * *

Stanley F. Mires,

Attorney, Federal Compliance.

[FR Doc. 2017–15311 Filed 7–20–17; 8:45 am]

BILLING CODE 7710–12–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R04–OAR–2016–0656; FRL–9965–14–Region 4]

Air Plan Approval; Florida: Unnecessary Rule Removal

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving a revision to the Florida State Implementation Plan submitted by the Florida Department of Environmental Protection (DEP) on February 20, 2013. The revision removes unnecessary and superseded rules from the Florida State Implementation Plan (SIP). Specifically, this revision removes non-regulatory introductory language, as well as a regulation that has been superseded by more stringent federal regulations. This action is being taken pursuant to the Clean Air Act (CAA or Act).

DATES: This direct final rule is effective September 19, 2017 without further notice, unless EPA receives adverse comment by August 21, 2017. If EPA receives such comments, it will publish a timely withdrawal of the direct final rule in the **Federal Register** and inform the public that the rule will not take effect.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R04–OAR–2016–0656 at *http://www.regulations.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. 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. EPA will generally not consider comments or comment

contents located outside of the primary submission (*i.e.,* on the Web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT:

Sean Lakeman, Air Regulatory Management Section, Air Planning and Implementation Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW., Atlanta, Georgia 30303–8960. The telephone number is (404) 562–9043. Mr. Lakeman can also be reached via electronic mail at *lakeman.sean@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with 40 CFR 51.103, DEP submitted for EPA to review and approve revisions to Florida's SIP under the CAA. The SIP revision removes four rules from the SIP that are unnecessary or have been superseded by federal regulations. The rules requested to be removed from the SIP are Rule 62–210.100, Florida Administrative Record (F.A.C.), ''Purpose and Scope;'' Rule 62–212.100, F.A.C., ''Purpose and Scope;'' Rule 62–296.407, F.A.C., ''Portland Cement Plants;'' and Rule 62–297.100, F.A.C., ''Purpose and Scope.''

II. Analysis of State's Submittal

On February 20, 2013, the DEP submitted a SIP revision to EPA for review and approval. This SIP revision requests the removal of Rules 62–210.100, 62–212.100, and 62–297.100, F.A.C., each of which is titled ''Purpose and Scope,'' because they contain unnecessary, introductory language for the associated rule chapters. This introductory language serves no regulatory purpose and can be removed without being considered a relaxation of a regulation. The language merely introduces the regulatory chapter that follows and does not impose any regulatory requirements.

This SIP revision also removes Rule 62–296.407, F.A.C., ''Portland Cement Plants,'' from the current SIP. Particulate matter (PM) emissions from Portland cement kilns and clinker coolers are more stringently regulated under 40 CFR part 60, subpart F (Standards of Performance for Portland Cement Plants), and 40 CFR part 63, subpart LLL (National Emission Standards for Hazardous Air Pollutants From the Portland Cement Manufacturing Industry), than under Rule 62–296.407, F.A.C. The Florida DEP has been delegated the authority to implement and enforce both part 60, subpart F, *see* 55 FR 23077 (June 6, 1990) and 63 FR 50163 (September 21, 1998), and part 63, subpart LLL, *see* 40 CFR 63.99(a)(10). All Portland cement facilities in Florida originally subject only to Rule 62–296.407, F.A.C., have either been permanently shut down or modernized such that the emission limits set forth in the federal regulations currently apply. Actual PM emissions are expected to decrease in the future as facilities come into compliance with 40 CFR part 63, subpart LLL, as most recently amended on September 11, 2015. *See* 80 FR 54728.

These changes are consistent with section 110 of the CAA and meet the regulatory requirements pertaining to SIPs. Pursuant to CAA section 110(l), the Administrator shall not approve a revision of a plan if the revision would interfere with any applicable requirement concerning attainment and reasonable further progress (as defined in CAA section 171), or any other applicable requirement of the Act. The revision of Rules 62–210.100, 62–212.100, 62–296.407, and 62–297.100 and, F.A.C., are approvable under section 110(l) because they would not interfere with the attainment and maintenance of the NAAQS.

III. Final Action

Pursuant to section 110 of the CAA, EPA is approving the revision to the Florida SIP removing unnecessary rules from the SIP. EPA has evaluated Florida's February 20, 2013, submittal and has determined that it meets the applicable requirements of the CAA and EPA regulations and is consistent with EPA policy.

EPA is publishing this rule without prior proposal because the Agency views this as a noncontroversial submittal and anticipates no adverse comments. However, in the proposed rules section of this **Federal Register** publication, EPA is publishing a separate document that will serve as the proposal to approve the SIP revision should adverse comments be filed. This rule will be effective September 19, 2017 without further notice unless the Agency receives adverse comments by August 21, 2017.

If EPA receives such comments, then EPA will publish a document withdrawing the final rule and informing the public that the rule will not take effect. All public comments received will then be addressed in a subsequent final rule based on the proposed rule. EPA will not institute a second comment period. Parties interested in commenting should do so at this time. If no such comments are received, the public is advised that this rule will be effective on September 19, 2017 and no further action will be taken on the proposed rule.

Please note that if we receive adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, we may adopt as final those provisions of the rule that are not the subject of an adverse comment.

IV. Statutory and Executive Order Reviews

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

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and

• does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

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

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

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by September 19, 2017. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. Parties with objections to this direct final rule are encouraged to file a comment in response to the parallel notice of proposed rulemaking for this action published in the proposed rules section of today's **Federal Register**, rather than file an immediate petition for judicial review of this direct final rule, so that EPA can withdraw this direct final rule and address the comment in the proposed rulemaking. This action may not be challenged later in proceedings to enforce its requirements. *See* section 307(b)(2).

List of Subjects in 40 CFR Part 52

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

Dated: July 7, 2017.

V. Anne Heard,

Acting Regional Administrator, Region 4.

40 CFR part 52 is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

Subpart K—Florida

§ 52.520 [Amended]

■ 2. Section 52.520(c) is amended by removing the entries for ''62–210.100,'' ''62–212.100,'' ''62–297.100,'' and ''62–296.407.''

[FR Doc. 2017–15268 Filed 7–20–17; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 82

[EPA–HQ–OAR–2003–0118; FRL–9964–73–OAR]

RIN 2060–AG12

Protection of Stratospheric Ozone: Determination 33 for Significant New Alternatives Policy Program

AGENCY: Environmental Protection Agency (EPA).

ACTION: Determination of acceptability.

SUMMARY: This determination of acceptability expands the list of acceptable substitutes pursuant to the U.S. Environmental Protection Agency's (EPA) Significant New Alternatives Policy (SNAP) program. This action lists as acceptable additional substitutes for use in the refrigeration and air conditioning sector and the cleaning solvents sector.

DATES: This determination is applicable on July 21, 2017.

ADDRESSES: EPA established a docket for this action under Docket ID No. EPA–HQ–OAR–2003–0118 (continuation of Air Docket A–91–42). All electronic documents in the docket are listed in the index at *www.regulations.gov.* Although listed in the index, some information is not publicly available, *i.e.,* Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Publicly available docket materials are available either electronically at *www.regulations.gov* or in hard copy at the EPA Air Docket (Nos. A–91–42 and EPA–HQ–OAR–2003–0118), EPA Docket Center (EPA/DC), William J. Clinton West, Room 3334, 1301 Constitution Avenue NW., Washington, DC 20460. 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 Air Docket is (202) 566–1742.

FOR FURTHER INFORMATION CONTACT: Gerald Wozniak by telephone at (202) 343–9624, by email at *wozniak.gerald@epa.gov,* or by mail at U.S. Environmental Protection Agency, Mail Code 6205T, 1200 Pennsylvania Avenue NW., Washington, DC 20460. Overnight or courier deliveries should be sent to the office location at 1201 Constitution Avenue NW., Washington, DC 20004.

For more information on the Agency's process for administering the SNAP program or criteria for the evaluation of substitutes, refer to the initial SNAP rulemaking published in the **Federal Register** on March 18, 1994 (59 FR 13044). Notices and rulemakings under the SNAP program, as well as other EPA publications on protection of stratospheric ozone, are available at EPA's Ozone Layer Protection Web site at *www.epa.gov/ozone-layer-protection* including the SNAP portion at *www.epa.gov/snap/.*

SUPPLEMENTARY INFORMATION:

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Appendix A: Summary of Decisions for New Acceptable Substitutes

I. Listing of New Acceptable Substitutes

This action presents EPA's most recent decision to list as acceptable several substitutes in the refrigeration and air conditioning sector and the cleaning solvents sector. New substitutes are:

• Hydrofluorocarbon (HFC)-134a in residential and light commercial air conditioning and heat pumps (retrofit equipment);

- Hydrofluoroether (HFE)-7300 in non-mechanical heat transfer systems (new and retrofit equipment);
- R-407H in retail food refrigeration—remote condensing units (new and retrofit equipment);
- R-442A in retail food refrigeration—remote condensing units (new and retrofit equipment);
- R-448A in multiple refrigeration and air conditioning end-uses (new and retrofit equipment);
- R-449A in multiple refrigeration and air conditioning end-uses (new and retrofit equipment);
- R-449B in multiple refrigeration and air conditioning end-uses (new and retrofit equipment);
- R-452A in multiple refrigeration and air conditioning end-uses (new and retrofit equipment);
- R-452C in multiple refrigeration and air conditioning end-uses (new and retrofit equipment);
- R-453A in multiple refrigeration and air conditioning end-uses (new and retrofit equipment);
- R-458A in multiple refrigeration and air-conditioning end-uses (new and retrofit equipment);
- R-513A in residential dehumidifiers (new and retrofit equipment); and
- HFE-7300 in electronics cleaning, metals cleaning, and precision cleaning end-uses.

EPA's review of certain substitutes listed in this document is pending for other uses. Listing in the end-uses and applications in this document does not prejudge EPA's listings of these substitutes for other uses. For many of the substitutes being added through this document to the acceptable lists for specific end-uses, there are other listed substitutes for the end-use whose overall risk is comparable except that they have a lower risk in one SNAP criterion, for example toxicity or atmospheric effects. However, for the end-uses addressed in this action, those alternatives have not yet proven feasible in those specific end-uses. If alternatives that pose significantly less overall risk—either those currently listed or new alternatives added to the list—are demonstrated in the future as feasible for one or more of the relevant end-uses, EPA may evaluate whether to change the listing status of the substitutes addressed in this document.

For copies of the full list of acceptable substitutes for ozone depleting substances (ODS) in all industrial sectors, visit the SNAP portion of EPA's Ozone Layer Protection Web site at *www.epa.gov/snap/substitutes-sector.* Substitutes listed as unacceptable; acceptable, subject to narrowed use limits; or acceptable, subject to use conditions are also listed in the appendices to 40 CFR part 82, subpart G.

The sections below discuss each substitute listing in detail. Appendix A contains tables summarizing today's listing decisions for these new substitutes. The statements in the ''Further Information'' column in the tables provide additional information but are not legally binding under section 612 of the Clean Air Act (CAA). In addition, the ''Further Information'' column may not include a comprehensive list of other legal obligations you may need to meet when using the substitute. Although you are not required to follow recommendations in the ''Further Information'' column of the table to use a substitute consistent with section 612 of the CAA, some of these statements may refer to obligations that are enforceable or binding under federal or state programs other than the SNAP program. In many instances, the information simply refers to standard operating practices in existing industry standards and/or building codes. When using these substitutes, EPA strongly encourages you to apply the information in this column. Many of these recommendations, if adopted, would not require significant changes to existing operating practices.

You can find submissions to EPA for the substitutes listed in this document, as well as other materials supporting the decisions in this action, in Docket EPA–HQ–OAR–2003–0118 at *www.regulations.gov.*

A. Refrigeration and Air Conditioning

1. HFC-134a

EPA's decision: EPA finds HFC-134a acceptable as a substitute for use in:

- Residential and light commercial air conditioning and heat pumps (retrofit equipment only)

HFC-134a is also known as R-134a, or 1,1,1,2-tetrafluoroethane (CAS Reg. No. 811–97–2). EPA has previously listed HFC-134a as acceptable for use in residential and light commercial air conditioning and heat pumps in new equipment, as well as in a number of other end-uses and sectors.

You may find the redacted submission in Docket EPA–HQ–OAR–2003–0118 at *www.regulations.gov* under the name, ''Supporting Documentation for Notice 33 Listing of HFC-134a in Residential and Light Commercial Air Conditioning and Heat Pumps. SNAP Submission Received February 3, 2014.'' EPA performed an assessment to examine the health and environmental risks of this substitute. This assessment is available in Docket EPA–HQ–OAR–2003–0118 under the following name:

- ''Risk Screen on Substitutes in Residential and Light Commercial Air Conditioning and Heat Pumps Substitute: HFC-134a''

Environmental information: HFC-134a has an ozone depletion potential (ODP) of approximately zero.[1] Its global warming potential (GWP) is 1,430, and it has an atmospheric lifetime[2] of approximately 14 years.[3] HFC-134a is excluded from the definition of volatile organic compounds (VOC) under CAA regulations (see 40 CFR 51.100(s)) addressing the development of state implementation plans (SIPs) to attain and maintain the National Ambient Air Quality Standards (NAAQS). Knowingly venting or releasing this refrigerant is limited by the venting prohibition under section 608(c)(2) of the CAA, codified at 40 CFR 82.154(a)(1).

Flammability information: HFC-134a is not flammable.

Toxicity and exposure data: Potential health effects of exposure to this substitute include drowsiness or dizziness. The substitute may also irritate the skin or eyes or cause frostbite. At sufficiently high concentrations, the substitute may cause irregular heartbeat when inhaled. The substitute could cause asphyxiation if air is displaced by vapors in a confined space. These potential health effects are common to many refrigerants.

The American Industrial Hygiene Association (AIHA) has established a workplace environmental exposure limit (WEEL) of 1,000 ppm as an eight-hour time-weighted average (8-hr TWA) for HFC-134a. EPA anticipates that users will be able to meet the AIHA WEEL and address potential health risks by following requirements and recommendations in the manufacturer's Safety Data Sheet (SDS), in the American Society for Heating, Refrigerating, and Air-Conditioning Engineers (ASHRAE) Standard 15, and other safety precautions common to the refrigeration and air conditioning industry.

[1] EPA assumes that compounds containing no chlorine, bromine, or iodine have an ODP of zero.

[2] We provide information on the atmospheric lifetime of individual chemicals where we have such information.

[3] Unless otherwise stated, all GWPs in this document are 100-year values from: IPCC, 2007: *Climate Change 2007: The Physical Science Basis. Contribution of Working Group I to the Fourth Assessment Report of the Intergovernmental Panel on Climate Change* [Solomon, S., Qin, D., Manning, M., Chen, Z., Marquis, M., Averyt, K.B., Tignor M., and Miller, H.L. (eds.)]. Cambridge University Press, Cambridge, United Kingdom and New York, NY, USA. This document is accessible at *www.ipcc.ch/publications_and_data/ar4/wg1/en/contents.html.*

Comparison to other substitutes in this end-use: HFC-134a has an ODP of zero, comparable [4] to the other listed substitutes in this end-use, all with an ODP of zero.

HFC-134a has a GWP of 1,430. All other substitutes listed as acceptable for residential and light commercial air conditioning and heat pumps in retrofit equipment have higher GWPs than HFC-134a, such as R-407C, R-438A, and R-507A with GWPs ranging from 1,770 to 3,990.

Flammability and toxicity risks are comparable to or lower than flammability and toxicity risks of other available substitutes in the same end-use. Toxicity risks can be minimized by use consistent with the AIHA WEELs, ASHRAE 15 and other industry standards, recommendations in the manufacturer's SDS, and other safety precautions common in the refrigeration and air conditioning industry.

EPA finds HFC-134a acceptable in the end-use listed above, because it does not pose greater overall environmental and human health risk than other available substitutes in the same end-use.

2. HFE-7300 (1,1,1,2,2,3,4,5,5,5-decafluoro-3-methoxy-4-(trifluoromethyl)pentane)

EPA's decision: EPA finds HFE-7300 acceptable as a substitute for use in:

- Non-mechanical heat transfer systems (new and retrofit equipment) [5]

HFE-7300 is also known as 1,1,1,2,2,3,4,5,5,5-decafluoro-3-methoxy-4-(trifluoromethyl)pentane (CAS Reg. No. 132182–92–4) and goes by the trade name of 3M™ Novec™ 7300 Engineered Fluid.

You may find the redacted submission in Docket EPA–HQ–OAR–2003–0118 at *www.regulations.gov* under the name, ''Supporting Documentation for Notice 33 Listing of HFE-7300 in Solvent Cleaning and Non-Mechanical Heat Transfer Systems. SNAP Submission Received October 13, 2016.'' EPA performed an assessment to examine the health and environmental risks of this substitute. This assessment is available in Docket EPA–HQ–OAR–2003–0118 under the following name:

- ''Risk Screen on Substitutes in Heat Transfer: HFE-7300''

Environmental information: HFE-7300 has an ODP of zero. The GWP of HFE-7300 is approximately 310, and it has an atmospheric lifetime of approximately 3.8 years.[6] HFE-7300 is excluded from the definition of VOC under CAA regulations (see 40 CFR 51.100(s)) addressing the development of SIPs to attain and maintain the NAAQS. This substitute is subject to a Toxic Substance Control Act (TSCA) section 5(a)(2) Significant New Use Rule (SNUR) (40 CFR 721.10061) which requires notification to EPA before release of manufacturing, process, or use streams containing the substitute into the waters of the United States. Knowingly venting or releasing this refrigerant is limited by the venting prohibition under section 608(c)(2) of the CAA, codified at 40 CFR 82.154(a)(1).

Flammability information: HFE-7300 is not flammable.

Toxicity and exposure data: Potential health effects of exposure to this substitute include eye irritation, skin irritation, and respiratory tract irritation. Ingestion of HFE-7300 may also be harmful. The substitute could cause asphyxiation if air is displaced by vapors in a confined space. These potential health effects are common to many refrigerants.

EPA anticipates that HFE-7300 will be used in a manner consistent with the recommendations specified in the SDS. The manufacturer recommends an acceptable exposure limit (AEL) of 100 ppm on an 8-hour TWA. EPA anticipates that users will be able to meet the manufacturer's AEL and address potential health risks by following requirements and recommendations in the manufacturer's SDS and in any other safety precautions common to the refrigeration and air conditioning industry.

Comparison to other substitutes in this end-use: HFE-7300 has an ODP of zero, comparable [7] to or lower than other acceptable substitutes in this same end-use, with ODPs ranging from zero to 0.00034.[8]

For non-mechanical heat transfer systems, HFE-7300's GWP of 310 is lower than or comparable to that of acceptable substitutes, such as HFE-7100, HFC-245fa, and HFC-236fa with GWPs ranging from about 300 to 9,810. HFE-7300's GWP is higher than the GWPs of other acceptable substitutes in non-mechanical heat transfer systems, including C7 Fluoroketone, HFO-1234ze(E), and HFE-7200 with GWPs ranging from one to approximately 60.

Flammability and toxicity risks are comparable to or lower than flammability and toxicity risks of other available substitutes in the same end-use. Toxicity risks can be minimized by use consistent with the manufacturer's AEL, recommendations in the manufacturer's SDS, and other safety precautions common in the refrigeration and air conditioning industry.

EPA finds HFE-7300 acceptable in the end-use listed above because it does not pose greater overall environmental and human health risk than other available substitutes in the same end-use.

3. R-407H

EPA's decision: EPA finds R-407H acceptable as a substitute for use in:

- Retail food refrigeration—remote condensing units (new and retrofit equipment)

R-407H, marketed under the trade name D407, is a weighted blend of 52.5 percent HFC-134a, which is also known as 1,1,1,2-tetrafluoroethane (CAS Reg. No. 811–97–2); 32.5 percent HFC-32, which is also known as difluoromethane (CAS Reg. No. 75–10–5); and 15 percent HFC-125, which is also known as 1,1,1,2,2-pentafluoroethane (CAS Reg. No. 354-33-6).

You may find the redacted submission in Docket EPA-HQ-OAR-2003-0118 at *www.regulations.gov* under the name, ''Supporting Documentation for Notice 33 Listing of R-407H in Retail Food Refrigeration (Remote Condensing Units). SNAP Submission Received January 26, 2017.'' EPA has performed an assessment to examine the health and environmental risks of this substitute. This assessment is available in Docket EPA–HQ–OAR–2003–0118 under the following name:

- ''Risk Screen on Substitutes for Use in Retail Food Refrigeration Substitute: R-407H''

Environmental information: R-407H has an ODP of zero. Its components, HFC-134a, HFC-32, and HFC-125, have GWPs of 1,430, 675, and 3,500, respectively. If these values are weighted by mass percentage, then R-407H has a GWP of about 1,500. The components of R-407H are excluded from the definition of VOC under CAA regulations (see 40 CFR 51.100(s)) addressing the development of SIPs to attain and maintain the NAAQS. Knowingly venting or releasing this refrigerant blend is limited by the venting prohibition under section 608(c)(2) of the CAA, codified at 40 CFR 82.154(a)(1).

[4] This is in contrast to the historically used ODS CFC-12, R-502, and HCFC-22 with ODPs ranging from 0.055 to 1.0.

[5] Acceptable substitutes for organic Rankine cycle have typically been included through listings in the non-mechanical heat transfer end-use. EPA may review organic Rankine cycle applications separately in the future.

[6] 3M (2016) as per IPCC 4th Assessment Report.

[7] This is in contrast to the historically used ODS CFC-11, CFC-12, CFC-113, CFC-114, and HCFC-22 with ODPs ranging from 0.055 to 1.0.

[8] Unless otherwise stated, all ODPs in this document are from EPA's regulations at appendix A to subpart A of 40 CFR part 82.

Flammability information: R-407H, as formulated and even considering the worst-case of fractionation for flammability, is not flammable.

Toxicity and exposure data: Potential health effects of exposure to this substitute include drowsiness or dizziness. The substitute may also irritate the skin or eyes or cause frostbite. At sufficiently high concentrations, the substitute may cause irregular heartbeat. The substitute could cause asphyxiation if air is displaced by vapors in a confined space. These potential health effects are common to many refrigerants.

EPA anticipates that R-407H will be used in a manner consistent with the recommendations specified in the SDS. The AIHA has established WEELs of 1,000 ppm as an 8-hr TWA for HFC-134a, HFC-32, and HFC-125, the components of R-407H. The manufacturer recommends an AEL of 1,000 ppm on an 8-hour TWA for the blend. EPA anticipates that users will be able to meet the manufacturer's AEL and the AIHA WEELs and to address potential health risks by following requirements and recommendations in the manufacturer's SDS, in ASHRAE 15, and other safety precautions common to the refrigeration and air conditioning industry.

Comparison to other substitutes in this end-use: R-407H has an ODP of zero, comparable [9] to or lower than the other listed substitutes in this end-use, with ODPs ranging from zero to 0.057.

For retail food refrigeration—remote condensing units, R-407H's GWP of about 1,500 is lower than that of acceptable substitutes, such as R-407A, R-407C, R-407F, R-410B, and R-421A, with GWPs ranging from 1,770 to 2,630. R-407H's GWP is higher than the GWPs of other acceptable substitutes in retail food refrigeration—remote condensing units, including CO_2, R-450A, and R-513A, with GWPs ranging from one to about 630.

Flammability and toxicity risks are comparable to or lower than flammability and toxicity risks of other available substitutes in the same end-use. Toxicity risks can be minimized by use consistent with the AIHA WEELs, manufacturer's AEL, ASHRAE 15, and other industry standards, recommendations in the manufacturer's SDS, and other safety precautions common in the refrigeration and air conditioning industry.

EPA finds R-407H acceptable in the end-use listed above because it does not pose greater overall environmental and human health risk than other available substitutes in the same end-use.

4. R-442A

EPA's decision: EPA finds R-442A acceptable as a substitute for use in:

- Retail food refrigeration—remote condensing units (new and retrofit equipment)

R-442A, marketed under the trade name RS-50, is a weighted blend of 31 percent HFC-32, which is also known as difluoromethane (CAS Reg. No. 75–10–5); 31 percent HFC-125, which is also known as 1,1,1,2,2-pentafluoroethane (CAS Reg. No. 354–33–6); 30 percent HFC-134a, which is also known as 1,1,1,2-tetrafluoroethane (CAS Reg. No. 811–97–2); five percent HFC-227ea, which is also known as 1,1,1,2,3,3,3-heptafluoropropane (CAS Reg. No. 431–89–0); and three percent HFC-152a, which is also known as 1,1-difluoroethane (CAS Reg. No. 75–37–6).

EPA previously listed R-442A as an acceptable refrigerant in a number of other refrigeration and air conditioning end-uses (May 17, 2013; 78 FR 29034).

You may find the redacted submission in Docket EPA–HQ–OAR–2003–0118 at *www.regulations.gov* under the name, ''Supporting Documentation for Notice 33 Listing of R-442A (RS 50) in Retail Food Refrigeration (Remote Condensing Units). SNAP Submission Received July 26, 2011.'' EPA has performed an assessment to examine the health and environmental risks of this substitute. This assessment is available in Docket EPA–HQ–OAR–2003–0118 under the following name:

- ''Risk Screen on Substitutes for Use in Retail Food Refrigeration Substitute: R-442A''

Environmental information: R-442A has an ODP of zero. Its components, HFC-32, HFC-125, HFC-134a, HFC-227ea, and HFC-152a, have GWPs of 675; 3,500; 1,430; 3,220; and 124, respectively. If these values are weighted by mass percentage, then R-442A has a GWP of about 1,890. The components of R-442A are excluded from the definition of VOC under CAA regulations (see 40 CFR 51.100(s)) addressing the development of SIPs to attain and maintain the NAAQS. Knowingly venting or releasing this refrigerant blend is limited by the venting prohibition under section 608(c)(2) of the CAA, codified at 40 CFR 82.154(a)(1).

Flammability information: R-442A, as formulated and even considering the worst-case of fractionation for flammability, is not flammable.

Toxicity and exposure data: Potential health effects of exposure to this substitute include drowsiness or dizziness. The substitute may also irritate the skin or eyes or cause frostbite. At sufficiently high concentrations, the substitute may cause irregular heartbeat. The substitute could cause asphyxiation if air is displaced by vapors in a confined space. These potential health effects are common to many refrigerants.

The AIHA has established WEELs of 1,000 ppm as an 8-hr TWA for HFC-32, HFC-125, HFC-134a, HFC-227ea, and HFC-152a, the components of R-442A. The manufacturer of R-442A recommends an AEL of 1,000 ppm on an 8-hour TWA for the blend. EPA anticipates that users will be able to meet the AIHA WEELs and address potential health risks by following requirements and recommendations in the manufacturer's SDS, in ASHRAE 15, and other safety precautions common to the refrigeration and air conditioning industry.

Comparison to other substitutes in this end-use: R-442A has an ODP of zero, comparable [10] to or lower than the other listed substitutes in this end-use, with ODPs ranging from zero to 0.057.

For retail food refrigeration—remote condensing units, R-442A's GWP of about 1,890 is lower than or comparable to that of acceptable substitutes, such as R-407A, R-407F, R-410B, and R-421A with GWPs ranging from 1,820 to 2,630. R-442A's GWP is higher than the GWPs of other acceptable substitutes in retail food refrigeration—remote condensing units, including CO_2 with a GWP of one and HFC-134a, R-407C, R-448A, R-449A, R-449B, R-450A, and R-513A with GWPs of about 600 to 1,770.

Flammability and toxicity risks are comparable to or lower than flammability and toxicity risks of other available substitutes in the same end-use. Toxicity risks can be minimized by use consistent with the AIHA WEELs, ASHRAE 15, and other industry standards, recommendations in the manufacturer's SDS, and other safety precautions common in the refrigeration and air conditioning industry.

EPA finds R-442A acceptable in the end-use listed above because it does not pose greater overall environmental and human health risk than other available substitutes in the same end-use.

5. R-448A

EPA's decision: EPA finds R-448A acceptable as a substitute for use in:

[9] This is in contrast to the historically used ODS CFC-12, HCFC-22, and R-502, with ODPs ranging from 0.055 to 1.0.

[10] This is in contrast to the historically used ODS CFC-12, HCFC-22, and R-502, with ODPs ranging from 0.055 to 1.0.

- Cold storage warehouses (new and retrofit equipment)
- Industrial process refrigeration (new and retrofit equipment)

R-448A, marketed under the trade name Solstice® N-40, is a weighted blend of 26 percent HFC-32, which is also known as difluoromethane (CAS Reg. No. 75-10-5); 26 percent HFC-125, which is also known as 1,1,1,2,2-pentafluoroethane (CAS Reg. No. 354–33–6); 21 percent HFC-134a, which is also known as 1,1,1,2-tetrafluoroethane (CAS Reg. No. 811–97–2); 20 percent HFO-1234yf, which is also known as 2,3,3,3-tetrafluoroprop-1-ene (CAS Reg. No 754–12–1); and seven percent HFO-1234ze(E), which is also known as *trans*-1,3,3,3-tetrafluoroprop-1-ene (CAS Reg. No. 29118-24-9).

You may find the redacted submission in Docket EPA–HQ–OAR–2003–0118 at *www.regulations.gov* under the name, ''Supporting Documentation for Notice 33 Listing of R-448A (N-40) in Industrial Process Refrigeration and Cold Storage Warehouses. SNAP Submission Received May 29, 2014.'' EPA performed assessments to examine the health and environmental risks of this substitute. These assessments are available in Docket EPA–HQ–OAR–2003–0118 under the following names:

- ''Risk Screen on Substitutes in Cold Storage Warehouses Substitute: R-448A (Solstice® N-40)''
- ''Risk Screen on Substitutes in Industrial Process Refrigeration Substitute: R-448A (Solstice® N-40)''

EPA previously listed R-448A as an acceptable refrigerant in a number of other refrigeration and air conditioning end-uses (*e.g.,* July 16, 2015, 80 FR 42053; October 11, 2016, 81 FR 70029).

Environmental information: R-448A has an ODP of zero. Its components, HFC-32, HFC-125, HFC-134a, HFO-1234yf, and HFO-1234ze(E) have GWPs of 675; 3,500; 1,430; one to four; [11] [12] and one to six; [13] respectively. If these values are weighted by mass percentage, then R-448A has a GWP of about 1,390. The components of R-448A are excluded from the definition of VOC under CAA regulations (see 40 CFR 51.100(s)) addressing the development of SIPs to attain and maintain the NAAQS. Knowingly venting or releasing this refrigerant blend is limited by the venting prohibition under section 608(c)(2) of the CAA, codified at 40 CFR 82.154(a)(1).

Flammability information: R-448A, as formulated and even considering the worst-case of fractionation for flammability, is not flammable.

Toxicity and exposure data: Potential health effects of exposure to this substitute include drowsiness or dizziness. The substitute may also irritate the skin or eyes or cause frostbite. At sufficiently high concentrations, the substitute may cause irregular heartbeat. The substitute could cause asphyxiation if air is displaced by vapors in a confined space. These potential health effects are common to many refrigerants.

The AIHA has established WEELs of 1,000 ppm as an 8-hr TWA for HFC-32, HFC-125, and HFC-134a; 500 ppm for HFO-1234yf; and 800 ppm for HFO-1234ze(E), the components of R-448A. The manufacturer of R-448A recommends an AEL of 890 ppm on an 8-hour TWA for the blend. EPA anticipates that users will be able to meet the AIHA WEELs and manufacturer's AEL and address potential health risks by following requirements and recommendations in the manufacturer's SDS, in ASHRAE 15, and other safety precautions common to the refrigeration and air conditioning industry.

Comparison to other substitutes in these end-uses: R-448A has an ODP of zero, comparable [14] to or lower than other listed substitutes in these end-uses, with ODPs ranging from zero to 0.057.

For cold storage warehouses, R-448A's GWP of 1,390 is lower than or comparable to that of acceptable substitutes, such as HFC-134a, R-407C, and R-407F, with GWPs ranging from 1,430 to 1,820. R-448A's GWP is higher than the GWPs of other acceptable substitutes for cold storage warehouses, including ammonia absorption, desiccant cooling, evaporative cooling, R-450A, and R-513A with GWPs ranging from zero to about 630.

For industrial process refrigeration, R-448A's GWP of 1,390 is lower than or comparable to that of acceptable substitutes, such as HFC-134a, R-404A, R-407C, and HFC-23 with GWPs ranging from 1,430 to 14,800. R-448A's GWP is higher than the GWPs of other acceptable substitutes for industrial process refrigeration, including ammonia absorption, ammonia vapor compression, Sterling cycle, CO_2, propane, R-450A, and R-513A with GWPs ranging from zero to about 630.

Flammability and toxicity risks are comparable to or lower than flammability and toxicity risks of other available substitutes in the same end-uses. Toxicity risks can be minimized by use consistent with the AIHA WEELs, ASHRAE 15 and other industry standards, recommendations in the manufacturer's SDS, and other safety precautions common in the refrigeration and air conditioning industry.

EPA finds R-448A acceptable in the end-uses listed above because it does not pose greater overall environmental and human health risk than other available substitutes in the same end-uses.

6. R-449A

EPA's decision: EPA finds R-449A acceptable as a substitute for use in:

- Cold storage warehouses (new and retrofit equipment)
- Industrial process refrigeration (new and retrofit equipment)

R-449A, marketed under the trade name Opteon® XP 40, is a weighted blend of 24.3 percent HFC-32, which is also known as difluoromethane (CAS Reg. No. 75–10–5); 24.7 percent HFC-125, which is also known as 1,1,1,2,2-pentafluoroethane (CAS Reg. No. 354–33–6); 25.7 percent HFC-134a, which is also known as 1,1,1,2-tetrafluoroethane (CAS Reg. No. 811–97–2); and 25.3 percent HFO-1234yf, which is also known as 2,3,3,3-tetrafluoroprop-1-ene (CAS Reg. No. 754–12–1).

You may find the redacted submission in Docket EPA–HQ–OAR–2003–0118 at *www.regulations.gov* under the name, ''Supporting Documentation for Notice 33 Listing of R-449A (XP40) in Industrial Process Refrigeration and Cold Storage Warehouses. SNAP Submission Received August 26, 2014.'' EPA performed assessments to examine the health and environmental risks of this substitute. These assessments are available in Docket EPA–HQ–OAR–2003–0118 under the following names:

- ''Risk Screen on Substitutes in Cold Storage Warehouses Substitute: R-449A (Opteon® XP40)''
- ''Risk Screen on Substitutes in Industrial Process Refrigeration Substitute: R-449A (Opteon® XP40)''

EPA previously listed R-449A as an acceptable refrigerant in a number of other refrigeration and air conditioning end-uses (*e.g.,* July 16, 2015, 80 FR 42053; October 11, 2016, 81 FR 70029).

Environmental information: R-449A has an ODP of zero. Its components, HFC-32, HFC-125, HFC-134a, and HFO-

[11] Hodnebrog *et al.,* 2013. *Op. cit.*

[12] Nielsen, O.J., Javadi, M.S., Sulbaek Andersen, M.P., Hurley, M.D., Wallington, T.J., Singh, R. Atmospheric chemistry of $CF_3CF{=}CH_2$: Kinetics and mechanisms of gas-phase reactions with Cl atoms, OH radicals, and O_3. *Chemical Physics Letters* 439, 18–22, 2007.

[13] Hodnebrog *et al.,* 2013 and Javadi *et al.,* 2008. *Op. cit.*

[14] This is in contrast to the historically used ODS CFC-12, R-502, and HCFC-22 with ODPs ranging from 0.055 to 1.0.

1234yf, have GWPs of 675; 3,500; 1,430; and one to four,[15] respectively. If these values are weighted by mass percentage, then R-449A has a GWP of about 1,400. The components of R-449A are excluded from the definition of VOC under CAA regulations (see 40 CFR 51.100(s)) addressing the development of SIPs to attain and maintain the NAAQS. Knowingly venting or releasing this refrigerant blend is limited by the venting prohibition under section 608(c)(2) of the CAA, codified at 40 CFR 82.154(a)(1).

Flammability information: R-449A, as formulated and even considering the worst-case of fractionation for flammability, is not flammable.

Toxicity and exposure data: Potential health effects of exposure to this substitute include drowsiness or dizziness. The substitute may also irritate the skin or eyes or cause frostbite. At sufficiently high concentrations, the substitute may cause irregular heartbeat. The substitute could cause asphyxiation if air is displaced by vapors in a confined space. These potential health effects are common to many refrigerants.

The AIHA has established WEELs of 1,000 ppm as an 8-hr TWA for HFC-32, HFC-125, and HFC-134a and 500 ppm for HFO-1234yf, the components of R-449A. The manufacturer of R-449A recommends an AEL of 830 ppm on an 8-hour TWA for the blend. EPA anticipates that users will be able to meet each of the AIHA WEELs and the manufacturer's AEL and address potential health risks by following requirements and recommendations in the manufacturer's SDS, in ASHRAE 15, and other safety precautions common to the refrigeration and air conditioning industry.

Comparison to other substitutes in these end-uses: R-449A has an ODP of zero, comparable [16] to or lower than the other listed substitutes in this end-use, with ODPs ranging from zero to 0.057.

For cold storage warehouses, R-449A's GWP of 1,400 is lower than or comparable to that of acceptable substitutes, such as HFC-134a, R-407C, and R-407F with GWPs ranging from 1,430 to 1,820. R-449A's GWP is higher than the GWPs of other acceptable substitutes for cold storage warehouses, including ammonia absorption, desiccant cooling, evaporative cooling, R-450A, and R-513A with GWPs ranging from zero to about 630.

For industrial process refrigeration, R-449A's GWP of 1,400 is lower than or comparable to that of acceptable substitutes, such as HFC-134a, R-404A, R-407C, and HFC-23 with GWPs ranging from 1,430 to 14,800. R-449A's GWP is higher than the GWPs of other acceptable substitutes for industrial process refrigeration including ammonia absorption, ammonia vapor compression, Sterling cycle, CO_2, propane, R-450A, and R-513A with GWPs ranging from zero to about 630.

Flammability and toxicity risks are comparable to or lower than flammability and toxicity risks of other available substitutes in the same end-uses. Toxicity risks can be minimized by use consistent with the AIHA WEELs, ASHRAE 15 and other industry standards, recommendations in the manufacturer's SDS, and other safety precautions common in the refrigeration and air conditioning industry.

EPA finds R-449A acceptable in the end-uses listed above because it does not pose greater overall environmental and human health risk than other available substitutes in the same end-uses.

7. R-449B

EPA's decision: EPA finds R-449B acceptable as a substitute for use in:

- Cold storage warehouses (new and retrofit equipment)
- Industrial process refrigeration (new and retrofit equipment)

R-449B, marketed under the trade name Forane® 449B, is a weighted blend of 25.2 percent HFC-32, which is also known as difluoromethane (CAS Reg. No. 75–10–5); 24.3 percent HFC-125, which is also known as 1,1,1,2,2-pentafluoroethane (CAS Reg. No. 354–33–6); 27.3 percent HFC-134a, which is also known as 1,1,1,2-tetrafluoroethane (CAS Reg. No. 811–97–2); and 23.2 percent HFO-1234yf, which is also known as 2,3,3,3-tetrafluoroprop-1-ene (CAS Reg. No. 754–12–1).

You may find the redacted submission in Docket EPA–HQ–OAR–2003–0118 at *www.regulations.gov* under the name, ''Supporting Documentation for Notice 33 Listing of R-449B in Industrial Process Refrigeration and Cold Storage Warehouses. SNAP Submission Received October 2, 2015.'' EPA performed assessments to examine the health and environmental risks of this substitute. These assessments are available in Docket EPA–HQ–OAR–2003–0118 under the following names:

- ''Risk Screen on Substitutes in Cold Storage Warehouses Substitute: R-449B (Forane® 449B)''
- ''Risk Screen on Substitutes in Industrial Process Refrigeration Substitute: R-449B (Forane® 449B)''

EPA previously listed R-449B as an acceptable refrigerant in a number of other refrigeration and air conditioning end-uses (*i.e.,* October 11, 2016, 81 FR 70029).

Environmental information: R-449B has an ODP of zero. Its components, HFC-32, HFC-125, HFC-134a, and HFO-1234yf, have GWPs of 675; 3,500; 1,430; and one to four,[17] respectively. If these values are weighted by mass percentage, then R-449B has a GWP of about 1,410. The components of R-449B are excluded from the definition of VOC under CAA regulations (see 40 CFR 51.100(s)) addressing the development of SIPs to attain and maintain the NAAQS. Knowingly venting or releasing this refrigerant blend is limited by the venting prohibition under section 608(c)(2) of the CAA, codified at 40 CFR 82.154(a)(1).

Flammability information: R-449B, as formulated and even considering the worst-case of fractionation for flammability, is not flammable.

Toxicity and exposure data: Potential health effects of exposure to this substitute include drowsiness or dizziness. The substitute may also irritate the skin or eyes or cause frostbite. At sufficiently high concentrations, the substitute may cause irregular heartbeat. The substitute could cause asphyxiation if air is displaced by vapors in a confined space. These potential health effects are common to many refrigerants.

The AIHA has established WEELs of 1,000 ppm as an 8-hr TWA for HFC-32, HFC-125, and HFC-134a and 500 ppm for HFO-1234yf, the components of R-449B. The manufacturer of R-449B recommends an AEL of 850 ppm on an 8-hour TWA for the blend. EPA anticipates that users will be able to meet each of the AIHA WEELs and the manufacturer's AEL and address potential health risks by following requirements and recommendations in the manufacturer's SDS, in ASHRAE 15, and other safety precautions common to the refrigeration and air conditioning industry.

Comparison to other substitutes in these end-uses: R-449B has an ODP of zero, comparable [18] to or lower than the other listed substitutes in this end-use, with ODPs ranging from zero to 0.057.

For cold storage warehouses, R-449B's GWP of 1,410 is lower than or

[15] Hodnebrog *et al.,* 2013 and Nielsen *et al.,* 2007. *Op. cit.*

[16] This is in contrast to the historically used ODS CFC-12, R-502, and HCFC-22 with ODPs ranging from 0.055 to 1.0.

[17] Hodnebrog *et al.,* 2013 and Nielsen *et al.,* 2007. *Op. cit.*

[18] This is in contrast to the historically used ODS CFC-12, R-502, and HCFC-22 with ODPs ranging from 0.055 to 1.0.

comparable to that of acceptable substitutes, such as HFC-134a, R-407C, and R-407F with GWPs ranging from 1,430 to 1,820. R-449B's GWP is higher than the GWPs of other acceptable substitutes for cold storage warehouses including ammonia absorption, desiccant cooling, evaporative cooling, R-450A, and R-513A with GWPs ranging from zero to about 630.

For industrial process refrigeration, many substitutes listed as acceptable have comparable or higher GWPs than R-449B's GWP of about 1,410, such as HFC-134a, R-404A, R-407C, and HFC-23 with GWPs ranging from 1,430 to 14,800; other substitutes listed as acceptable substitutes for industrial process refrigeration have a lower GWP including ammonia absorption, ammonia vapor compression, Sterling cycle, CO_2, propane, R-450A, and R-513A with GWPs ranging from zero to about 630.

Flammability and toxicity risks are comparable to or lower than flammability and toxicity risks of other available substitutes in the same end-uses. Toxicity risks can be minimized by use consistent with the AIHA WEELs, ASHRAE 15 and other industry standards, recommendations in the manufacturer's SDS, and other safety precautions common in the refrigeration and air conditioning industry.

EPA finds R-449B acceptable in the end-uses listed above because it does not pose greater overall environmental and human health risk than other available substitutes in the same end-uses.

8. R-452A

EPA's decision: EPA finds R-452A acceptable as a substitute for use in:

- Refrigerated transport—refrigerated trucks and trailers [19] (new and retrofit equipment)
- Retail food refrigeration—remote condensing units (new and retrofit equipment)

R-452A, marketed under the trade name Opteon® XP 44, is a weighted blend of 11 percent HFC-32, which is also known as difluoromethane (CAS Reg. No. 75–10–5); 59 percent HFC-125, which is also known as 1,1,1,2,2-pentafluoroethane (CAS Reg. No. 354–33–6); and 30 percent HFO-1234yf, which is also known as 2,3,3,3-tetrafluoro-prop-1-ene (CAS Reg. No. 754–12–1).

You may find the redacted submission in Docket EPA–HQ–OAR–2003–0118 at *www.regulations.gov* under the name, ''Supporting Documentation for Notice 33 Listing of R-452A (XP44) in Refrigerated Transport (Refrigerated Trucks and Trailers) and Retail Food Refrigeration (Remote Condensing Units). SNAP Submission Received August 8, 2014.'' EPA has performed assessments to examine the health and environmental risks of this substitute. These assessments are available in Docket EPA–HQ–OAR–2003–0118 under the following names:

- ''Risk Screen on Substitutes for Use in Refrigerated Transport Substitute: R-452A''
- ''Risk Screen on Substitutes for Use in Retail Food Refrigeration Substitute: R-452A''

Environmental information: R-452A has an ODP of zero. Its components, HFC-32, HFC-125, and HFO-1234yf, have GWPs of 675; 3,500; and one to four, respectively. If these values are weighted by mass percentage, then R-452A has a GWP of about 2,140. The components of R-452A are excluded from the definition of VOC under CAA regulations (see 40 CFR 51.100(s)) addressing the development of SIPs to attain and maintain the NAAQS. Knowingly venting or releasing this refrigerant blend is limited by the venting prohibition under section 608(c)(2) of the CAA, codified at 40 CFR 82.154(a)(1).

Flammability information: R-452A, as formulated and even considering the worst-case of fractionation for flammability, is not flammable.

Toxicity and exposure data: Potential health effects of this substitute include drowsiness or dizziness. The substitute may also irritate the skin or eyes or cause frostbite. At sufficiently high concentrations, the substitute may cause irregular heartbeat. The substitute could cause asphyxiation if air is displaced by vapors in a confined space. These potential health effects are common to many refrigerants.

The AIHA has established WEELs for the components of R-452A of 1,000 ppm as an 8-hr TWA for HFC-32 and HFC-125, and of 500 ppm as an 8-hr TWA for HFO-1234yf. The manufacturer of R-452A recommends an AEL of 786 ppm on an 8-hour TWA for the blend. EPA anticipates that users will be able to meet each of the AIHA WEELs and address potential health risks by following requirements and recommendations in the manufacturer's SDS, in ASHRAE 15, and other safety precautions common to the refrigeration and air conditioning industry.

Comparison to other substitutes in these end-uses: R-452A has an ODP of zero, comparable [20] to or lower than the other listed substitutes in these end-uses, with ODPs ranging from zero to 0.057.

For refrigerated transport—refrigerated trucks and trailers, R-452A's GWP of about 2,140 is lower than or comparable to that of acceptable substitutes, such as R-404A, R-507A, and a number of HFC refrigerant blends (with GWPs ranging from approximately 2,230 to 3,990). R-452A's GWP is higher than the GWPs of other acceptable substitutes for refrigerated transport, including CO_2, direct nitrogen expansion, HFC-134a, R-407A, R-407C, R-407F, R-410A, R-448A, R-449A, R-450A, R-513A, and Stirling cycle, with GWPs ranging from zero to about 2,110.

For retail food refrigeration—remote condensing units, R-452A's GWP of about 2,140 is lower than or comparable to that of acceptable substitutes, such as R-410B and R-421A, with GWPs ranging from 2,230 to 2,630. R-452A's GWP is higher than the GWPs of other acceptable substitutes in retail food refrigeration—remote condensing units, including CO_2 with a GWP of one, and HFC-134a and a number of HFC blends and HFC/HFO blends with GWPs of about 600 to 2,110.

Flammability and toxicity risks are comparable to or lower than flammability and toxicity risks of other available substitutes in the same end-uses. Toxicity risks can be minimized by use consistent with the AIHA WEELs, ASHRAE 15 and other industry standards, recommendations in the manufacturer's SDS, and other safety precautions common in the refrigeration and air conditioning industry.

EPA finds R-452A acceptable in the end-uses listed above because it does not pose greater overall environmental and human health risk than other available substitutes in the same end-uses.

9. R-452C

EPA's decision: EPA finds R-452C acceptable as a substitute for use in:

- Refrigerated transport—refrigerated trucks and trailers (new and retrofit equipment)

[19] This end-use category covers a subset of on-road vehicles, *i.e.,* refrigerated trucks and trailers with a separate refrigeration unit with the condenser typically located either in the main engine compartment or at the front of a refrigerated trailer. It does not include refrigerated vans or other vehicles where a single system also supplies passenger comfort cooling, refrigerated intermodal shipping containers (*e.g.,* containers designed to be moved between ships, trucks, or other modes of transportation for uninterrupted storage), railway refrigeration, or ship holds.

[20] This is in contrast to the historically used ODS CFC-12, R-502, and HCFC-22 with ODPs ranging from 0.055 to 1.0.

- Retail food refrigeration—remote condensing units (new and retrofit equipment)

R-452C, marketed under the trade name Forane® 452C, is a weighted blend of 12.5 percent HFC-32, which is also known as difluoromethane (CAS Reg. No. 75–10–5); 61 percent HFC-125, which is also known as 1,1,1,2,2-pentafluoroethane (CAS Reg. No. 354–33–6); and 26.5 percent HFO-1234yf, which is also known as 2,3,3,3-tetrafluoro-prop-1-ene (CAS Reg. No. 754–12–1).

You may find the redacted submission in Docket EPA–HQ–OAR–2003–0118 at *www.regulations.gov* under the name, ''Supporting Documentation for Notice 33 Listing of R-452C in Refrigerated Transport (Refrigerated Trucks and Trailers) and Retail Food Refrigeration (Remote Condensing Units). SNAP Submission Received July 8, 2016.'' EPA has performed assessments to examine the health and environmental risks of this substitute. These assessments are available in Docket EPA–HQ–OAR–2003–0118 under the following names:

- ''Risk Screen on Substitutes for Use in Refrigerated Transport Substitute: R-452C''
- ''Risk Screen on Substitutes for Use in Retail Food Refrigeration Substitute: R-452C''

Environmental information: R-452C has an ODP of zero. Its components, HFC-32, HFC-125, and HFO-1234yf, have GWPs of 675; 3,500; and one to four,[21] respectively. If these values are weighted by mass percentage, then R-452C has a GWP of about 2,220. The components of R-452C are excluded from the definition of VOC under CAA regulations (see 40 CFR 51.100(s)) addressing the development of SIPs to attain and maintain the NAAQS. Knowingly venting or releasing this refrigerant blend is limited by the venting prohibition under section 608(c)(2) of the CAA, codified at 40 CFR 82.154(a)(1).

Flammability information: R-452C, as formulated and even considering the worst-case of fractionation for flammability, is not flammable.

Toxicity and exposure data: Potential health effects of this substitute include drowsiness or dizziness. The substitute may irritate the skin or eyes or cause frostbite. At sufficiently high concentrations, the substitute may cause irregular heartbeat. The substitute could cause asphyxiation if air is displaced by vapors in a confined space. These potential health effects are common to many refrigerants.

The AIHA has established WEELs for the components of R-452C of 1,000 ppm as an 8-hr TWA for HFC-32 and HFC-125 and 500 ppm for HFO-1234yf. EPA anticipates that users will be able to meet each of the AIHA WEELs and address potential health risks by following requirements and recommendations in the manufacturer's SDS, in ASHRAE 15, and other safety precautions common to the refrigeration and air conditioning industry.

Comparison to other substitutes in these end-uses: R-452C has an ODP of zero, comparable[22] to or lower than the other listed substitutes in these end-uses, with ODPs ranging from zero to 0.057.

For refrigerated transport—refrigerated trucks and trailers, R-452C's GWP of about 2,220 is lower than or comparable to that of acceptable substitutes, such as R-404A, R-507A, and a number of HFC refrigerant blends (with GWPs ranging from approximately 2,230 to 3,990). R-452C's GWP is higher than the GWPs of other acceptable substitutes for refrigerated transport, including CO_2, direct nitrogen expansion, HFC-134a, R-407A, R-407C, R-407F, R-410A, R-448A, R-449A, R-450A, R-513A, and Stirling cycle, with GWPs ranging from zero to about 2,110.

For retail food refrigeration—remote condensing units, R-452C's GWP of about 2,220 is lower than or comparable to that of acceptable substitutes, such as R-410B and R-421A, with GWPs ranging from 2,230 to 2,630. R-452C's GWP is higher than the GWPs of other acceptable substitutes in retail food refrigeration—remote condensing units, including CO_2 with a GWP of one and HFC-134a and a number of HFC blends and HFC/HFO blends of about 600 to 2,110.

Flammability and toxicity risks are comparable to or lower than flammability and toxicity risks of other available substitutes in the same end-uses. Toxicity risks can be minimized by use consistent with the AIHA WEELs, ASHRAE 15 and other industry standards, recommendations in the manufacturer's SDS, and other safety precautions common in the refrigeration and air conditioning industry.

EPA finds R-452C acceptable in the end-uses listed above because it does not pose greater overall environmental and human health risk than other available substitutes in the same end-uses.

10. R-453A

EPA's decision: EPA finds R-453A acceptable as a substitute for use in:

- Cold storage warehouses (new and retrofit equipment)
- Industrial process refrigeration (new and retrofit equipment)
- Retail food refrigeration—remote condensing units (new and retrofit equipment)

R-453A, marketed under the trade name RS-70, is a weighted blend of 20.0 percent HFC-32, which is also known as difluoromethane (CAS Reg. No. 75–10–5); 20.0 percent HFC-125, which is also known as 1,1,1,2,2-pentafluoroethane (CAS Reg. No. 354-33-6); 53.8 percent HFC-134a, which is also known as 1,1,1,2-tetrafluoroethane (CAS Reg. No. 811–97–2); five percent HFC-227ea, which is also known as 1,1,1,2,3,3,3-heptafluoropropane (CAS Reg. No. 439–89–0); 0.6 percent R-600, which is also known as butane (CAS Reg. No. 75–28–5); and 0.6 percent R-601a, which is also known as isopentane (CAS Reg. 78–78–4).

You may find the redacted submission in Docket EPA–HQ–OAR–2003–0118 at *www.regulations.gov* under the name, ''Supporting Documentation for Notice 33 Listing of R-453A (RS-70) in Industrial Process Refrigeration, Cold Storage Warehouses, and Retail Food Refrigeration (Remote Condensing Units). SNAP Submission Received March 12, 2015.'' EPA performed assessments to examine the health and environmental risks of this substitute. These assessments are available in Docket EPA–HQ–OAR–2003–0118 under the following names:

- ''Risk Screen on Substitutes in Cold Storage Warehouses Substitute: R-453A (RS-70)''
- ''Risk Screen on Substitutes in Industrial Process Refrigeration Substitute: R-453A (RS-70)''
- ''Risk Screen on Substitutes for Use in Retail Food Refrigeration Substitute: R-453A''

Environmental information: R-453A has an ODP of zero. Its components, HFC-32, HFC-125, HFC-134a, HFC-227ea, butane, and isopentane, have GWPs of 675, 3,500, 1,430, 3,220, 4, and 5, respectively. If these values are weighted by mass percentage, then R-453A has a GWP of about 1,770. Except for butane and isopentane, which together make up approximately 1.2 percent of the blend, the components of R-453A are excluded from the definition of VOC under CAA regulations (see 40 CFR 51.100(s)) addressing the development of SIPs to attain and maintain the NAAQS. Knowingly

[21] Hodnebrog *et al.,* 2013 and Nielsen *et al.,* 2007. *Op. cit.*

[22] This is in contrast to the historically used ODS CFC-12, R-502, and HCFC-22 with ODPs ranging from 0.055 to 1.0.

venting or releasing this refrigerant blend is limited by the venting prohibition under section 608(c)(2) of the CAA, codified at 40 CFR 82.154(a)(1).

Flammability information: R-453A, as formulated and even considering the worst-case of fractionation for flammability, is not flammable.

Toxicity and exposure data: Potential health effects of exposure to this substitute include drowsiness or dizziness. The substitute may also irritate the skin or eyes or cause frostbite. At sufficiently high concentrations, the substitute may cause irregular heartbeat. The substitute could cause asphyxiation if air is displaced by vapors in a confined space. These potential health effects are common to many refrigerants.

For the components of R-453A, the AIHA has established WEELs of 1,000 ppm as an 8-hr TWA for HFC-32, HFC-125, HFC-134a, and HFC-227ea, and the American Conference of Governmental Industrial Hygienists (ACGIH) has established a Threshold Limit Value (TLV) of 1,000 ppm for R-600 and a TLV of 600 ppm for R-601a, both as an 8-hr TWA. The manufacturer of R-453A recommends an AEL of 1,000 ppm on an 8-hour TWA for the blend. EPA anticipates that users will be able to meet each of the AIHA WEELs, the ACGIH's TLVs, and the manufacturer's AEL and address potential health risks by following requirements and recommendations in the manufacturer's SDS, in ASHRAE 15, and other safety precautions common to the refrigeration and air conditioning industry.

Comparison to other substitutes in these end-uses: R-453A has an ODP of zero, comparable [23] to or lower than the other listed substitutes in these end-uses, with ODPs ranging from zero to 0.057.

For cold storage warehouses, R-453A's GWP of about 1,770 is lower than or comparable to that of acceptable substitutes, such as R-407C and R-407F, with GWPs ranging from 1,770 to 1,820. R-453A's GWP is higher than the GWPs of other acceptable substitutes for cold storage warehouses, including ammonia absorption, desiccant cooling, evaporative cooling, HFC-134a, R-450A, and R-513A with GWPs ranging from zero to 1,510.

For industrial process refrigeration, R-453A's GWP of about 1,770 is lower than or comparable to that of acceptable substitutes, such as R-404A, R-407C, and HFC-23 with GWPs ranging from 1,770 to 14,800. R-453A's GWP is higher than the GWPs of other acceptable substitutes for industrial process refrigeration, including ammonia absorption, ammonia vapor compression, Sterling cycle, CO_2, HFC-134a, propane, R-426A, R-450A, and R-513A with GWPs ranging from zero to about 1,510.

For retail food refrigeration—remote condensing units, R-453A's GWP of about 1,770 is lower than or comparable to that of acceptable substitutes, such as R-407A, R-407C, R-410B, and R-421A, with GWPs ranging from about 1,770 to 2,630. R-453A's GWP is higher than the GWPs of other acceptable substitutes in remote condensing units, including CO_2 with a GWP of one and HFC-134a, R-426A, R-448A, R-449A, R-449B, R-450A, and R-513A with GWPs of about 600 to 1,510.

Flammability and toxicity risks are comparable to or lower than flammability and toxicity risks of other available substitutes in the same end-uses. Toxicity risks can be minimized by use consistent with the AIHA WEELs, ASHRAE 15 and other industry standards, recommendations in the manufacturer's SDS, and other safety precautions common in the refrigeration and air conditioning industry.

EPA finds R-453A acceptable in the end-uses listed above because it does not pose greater overall environmental and human health risk than other available substitutes in the same end-uses.

11. R-458A

EPA's decision: EPA finds R-458A acceptable as a substitute for use in:

- Industrial process refrigeration (new and retrofit equipment)
- Residential and light commercial air conditioning and heat pumps (retrofit equipment only)
- Retail food refrigeration—remote condensing units (new and retrofit equipment)

R-458A, marketed under the trade name Bluon TdX 20, is a weighted blend of 20.5 percent HFC-32, which is also known as difluoromethane (CAS Reg. No. 75–10–5); 4.0 percent HFC-125, which is also known as 1,1,1,2,2-pentafluoroethane (CAS Reg. No. 354–33–6); 61.4 percent HFC-134a, which is also known as 1,1,1,2-tetrafluoroethane (CAS Reg. No. 811–97–2); 13.5 percent HFC-227ea, which is also known as 1,1,1,2,3,3,3-heptafluoropropane (CAS Reg. No. 431–89–0); and 0.6 percent HFC-236fa, which is also known as 1,1,1,3,3,3-hexafluoropropane (CAS Reg. No. 690–39–1).

You may find the redacted submission in Docket EPA–HQ–OAR–2003–0118 at *www.regulations.gov* under the name, ''Supporting Documentation for Notice 33 Listing of R-458A (TdX20) in Industrial Process Refrigeration, Retail Food Refrigeration (Remote Condensing Units), and Residential and Light Commercial Air Conditioning and Heat Pumps. SNAP Submission Received November 7, 2014.'' EPA performed assessments to examine the health and environmental risks of this substitute. These assessments are available in Docket EPA–HQ–OAR–2003–0118 under the following names:

- ''Risk Screen on Substitutes in Industrial Process Refrigeration Substitute: R-458A (TdX 20)''
- ''Risk Screen on Substitutes in Residential and Light Commercial Air Conditioning and Heat Pumps Substitute: R-458A (TdX 20)''
- ''Risk Screen on Substitutes for Use in Retail Food Refrigeration Substitute: R-458A (TdX 20)''

Environmental information: R-458A has an ODP of zero. Its components, HFC-32, HFC-125, HFC-134a, HFC-227ea, and HFC-236fa, have GWPs of 675, 3,500, 1,430, 3,220, and 9,810, respectively. If these values are weighted by mass percentage, then R-458A has a GWP of about 1,650. The components of R-458A are excluded from the definition of VOC under CAA regulations (see 40 CFR 51.100(s)) addressing the development of SIPs to attain and maintain the NAAQS. Knowingly venting or releasing this refrigerant blend is limited by the venting prohibition under section 608(c)(2) of the CAA, codified at 40 CFR 82.154(a)(1).

Flammability information: R-458A, as formulated and even considering the worst-case of fractionation for flammability, is not flammable.

Toxicity and exposure data: Potential health effects of exposure to this substitute include drowsiness or dizziness. The substitute may also irritate the skin or eyes or cause frostbite. At sufficiently high concentrations, the substitute may cause irregular heartbeat when inhaled. The substitute could cause asphyxiation if air is displaced by vapors in a confined space. These potential health effects are common to many refrigerants.

The AIHA has established WEELs of 1,000 ppm as an 8-hr TWA for HFC-32, HFC-125, HFC-134a, HFC-227ea, and HFC-236fa, the components of R-458A. EPA anticipates that users will be able to meet the AIHA WEELs and address potential health risks by following requirements and recommendations in the manufacturer's SDS, in ASHRAE 15,

[23] This is in contrast to the historically used ODS CFC-12, R-502, and HCFC-22 with ODPs ranging from 0.055 to 1.0.

and other safety precautions common to the refrigeration and air conditioning industry.

Comparison to other substitutes in these end-uses: R-458A has an ODP of zero, comparable [24] to or lower than the other listed substitutes in these end-uses, with ODPs ranging from zero to 0.057.

For industrial process refrigeration, R-458A's GWP of about 1,650 is lower than or comparable to that of acceptable substitutes, such as R-404A, R-407C, and HFC-23, with GWPs ranging from 1,770 to 14,800. R-458A's GWP is higher than the GWPs of other acceptable substitutes for industrial process refrigeration, including ammonia absorption, ammonia vapor compression, Sterling cycle, CO_2, HFC-134a, propane, R-426A, R-450A, and R-513A, with GWPs ranging from zero to about 1,510.

For residential and light commercial air conditioning and heat pumps in retrofit equipment, R-458A's GWP of about 1,650 is lower than all other substitutes listed as acceptable, such as R-407C, R-438A, and R-507A, with GWPs ranging from 1,770 to 3,990.

For retail food refrigeration—remote condensing units, R-458A's GWP of about 1,650 is lower than that of acceptable substitutes, such as R-407A, R-407C, R-410B, and R-421A, with GWPs ranging from about 1,770 to 2,630. R-458A's GWP is higher than the GWPs of other acceptable substitutes in remote condensing units, including CO_2 with a GWP of one and HFC-134a, R-426A, R-448A, R-449A, R-449B, R-450A, and R-513A, with GWPs of about 600 to 1,510.

Flammability and toxicity risks are comparable to or lower than flammability and toxicity risks of other available substitutes in the same end-uses. Toxicity risks can be minimized by use consistent with the AIHA WEELs, ASHRAE 15, and other industry standards, recommendations in the manufacturer's SDS, and other safety precautions common in the refrigeration and air conditioning industry.

EPA finds R-458A acceptable in the end-uses listed above because it does not pose greater overall environmental and human health risk than other available substitutes in the same end-uses.

12. R-513A

EPA's decision: EPA finds R-513A acceptable as a substitute for use in:

- Residential dehumidifiers (new and retrofit equipment)

R-513A, marketed under the trade name Opteon® XP 10, is a weighted blend of 44 percent HFC-134a, which is also known as 1,1,1,2 tetrafluoroethane (CAS Reg. No. 811–97–2), and 56 percent HFO-1234yf, which is also known as 2,3,3,3-tetrafluoroprop-1-ene (CAS Reg. No. 754–12–1).

You may find the redacted submission in Docket EPA–HQ–OAR–2003–0118 at *www.regulations.gov* under the name, ''Supporting Documentation for Notice 33 Listing of R-513A (XP10) in Residential Dehumidifiers. SNAP Submission Received July 24, 2014.'' EPA performed an assessment to examine the health and environmental risks of this substitute. This assessment is available in Docket EPA–HQ–OAR–2003–0118 under the following name:

- ''Risk Screen on Substitutes for Use in Residential Dehumidifiers Substitute: R-513A''

EPA previously listed R-513A as acceptable for use as a refrigerant in several refrigeration and air conditioning end-uses (May 23, 2016, 81 FR 32241; July 16, 2015, 80 FR 42053).

Environmental information: R-513A has an ODP of zero. Its components, HFC-134a and HFO-1234yf, have GWPs of 1,430 and one to four,[25] respectively. If these values are weighted by mass percentage, then R-513A has a GWP of about 630. The components of R-513A are both excluded from the definition of VOC under CAA regulations (see 40 CFR 51.100(s)) addressing the development of SIPs to attain and maintain the NAAQS. Knowingly venting or releasing this refrigerant blend is limited by the venting prohibition under section 608(c)(2) of the CAA, codified at 40 CFR 82.154(a)(1).

Flammability information: R-513A, as formulated and even considering the worst-case of fractionation for flammability, is not flammable.

Toxicity and exposure data: Potential health effects of exposure to this substitute include drowsiness or dizziness. The substitute may also irritate the skin or eyes or cause frostbite. At sufficiently high concentrations, the substitute may cause irregular heartbeat. The substitute could cause asphyxiation if air is displaced by vapors in a confined space. These potential health effects are common to many refrigerants.

The AIHA has established WEELs of 1,000 ppm and 500 ppm as an 8-hour TWA for HFC-134a and HFO-1234yf, respectively, the components of R-513A. The manufacturer of R-513A recommends an AEL of 653 ppm on an 8-hour TWA for the blend. EPA anticipates that users will be able to meet each of the manufacturer's AEL and AIHA WEELs and address potential health risks by following requirements and recommendations in the manufacturer's SDS, in ASHRAE 15, and other safety precautions common to the refrigeration and air conditioning industry.

Comparison to other substitutes in this end-use: R-513A has an ODP of zero, comparable [26] to other listed substitutes in this end-use, with ODPs ranging from zero to 0.057.

For residential dehumidifiers, R-513A's GWP of 630 is lower than that of other acceptable substitutes, such as HFC-134a, R-404A, R-407C, R-410A, and R-507A with GWPs ranging from 1,430 to 3,990.

Flammability and toxicity risks are comparable to or lower than flammability and toxicity risks of other available substitutes in the same end-use. Toxicity risks can be minimized by use consistent with the AIHA WEELs, ASHRAE 15, and other industry standards, recommendations in the manufacturer's SDS, and other safety precautions common in the refrigeration and air conditioning industry.

EPA finds R-513A acceptable in the end-use listed above because it does not pose greater overall environmental and human health risk than other available substitutes in the same end-use.

B. Cleaning Solvents

1. HFE-7300

EPA's decision: EPA finds HFE-7300 acceptable as a substitute for use in:

- Electronics cleaning
- Metals cleaning
- Precision cleaning

HFE-7300 is also known as 1,1,1,2,2,3,4,5,5,5-decafluoro-3-methoxy-4-(trifluoromethyl)pentane (CAS Reg. No. 132182–92–4) and goes by the trade name of 3M™ Novec™7300 Engineered Fluid.

You may find the redacted submission in Docket EPA–HQ–OAR–2003–0118 at *www.regulations.gov* under the name, ''Supporting Documentation for Notice 33 Listing of HFE-7300 in Solvent Cleaning and Non-Mechanical Heat Transfer Systems. SNAP Submission Received October 13, 2016.'' EPA performed an assessment to

[24] This is in contrast to the historically used ODS CFC-12, R-502, and HCFC-22 with ODPs ranging from 0.055 to 1.0.

[25] Hodnebrog *et al.,* 2013 and Nielsen *et al.,* 2007. *Op. cit.*

[26] This is in contrast to the historically used ODS CFC-12, R-502, and HCFC-22 with ODPs ranging from 0.055 to 1.0.

examine the health and environmental risks of this substitute. This assessment is available in Docket EPA–HQ–OAR–2003–0118 under the following name:

- ''Risk Screen on Substitutes in Electronics Cleaning, Metals Cleaning, and Precision Cleaning Substitute: HFE-7300.''

Environmental information: The environmental information for this substitute is set forth in the ''Environmental information'' section in listing I.A.2.

Flammability information: HFE-7300 is not flammable.

Toxicity and exposure data: The toxicity information for this substitute is set forth in the ''Toxicity and exposure data'' section in listing I.A.2. The potential health effects of HFE-7300 are common to many solvents. EPA anticipates that users will be able to meet the manufacturer's AEL of 100 ppm on an 8-hr TWA and address potential health risks by following requirements and recommendations in the manufacturer's SDS and in any other safety precautions common to the solvent cleaning industry.

Comparison to other substitutes in these end-uses: HFE-7300 has an ODP of zero, comparable [27] to or lower than the ODP of other substitutes in the same end-uses, with ODPs ranging from zero to 0.033.

For both electronics cleaning and precision cleaning, HFE-7300's GWP of 310 is lower than or comparable to that of acceptable substitutes, such as HFE-7000, HFE-7100, HFC-365mfc, and HFC-43-10mee, with GWPs ranging from about 300 to 1,640. HFE-7300's GWP is higher than the GWPs of other acceptable substitutes for these end-uses, including acetone, *trans*-1,2-dichloroethylene, and HFE-7200 with GWPs ranging from less than 1 to 59. Its climate impacts cannot be compared directly to those of aqueous cleaners, which have zero GWP.

For metals cleaning, HFE-7300's GWP of 310 is lower than or comparable to that of acceptable substitutes, such as HFE-7100, HFC-365mfc and HFC-43-10mee, with GWPs ranging from about 300 to 1,640. HFE-7300's GWP is higher than the GWPs of other acceptable substitutes for this end-use including acetone, *trans*-1,2-dichloroethylene, and HFE-7200 with GWPs ranging from less than 1 to 59. Its climate impacts cannot be compared directly to those of aqueous cleaners, which have zero GWP.

Flammability and toxicity risks are comparable to or lower than flammability and toxicity risks of other available substitutes in the same end-uses. Toxicity risks can be minimized by use consistent with the manufacturer's AEL, recommendations in the SDS, and other safety precautions common in the solvent cleaning industry.

EPA finds HFE-7300 acceptable in the end-uses listed above because it does not pose greater overall environmental and human health risk than other available substitutes in the same end-uses.

II. Section 612 Program

A. Statutory Requirements and Authority for the SNAP Program

Section 612 of the CAA requires EPA to develop a program for evaluating alternatives to ozone-depleting substances. EPA refers to this program as the Significant New Alternatives Policy (SNAP) program. The major provisions of section 612 are:

1. Rulemaking

Section 612(c) requires EPA to promulgate rules making it unlawful to replace any class I substance (CFC, halon, carbon tetrachloride, methyl chloroform, methyl bromide, hydrobromofluorocarbon, and chlorobromomethane) or class II substance (HCFC) with any substitute that the Administrator determines may present adverse effects to human health or the environment where the Administrator has identified an alternative that (1) reduces the overall risk to human health and the environment, and (2) is currently or potentially available.

2. Listing of Unacceptable/Acceptable Substitutes

Section 612(c) requires EPA to publish a list of the substitutes unacceptable for specific uses and to publish a corresponding list of acceptable alternatives for specific uses. The list of ''acceptable'' substitutes is found at *www.epa.gov/snap/substitutes-sector* and the lists of ''unacceptable,'' ''acceptable subject to use conditions,'' and ''acceptable subject to narrowed use limits'' substitutes are found in the appendices to 40 CFR part 82 subpart G.

3. Petition Process

Section 612(d) grants the right to any person to petition EPA to add a substance to, or delete a substance from, the lists published in accordance with section 612(c). The Agency has 90 days to grant or deny a petition. Where the Agency grants the petition, EPA must publish the revised lists within an additional six months.

4. 90-Day Notification

Section 612(e) directs EPA to require any person who produces a chemical substitute for a class I substance to notify the Agency not less than 90 days before new or existing chemicals are introduced into interstate commerce for significant new uses as substitutes for a class I substance. The producer must also provide the Agency with the producer's unpublished health and safety studies on such substitutes.

5. Outreach

Section 612(b)(1) states that the Administrator shall seek to maximize the use of federal research facilities and resources to assist users of class I and II substances in identifying and developing alternatives to the use of such substances in key commercial applications.

6. Clearinghouse

Section 612(b)(4) requires the Agency to set up a public clearinghouse of alternative chemicals, product substitutes, and alternative manufacturing processes that are available for products and manufacturing processes which use class I and II substances.

B. EPA's Regulations Implementing Section 612

On March 18, 1994, EPA published the initial SNAP rule (59 FR 13044) which established the process for administering the SNAP program and issued EPA's first lists identifying acceptable and unacceptable substitutes in the major industrial use sectors (subpart G of 40 CFR part 82). These sectors are the following: Refrigeration and air conditioning; foam blowing; solvents cleaning; fire suppression and explosion protection; sterilants; aerosols; adhesives, coatings and inks; and tobacco expansion. These sectors comprise the principal industrial sectors that historically consumed the largest volumes of ODS.

Section 612 of the CAA requires EPA to list as acceptable those substitutes that do not present a significantly greater risk to human health and the environment as compared with other substitutes that are currently or potentially available.

C. How the Regulations for the SNAP Program Work

Under the SNAP regulations, anyone who plans to market or produce a substitute to replace a class I substance or class II substance in one of the eight

[27] In contrast, the historically used ODS CFC-113, methyl chloroform, HCFC-225ca, and HCFC-225cb have ODPs ranging from 0.02 to 0.8.

major industrial use sectors must provide the Agency with notice and the required health and safety information on the substitute at least 90 days before introducing it into interstate commerce for significant new use as an alternative (40 CFR 82.176(a)). While this requirement typically applies to chemical manufacturers as the entity likely to be planning to introduce the substitute into interstate commerce,[28] it may also apply to importers, formulators, equipment manufacturers, and end users [29] when they are responsible for introducing a substitute into commerce. The 90-day SNAP review process begins once EPA receives the submission and determines that the submission includes complete and adequate data (40 CFR 82.180(a)). The CAA and the SNAP regulations, 40 CFR 82.174(a), prohibit use of a substitute earlier than 90 days after notice has been provided to the Agency.

The Agency has identified four possible decision categories for substitute submissions: Acceptable; acceptable subject to use conditions; acceptable subject to narrowed use limits; and unacceptable (40 CFR 82.180(b)).[30] Use conditions and narrowed use limits are both considered ''use restrictions'' and are explained below. Substitutes that are deemed acceptable without use conditions may be used for all applications within the relevant end-uses within the sector and without limits under SNAP on how they may be used. Substitutes that are acceptable subject to use restrictions may be used only in accordance with those restrictions. Substitutes that are found to be unacceptable may not be used after the date specified in the rulemaking adding such substitute to the list of unacceptable substitutes.[31]

After reviewing a substitute, the Agency may make a determination that a substitute is acceptable only if certain conditions in the way that the substitute is used are met to minimize risks to human health and the environment. EPA describes such substitutes as ''acceptable subject to use conditions.'' Entities that use these substitutes without meeting the associated use conditions are in violation of EPA's SNAP regulations (40 CFR 82.174(c)).

For some substitutes, the Agency may permit a narrowed range of use within an end-use or sector. For example, the Agency may limit the use of a substitute to certain end-uses or specific applications within an industry sector. The Agency generally requires a user of a substitute subject to narrowed use limits to demonstrate that no other acceptable substitutes are available for their specific application.[32] EPA describes these substitutes as ''acceptable subject to narrowed use limits.'' A person using a substitute that is acceptable subject to narrowed use limits in applications and end-uses that are not consistent with the narrowed use limit is using the substitute in violation of section 612 of the CAA and EPA's SNAP regulations (40 CFR 82.174(c)).

The section 612 mandate for EPA to prohibit the use of a substitute that may present risk to human health or the environment where a lower risk alternative is available or potentially available'' [33] provides EPA with the authority to change the listing status of a particular substitute if such a change is justified by new information or changed circumstance.

As described in this document and elsewhere, including the initial SNAP rule published in the **Federal Register** at 59 FR 13044 on March 18, 1994, the SNAP program evaluates substitutes within a comparative risk framework. The SNAP program compares new substitutes both to the ozone-depleting substances being phased out under the *Montreal Protocol on Substances that Deplete the Ozone Layer* and the CAA, and to other available or potentially available alternatives for the same end-uses. The environmental and health risk factors that the SNAP program considers include ozone depletion potential, flammability, toxicity, occupational and consumer health and safety, as well as contributions to global warming and other environmental factors. Environmental and human health exposures can vary significantly depending on the particular application of a substitute—and over time, information applicable to a substitute can change. This approach does not imply fundamental tradeoffs with respect to different types of risk, either to the environment or to human health. Over the past twenty years, the menu of substitutes has become much broader and a great deal of new information has been developed on many substitutes. Because the overall goal of the SNAP program is to ensure that substitutes listed as acceptable do not pose significantly greater risk to human health and the environment than other available substitutes, the SNAP criteria should be informed by our current overall understanding of environmental and human health impacts and our experience with and current knowledge about available and potentially available substitutes. Over time, the range of substitutes reviewed by SNAP has changed, and, at the same time, scientific approaches have evolved to more accurately assess the potential environmental and human health impacts of these chemicals and alternative technologies. The Agency publishes its SNAP program decisions in the **Federal Register**. EPA uses notice-and-comment rulemaking to place any alternative on the list of prohibited substitutes, to list a substitute as acceptable only subject to use conditions or narrowed use limits, or to remove a substitute from either the list of prohibited or acceptable substitutes.

In contrast, EPA publishes ''notices of acceptability'' or ''determinations of acceptability,'' to notify the public of substitutes that are deemed acceptable with no restrictions. As described in the

[28] As defined at 40 CFR 82.104, ''interstate commerce'' means the distribution or transportation of any product between one state, territory, possession or the District of Columbia, and another state, territory, possession or the District of Columbia, or the sale, use or manufacture of any product in more than one state, territory, possession or District of Columbia. The entry points for which a product is introduced into interstate commerce are the release of a product from the facility in which the product was manufactured, the entry into a warehouse from which the domestic manufacturer releases the product for sale or distribution, and at the site of United States Customs clearance.

[29] As defined at 40 CFR 82.172, ''end-use'' means processes or classes of specific applications within major industrial sectors where a substitute is used to replace an ODS.

[30] The SNAP regulations also include ''pending,'' referring to submissions for which EPA has not reached a determination, under this provision.

[31] As defined at 40 CFR 82.172, ''use'' means any use of a substitute for a Class I or Class II ozone-depleting compound, including but not limited to use in a manufacturing process or product, in consumption by the end-user, or in intermediate uses, such as formulation or packaging for other subsequent uses. This definition of use encompasses manufacturing process of products both for domestic use and for export. Substitutes manufactured within the United States exclusively for export are subject to SNAP requirements since the definition of use in the rule includes use in the manufacturing process, which occurs within the United States.

[32] In the case of the July 20, 2015, final rule, EPA established narrowed use limits for certain substitutes over a limited period of time for specific MVAC and foam applications, on the basis that other acceptable alternatives would not be available for those specific applications within broader end-uses, but acceptable alternatives were expected to become available over time, *e.g.,* after military qualification testing for foam blowing agents in military applications or after development of improved servicing infrastructure in a destination country for MVAC in vehicles destined for export.

[33] In addition to acceptable commercially available substitutes, the SNAP program may consider potentially available substitutes. The SNAP program's definition of ''potentially available'' is ''any alternative for which adequate health, safety, and environmental data, as required for the SNAP notification process, exist to make a determination of acceptability, and which the agency reasonably believes to be technically feasible, even if not all testing has yet been completed and the alternative is not yet produced or sold.'' (40 CFR 82.172)

preamble to the rule initially implementing the SNAP program (59 FR 13044; March 18, 1994), EPA does not believe that rulemaking procedures are necessary to list alternatives that are acceptable without restrictions because such listings neither impose any sanction nor prevent anyone from using a substitute.

Many SNAP listings include ''comments'' or ''further information'' to provide additional information on substitutes. Since this additional information is not part of the regulatory decision, these statements are not binding for use of the substitute under the SNAP program. However, regulatory requirements so listed are binding under other regulatory programs (*e.g.,* worker protection regulations promulgated by OSHA). The ''further information'' classification does not necessarily include all other legal obligations pertaining to the use of the substitute. While the items listed are not legally binding under the SNAP program, EPA encourages users of substitutes to apply all statements in the ''further information'' column in their use of these substitutes. In many instances, the information simply refers to sound operating practices that have already been identified in existing industry and/or building codes or standards. Thus many of the statements, if adopted, would not require the affected user to make significant changes in existing operating practices.

D. Additional Information About the SNAP Program

For copies of the comprehensive SNAP lists of substitutes or additional information on SNAP, refer to EPA's Ozone Depletion Web site at: *www.epa.gov/snap.* For more information on the Agency's process for administering the SNAP program or criteria for evaluation of substitutes, refer to the initial SNAP rulemaking published March 18, 1994 (59 FR 13044), codified at 40 CFR part 82, subpart G. SNAP decisions and the appropriate **Federal Register** citations are found at: *www.epa.gov/snap/snap-regulations.*

List of Subjects in 40 CFR Part 82

Environmental protection, Administrative practice and procedure, Air pollution control, Reporting and recordkeeping requirements.

Dated: June 28, 2017.

Reid P. Harvey,

Acting Director, Office of Atmospheric Programs.

Appendix A: Summary of Decisions for New Acceptable Substitutes

REFRIGERATION AND AIR CONDITIONING

End-use	Substitute	Decision	Further information [1]
Cold storage warehouses *(new and retrofit equipment).*	R-448A	Acceptable	R-448A has a 100-yr global warming potential (GWP) of approximately 1,390. This substitute is a blend of HFC-32, which is also known as difluoromethane (CAS Reg. No. 75–10–5); HFC-125, which is also known as 1,1,1,2,2-pentafluoroethane (CAS Reg. No. 354–33–6); HFC-134a, which is also known as 1,1,1,2-tetrafluoroethane (CAS Reg. No. 811–97–2); HFO-1234yf, which is also known as 2,3,3,3-tetrafluoro-prop-l-ene (CAS Reg. No. 754–12–1); and HFO-1234ze(E), which is also known as *trans*-1,3,3,3-tetrafluoroprop-l-ene (CAS Reg. No. 29118–24–9). The blend is nonflammable. The American Industrial Hygiene Association (AIHA) has established Workplace Environmental Exposure Limits (WEELs) of 1,000 ppm on an eight-hour time-weighted average (8-hr TWA) basis for HFC-32, HFC-125, and HFC-134a; 500 ppm for HFO-1234yf; and 800 ppm for HFO-1234ze(E). The manufacturer recommends an acceptable exposure limit (AEL) for the workplace for R-448A of 890 ppm (8-hr TWA).
Cold storage warehouses *(new and retrofit equipment).*	R-449A	Acceptable	R-449A has a 100-year GWP of approximately 1,400. This substitute is a blend of HFC-32, which is also known as difluoromethane (CAS Reg. No. 75–10–5); HFC-125, which is also known as 1,1,1,2,2-pentafluoroethane (CAS Reg. No. 354–33–6); HFC-134a, which is also known as 1,1,1,2-tetrafluoroethane (CAS Reg. No. 811–97–2); and HFO-1234yf, which is also known as 2,3,3,3-tetrafluoroprop-l-ene (CAS Reg. No. 754–12–1). The blend is nonflammable. The AIHA has established WEELs of 1,000 ppm (8-hr TWA) for HFC-32, HFC-125, and HFC-134a; and 500 ppm for HFO-1234yf. The manufacturer recommends an AEL for the workplace for R-449A of 830 ppm (8-hr TWA).
Cold storage warehouses *(new and retrofit equipment).*	R-449B	Acceptable	R-449B has a 100-year GWP of approximately 1,410. This substitute is a blend of HFC-32, which is also known as difluoromethane (CAS Reg. No. 75–10–5); HFC-125, which is also known as 1,1,1,2,2-pentafluoroethane (CAS Reg. No. 354–33–6); HFC-134a, which is also known as 1,1,1,2-tetrafluoroethane (CAS Reg. No. 811–97–2); and HFO-1234yf, which is also known as 2,3,3,3-tetrafluoroprop-l-ene (CAS Reg. No. 754–12–1). The blend is nonflammable. The AIHA has established WEELs of 1,000 ppm (8-hr TWA) for HFC-32, HFC-125, and HFC-134a; and 500 ppm for HFO-1234yf. The manufacturer recommends an AEL for the workplace for R-449B of 850 ppm (8-hr TWA).

REFRIGERATION AND AIR CONDITIONING—Continued

End-use	Substitute	Decision	Further information [1]
Cold storage warehouses *(new and retrofit equipment)*.	R-453A	Acceptable	R-453A has a 100-year GWP of approximately 1,770. This substitute is a blend of HFC-32, which is also known as difluoromethane (CAS Reg. No. 75–10–5); HFC-125, which is also known as 1,1,1,2,2-pentafluoroethane (CAS Reg. No. 354–33–6); HFC-134a, which is also known as 1,1,1,2-tetrafluoroethane (CAS Reg. No. 811–97–2); HFC-227ea, which is also known as 1,1,1,2,3,3,3-heptafluoropropane (CAS Reg. No. 439–89–0); R-;600, which is also known as butane (CAS Reg. No. 75–28–5); and R-601a, which is also known as isopentane (CAS Reg. No. 78–78–4). The blend is nonflammable. The AIHA has established WEELs of 1,000 ppm (8-hr TWA) for HFC-32, HFC-125, HFC-134a, and HFC-227ea, and the American Conference of Governmental Industrial Hygienists has established a Threshold Limit Value (TLV) of 1,000 ppm for R-600 and a TLV of 600 ppm for R-601a, both as an 8-hr TWA. The manufacturer recommends an AEL for the workplace for R-453A of 1000 ppm (8-hour TWA).
Industrial process refrigeration *(new and retrofit equipment)*.	R-448A	Acceptable	R-448A has a 100-yr GWP of approximately 1,390. This substitute is a blend of HFC-32, which is also known as difluoromethane (CAS Reg. No. 75–10–5); HFC-125, which is also known as 1,1,1,2,2-pentafluoroethane (CAS Reg. No. 354–33–6); HFC-134a, which is also known as 1,1,1,2-tetrafluoroethane (CAS Reg. No. 811–97–2); HFO-1234yf, which is also known as 2,3,3,3-tetrafluoro-prop-l-ene (CAS Reg. No. 754–12–1); and HFO-1234ze(E), which is also known as *trans*-1,3,3,3-tetrafluoroprop-l-ene (CAS Reg. No. 29118–24–9). The blend is nonflammable. The AIHA has established WEELs of 1,000 ppm (8-hr TWA) for HFC-32, HFC-125, and HFC-134a; 500 ppm for HFO-1234yf; and 800 ppm for HFO-1234ze(E). The manufacturer recommends an AEL for the workplace for R-448A of 890 ppm (8-hr TWA).
Industrial process refrigeration *(new and retrofit equipment)*.	R-449A	Acceptable	R-449A has a 100-year GWP of approximately 1,400. This substitute is a blend of HFC-32, which is also known as difluoromethane (CAS Reg. No. 75–10–5); HFC-125, which is also known as 1,1,1,2,2-pentafluoroethane (CAS Reg. No. 354–33–6); HFC-134a, which is also known as 1,1,1,2-tetrafluoroethane (CAS Reg. No. 811–97–2); and HFO-1234yf, which is also known as 2,3,3,3-tetrafluoroprop-l-ene (CAS Reg. No. 754–12–1). The blend is nonflammable. The AIHA has established WEELs of 1,000 ppm (8-hr TWA) for HFC-32, HFC-125, and HFC-134a; and 500 ppm for HFO-1234yf. The manufacturer recommends an AEL for the workplace for R-449A of 830 ppm (8-hr TWA).
Industrial process refrigeration *(new and retrofit equipment)*.	R-449B	Acceptable	R-449B has a 100-year GWP of approximately 1,410. This substitute is a blend of HFC-32, which is also known as difluoromethane (CAS Reg. No. 75–10–5); HFC-125, which is also known as 1,1,1,2,2-pentafluoroethane (CAS Reg. No. 354–33–6); HFC-134a, which is also known as 1,1,1,2-tetrafluoroethane (CAS Reg. No. 811–97–2); and HFO-1234yf, which is also known as 2,3,3,3-tetrafluoroprop-l-ene (CAS Reg. No. 754–12–1). The blend is nonflammable. The AIHA has established WEELs of 1,000 ppm (8-hr TWA) for HFC-32, HFC-125, and HFC-134a; and 500 ppm for HFO-1234yf. The manufacturer recommends an AEL for the workplace for R-449B of 850 ppm (8-hr TWA).
Industrial process refrigeration *(new and retrofit equipment)*.	R-453A	Acceptable	R-453A has a 100-year GWP of approximately 1,770. This substitute is a blend of HFC-32, which is also known as difluoromethane (CAS Reg. No. 75–10–5); HFC-125, which is also known as 1,1,1,2,2-pentafluoroethane (CAS Reg. No. 354–33–6); HFC-134a, which is also known as 1,1,1,2-tetrafluoroethane (CAS Reg. No. 811–97–2); HFC227ea, which is also known as 1,1,1,2,3,3,3-heptafluoropropane (CAS Reg. No. 439–89–0); R-600, which is also known as butane (CAS Reg. No. 75–28–5); and R-601a, which is also known as isopentane (CAS Reg. No. 78–78–4). The blend is nonflammable. The AIHA has established WEELs of 1,000 ppm (8-hr TWA) for HFC-32, HFC-125, HFC-134a, and HFC-227ea, and the American Conference of Governmental Industrial Hygienists has established a Threshold Limit Value (TLV) of 1,000 ppm for R-600 and a TLV of 600 ppm for R-601a, both as an 8-hr TWA. The manufacturer recommends an AEL for the workplace for R-453A of 1000 ppm (8-hour TWA).

REFRIGERATION AND AIR CONDITIONING—Continued

End-use	Substitute	Decision	Further information [1]
Industrial process refrigeration *(new and retrofit equipment)*.	R-458A	Acceptable	R-458A has a 100-yr GWP of approximately 1,650. This substitute is a blend of HFC-32, which is also known as difluoromethane (CAS Reg. No. 75–10–5); HFC-125, which is also known as 1,1,1,2,2-pentafluoroethane (CAS Reg. No. 354–33–6); HFC-134a, which is also known as 1,1,1,2-tetrafluoroethane (CAS Reg. No. 811–97–2); HFC-227ea, which is also known as 1,1,1,2,3,3,3-heptafluoropropane (CAS Reg. No. 431–89–0); and HFC-236fa, which is also known as 1,1,1,3,3,3-hexafluoropropane (CAS Reg. No. 690–39–1). The blend is nonflammable. The AIHA has established WEELs of 1,000 ppm (8-hr TWA) for HFC-32, HFC-125, HFC-134a, HFC-227ea, and HFC-236fa.
Non-mechanical heat transfer systems *(new and retrofit equipment)*.	HFE-7300 (1,1,1,2,2,3,4,5,5,5-decafluoro-3-methoxy-4-(trifluoromethyl)pentane).	Acceptable	HFE-7300 (CAS Reg. No. 132182–92–4) has no ozone depletion potential (ODP) and a 100-year GWP of approximately 310. This compound is nonflammable. The manufacturer recommends an AEL for the workplace for HFE-7300 of 100 ppm (8-hr TWA). This substitute is subject to a Toxic Substance Control Act (TSCA) section 5(a)(2) Significant New Use Rule (SNUR) (40 CFR 721.10061).
Refrigerated transport—refrigerated trucks and trailers *(new and retrofit equipment)*.	R-452A	Acceptable	R-452A has a 100-year GWP of approximately 2,140. This substitute is a blend of HFC-32, which is also known as difluoromethane (CAS Reg. No. 75–10–5); HFC-125, which is also known as 1,1,1,2,2-pentafluoroethane (CAS Reg. No. 354–33–6); and HFO-1234yf, which is also known as 2,3,3,3-tetrafluoroprop-l-ene (CAS Reg. No. 754–12–1). The blend is nonflammable. The AIHA has established WEELs of 1,000 ppm (8-hr TWA) for HFC-32 and HFC-125; and 500 ppm for HFO-1234yf. The manufacturer recommends an AEL for the workplace for R-452A of 786 ppm (8-hour TWA).
Refrigerated transport—refrigerated trucks and trailers *(new and retrofit equipment)*.	R-452C	Acceptable	R-452C has a 100-year GWP of approximately 2,220. This substitute is a blend of HFC-32, which is also known as difluoromethane (CAS Reg. No. 75–10–5); HFC-125, which is also known as 1,1,1,2,2-pentafluoroethane (CAS Reg. No. 354–33–6); and HFO-1234yf, which is also known as 2,3,3,3-tetrafluoroprop-l-ene (CAS Reg. No. 754–12–1). The blend is nonflammable. The AIHA has established WEELs of 1,000 ppm (8-hr TWA) for HFC-32 and HFC-125; and 500 ppm for HFO-1234yf.
Residential dehumidifiers *(new and retrofit equipment)*.	R-513A	Acceptable	R-513A has a 100-year GWP of approximately 630. This substitute is a blend of HFC-134a, which is also known as 1,1,1,2-tetrafluoroethane (CAS Reg. No. 811–97–2); and HFO-1234yf, which is also known as 2,3,3,3-tetrafluoroprop-l-ene (CAS Reg. No. 754–12–1). This blend is nonflammable. The AIHA has established WEELs of 1,000 ppm and 500 ppm (8-hr TWA) for HFC-134a and HFO-1234yf, respectively. The manufacturer recommends an AEL for the workplace for R-513A of 653 ppm (8-hr TWA).
Residential and light commercial air conditioning and heat pumps *(retrofit equipment)*.	HFC-134a	Acceptable	HFC-134a has a 100-year GWP of 1,430. HFC-134a is also known as 1,1,1,2-tetrafluoroethane (CAS Reg. No. 811–97–2). HFC-134a is nonflammable. The AIHA has established a WEEL of 1,000 ppm (8-hr TWA) for HFC-134a.
Residential and light commercial air conditioning and heat pumps *(retrofit equipment)*.	R-458A	Acceptable	R-458A has a 100-yr GWP of approximately 1,650. This substitute is a blend of HFC-32, which is also known as difluoromethane (CAS Reg. No. 75–10–5); HFC-125, which is also known as 1,1,1,2,2-pentafluoroethane (CAS Reg. No. 354–33–6); HFC-134a, which is also known as 1,1,1,2-tetrafluoroethane (CAS Reg. No. 811–97–2); HFC-227ea, which is also known as 1,1,1,2,3,3,3-heptafluoropropane (CAS Reg. No. 431–89–0); and HFC-236fa, which is also known as 1,1,1,3,3,3-hexafluoropropane (CAS Reg. No. 690–39–1). This blend is nonflammable. The AIHA has established WEELs of 1,000 ppm (8-hr TWA) for HFC-32, HFC-125, HFC-134a, HFC-227ea, and HFC-236fa.

REFRIGERATION AND AIR CONDITIONING—Continued

End-use	Substitute	Decision	Further information [1]
Retail food refrigeration—remote condensing units *(new and retrofit equipment)*.	R-407H	Acceptable	R-407H has a 100-yr GWP of approximately 1,500. This substitute is a blend of HFC-134a, which is also known as 1,1,1,2-tetrafluoroethane (CAS Reg. No. 811–97–2); HFC-32, which is also known as difluoromethane (CAS Reg. No. 75–10–5); and HFC-125, which is also known as 1,1,1,2,2-pentafluoroethane (CAS Reg. No. 354–33–6). This blend is nonflammable. The AIHA has established WEELs of 1,000 ppm (8-hr TWA) for HFC-134a, HFC-32, and HFC-125. The manufacturer recommends an AEL for the workplace for R-407H of 1,000 ppm (8-hour TWA).
Retail food refrigeration—remote condensing units *(new and retrofit equipment)*.	R-442A	Acceptable	R-442A has a 100-yr GWP of approximately 1,890. This substitute is a blend of HFC-32, which is also known as difluoromethane (CAS Reg. No. 75–10–5); HFC-125, which is also known as 1,1,1,2,2-pentafluoroethane (CAS Reg. No. 354–33–6); HFC-134a, which is also known as 1,1,1,2-tetrafluoroethane (CAS Reg. No. 811–97–2); HFC-227ea, which is also known as 1,1,1,2,3,3,3-heptafluoropropane (CAS Reg. No. 431–89–0); and HFC-152a, which is known as 1,1-difluoroethane (CAS Reg. No. 75–37–6). This blend is nonflammable. The AIHA has established WEELs of 1,000 ppm (8-hr TWA) for HFC-32, HFC-125, HFC-134a, HFC-227ea, and HFC-152a. The manufacturer of R-442A recommends an AEL of 1,000 ppm on an 8-hour TWA for the blend.
Retail food refrigeration—remote condensing units *(new and retrofit equipment)*.	R-452A	Acceptable	R-452A has a 100-year GWP of approximately 2,140. This substitute is a blend of HFC-32, which is also known as difluoromethane (CAS Reg. No. 75–10–5); HFC-125, which is also known as 1,1,1,2,2-pentafluoroethane (CAS Reg. No. 354–33–6); and HFO-1234yf, which is also known as 2,3,3,3-tetrafluoroprop-l-ene (CAS Reg. No. 754–12–1). The blend is nonflammable. The AIHA has established WEELs of 1,000 ppm (8-hr TWA) for HFC-32 and HFC-125; and 500 ppm for HFO-1234yf. The manufacturer recommends an AEL for the workplace for R-452A of 786 ppm (8-hour TWA).
Retail food refrigeration— remote condensing units *(new and retrofit equipment)*.	R-452C	Acceptable	R-452C has a 100-year GWP of approximately 2,220. This substitute is a blend of HFC-32, which is also known as difluoromethane (CAS Reg. No. 75–10–5); HFC-125, which is also known as 1,1,1,2,2-pentafluoroethane (CAS Reg. No. 354–33–6); and HFO-1234yf, which is also known as 2,3,3,3-tetrafluoroprop-l-ene (CAS Reg. No. 754–12–1). The blend is nonflammable. The AIHA has established WEELs of 1,000 ppm (8-hr TWA) for HFC-32 and HFC-125; and 500 ppm for HFO-1234yf.
Retail food refrigeration—remote condensing units *(new and retrofit equipment)*.	R-453A	Acceptable	R-453A has a 100-year GWP of approximately 1,770. This substitute is a blend of HFC-32, which is also known as difluoromethane (CAS Reg. No. 75–10–5); HFC-125, which is also known as 1,1,1,2,2-pentafluoroethane (CAS Reg. No. 354–33–6); HFC-134a, which is also known as 1,1,1,2-tetrafluoroethane (CAS Reg. No. 811–97–2); HFC227ea, which is also known as 1,1,1,2,3,3,3-heptafluoropropane (CAS Reg. No. 439–89–0); R-600, which is also known as butane (CAS Reg. No. 75–28–5); and R-601a, which is also known as isopentane (CAS Reg. No. 78–78–4). The blend is nonflammable. The AIHA has established WEELs of 1,000 ppm (8-hr TWA) for HFC-32, HFC-125, HFC-134a, and HFC-227ea, and the American Conference of Governmental Industrial Hygienists has established a Threshold Limit Value (TLV) of 1,000 ppm for R-600 and a TLV of 600 ppm for R-601a, both as an 8-hr TWA. The manufacturer recommends an AEL for the workplace for R-453A of 1000 ppm (8-hour TWA).
Retail food refrigeration—remote condensing units *(new and retrofit equipment)*.	R-458A	Acceptable	R-458A has a 100-yr GWP of approximately 1,650. This substitute is a blend of HFC-32, which is also known as difluoromethane (CAS Reg. No. 75–10–5); HFC-125, which is also known as 1,1,1,2,2-pentafluoroethane (CAS Reg. No. 354–33–6); HFC-134a, which is also known as 1,1,1,2-tetrafluoroethane (CAS Reg. No. 811–97–2); HFC-227ea, which is also known as 1,1,1,2,3,3,3-heptafluoropropane (CAS Reg. No. 431–89–0); and HFC–236fa, which is also known as 1,1,1,3,3,3-hexafluoropropane (CAS Reg. No. 690–39–1). This blend is nonflammable. The AIHA has established WEELs of 1,000 ppm (8-hr TWA) for HFC-32, HFC-125, HFC-134a, HFC-227ea, and HFC-236fa.

CLEANING SOLVENTS

End-use	Substitute	Decision	Further information [1]
Electronics cleaning, metals cleaning, precision cleaning.	HFE-7300 ..... (1,1,1,2,2,3,4,5,5,5-decafluoro-3-methoxy-4-(trifluoromethyl)pentane).	Acceptable	HFE-7300 (CAS Reg. No. 132182–92–4) has no ozone depletion potential (ODP) and a 100-year GWP of approximately 310. It is excluded from the definition of volatile organic compounds under CAA regulations (see 40 CFR 51.100(s)) addressing the development of state implementation plans (SIPs) to attain and maintain the National Ambient Air Quality Standards (NAAQS). This compound is nonflammable. The manufacturer recommends an AEL for the workplace for HFE-7300 of 100 ppm (8-hr TWA). This substitute is subject to a Toxic Substance Control Act (TSCA) section 5(a)(2) Significant New Use Rule (SNUR) (40 CFR 721.10061).

[1] Observe recommendations in the manufacturer's SDS and guidance for all listed substitutes.

[FR Doc. 2017–15379 Filed 7–20–17; 8:45 am]
BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 1, 73 and 74

[AU Docket No. 17–143; DA 17–533; DA 17–668]

Filing Instructions for Cross-Service FM Translator Auction Filing Window for AM Broadcasters To Be Open July 26–August 2, 2017; Freeze on FM Translator and Low-Power FM Station Minor Change Applications and FM Booster Applications July 19–August 2, 2017; Availability of Online Tutorial; Clarification of Eligible Applicants

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: In the document released June 6, 2017, the Media Bureau and the Wireless Telecommunications Bureau released instructions for filing applications in a filing window to be open from July 26, 2017, through August 2, 2017, in which certain AM station licensees and proposed assignees may seek new FM translator construction permits to retransmit the signals of the primary AM stations. In addition, the Media Bureau announced that it will not accept low-power FM and FM translator minor change construction permit applications and FM booster construction permit applications between July 19 and August 2, 2017. In the document released July 13, 2017, Commission staff announced that an online tutorial would be available for this auction, which is designated as Auction 99, and addressed a petition for clarification on an issue of applicant eligibility for this filing window opportunity.

DATES: From 12:01 a.m. Eastern Time (ET) on July 19, 2017, until midnight ET on August 2, 2017, there is a filing freeze for low-power FM and FM translator minor change construction permit applications and for FM booster construction permit applications. Starting at 12:01 a.m. ET on July 26, 2017, and prior to 6:00 p.m. on August 2, 2017, an eligible applicant may file its FCC Form 349. Starting at 9:00 a.m. ET on July 26, 2017, and prior to 6:00 p.m. ET on August 2, 2017, an eligible applicant may file its FCC Form 175.

FOR FURTHER INFORMATION CONTACT: About broadcast radio or FCC Form 349, James Bradshaw, Lisa Scanlan or Tom Nessinger in the Media Bureau's Audio Division at (202) 418–2700. About FCC Form 175 and competitive bidding rules, Lynne Milne in the Wireless Telecommunications Bureau's Auctions and Spectrum Access Division at (202) 418–0660. About general auction procedures, the Auctions Hotline at (717) 338–2868.

SUPPLEMENTARY INFORMATION: This is a summary of a public notice released on June 6, 2017, supplemented by a related public notice released on July 13, 2017. The complete texts of these documents are available for public inspection and copying from 8:00 a.m. to 4:30 p.m. ET Monday through Thursday or from 8:00 a.m. to 11:30 a.m. ET on Fridays in the FCC Reference Information Center, 445 12th St. SW., Room CY–A257, Washington, DC 20554. The complete texts also are available on the Commission's Web site at *http://wireless.fcc.gov.* Alternative formats are available for persons with disabilities by sending an email to *FCC504@fcc.gov* or by calling the Consumer & Governmental Affairs Bureau at (202) 418–0530 (voice), (202) 418–0432 (TTY).

1. The Media Bureau will institute a freeze on the acceptance of FM booster construction permit applications, as well as minor change construction permit applications for FM translators or Low Power FM stations on all channels (channels 201–300) starting at 12:01 a.m. ET on July 19, 2017 until midnight ET on August 2, 2017. Any such applications filed during this freeze will be dismissed.

2. On June 6, 2017, the Media Bureau and the Wireless Telecommunications Bureau announced in a public notice (Filing Instructions Public Notice) details and filing instructions for certain AM broadcasters to apply for cross-service FM translator station construction permits in Auction 99. Eligibility for this filing opportunity is limited to any Class C or D AM station licensee or permittee, or the proposed assignee of such an AM station, wishing to file an application to establish a new cross-service FM translator to retransmit its AM station signal full time, provided that the AM primary station was not listed as the AM primary station in a FM translator modification application filed in either of the 2016 modification windows.

3. During this upcoming filing window, an applicant may propose only one cross-service FM translator for each Class C or D AM primary station to be rebroadcast. Any FM translator awarded through this filing window will only be authorized to rebroadcast the AM primary station identified in the applicant's FCC Form 349 Tech Box (or to originate nighttime programming during periods when a daytime-only AM primary station is not operating), on a permanent basis. The authorization for any FM translator station awarded through this filing window will be subject to a condition that it may not be assigned or transferred except in conjunction with the AM primary station that it rebroadcasts and with which it is commonly owned.

4. An eligible licensee or permittee, or proposed assignee if applicable, seeking a new cross-service FM translator for its AM station(s) must file electronically in the Media Bureau's Consolidated Database System (CDBS) prior to 6:00

p.m. ET on August 2, 2017, a separate FCC Form 349, Application for Authority to Construct or Make Changes in a FM Translator or FM Booster Station, for a construction permit for each such proposed FM translator. An applicant may designate in its FCC Form 349 Tech Box any non-reserved FM channel (Channels 221–300, 92.1–107.9 MHz) for its proposed cross-service translator. Only Section I, the Tech Box of Section III–A, and the Section VI Certification must be completed at this time. The applicant name entered in the FCC Form 349 must be identical with the name of the licensee or permittee on the AM primary station license or construction permit, unless it is the name of the assignee of a pending or granted assignment application for that eligible AM primary station.

5. Applicants must review carefully each Form 349 Tech Box submission for compliance with section 74.1201(g) and all other Commission technical rules relating to FM translator stations, as well as insuring that only one Form 349 is submitted for each qualified AM station. At the end of the initial filing window, if an applicant has filed more than one FM translator proposal (Form 349 Tech Box) designating the same AM primary station, only the first-filed FM translator engineering proposal (Form 349 Tech Box) will be considered. To avoid staff consideration of an unintended proposal, each applicant must carefully review its Forms 349 before submission, and delete each undesired engineering proposal that specifies the identical AM primary station. Any request to delete an undesired proposal must be emailed before the initial filing window closes to *James.Bradshaw@fcc.gov.*

6. After the August 2, 2017, application deadline, an Auction 99 applicant may only file a technical amendment during the settlement period to be specified in a future public notice. No amendment, technical or otherwise, to a cross-service FM translator Form 349 filed during this filing window will be accepted between the close of the application filing window on August 2, 2017, and the release of the public notice listing mutually exclusive (MX) FM translator engineering proposals (if the engineering proposal is MX) or the release of the public notice listing the non-mutually exclusive FM translator engineering proposals (if the engineering proposal is not MX). Additional instructions about the filing of a Form 349 in the upcoming filing window are provided in Attachment A of the Filing Instructions Public Notice.

7. Each eligible AM station licensee or permittee applicant, or proposed assignee if applicable, for a new FM translator station must file electronically via the FCC Auction System one FCC Form 175, an Application to Participate in an Auction, in compliance with the Commission's rules and the instructions provided in the Filing Instructions Public Notice. A Form 175 must be submitted and confirmed prior to 6:00 p.m. ET on August 2, 2017. The applicant name entered in the FCC Form 175 must be identical with the name of the licensee or permittee on the AM primary station license or construction permit, unless the applicant name is identical with the name of a pending or granted assignment application assignee, if applicable.

8. An individual or entity may not submit more than one FCC Form 175 during this filing window, regardless of the number of Forms 349 it files. As explained in the Filing Instructions Public Notice, the Bureaus waived for Auction 99 the prohibition of section 1.2105(a)(3) on the filing of more than one FCC Form 175 by entities with any of the same controlling interests, but will continue to apply the prohibition against the filing of more than one FCC Form 175 by the same individual or entity.

9. An applicant's one Form 175 must cover all proposed FM translator stations for which that applicant files a FCC Form 349 Tech Box. It is the applicant's responsibility to ensure that the CDBS-assigned file number(s) and facility identification (ID) number(s) from its Form(s) 349 are entered accurately in the View/Edit Engineering Proposals section of the applicant's Form 175. Any inaccuracy in data entry in the Form 175 of the CDBS-assigned file number(s) or facility ID number(s) could result in the Form 349 being excluded from auction processing. Also, any Form 349 submitted during the initial filing window that is not referenced on that applicant's Form 175 will be dismissed in CDBS.

10. Commission staff will not consider any proposal for which the required information is not on file by the close of the initial application filing window. No consideration will be given to the following: (a) Any application for which both a FCC Form 175 and a complete FCC Form 349 proposal are not on file by the close of the initial application filing window; (b) any proposal filed by an applicant that is not a licensee or permittee, or proposed assignee if applicable, of a Class C or D AM broadcast station (including but not limited to any proposal filed by the licensee or permittee of a Class A or B AM broadcast station); (c) any proposal designating an AM primary station that was designated as the primary station on any application filed in either of the 2016 modifications windows; or (d) any proposal that specifies a channel in the reserved FM broadcast band (Channels 200–220, 88.1–91.9 MHz).

11. Each prospective Auction 99 applicant must review carefully the instructions provided about completing and submitting a FCC Form 175 in the Filing Instructions Public Notice, including guidance in Attachments A and B to that document. This Filing Instructions Public Notice provided specific information about reporting authorized bidders, the disclosure of agreements relating to construction permits subject to Auction 99, disclosure requirements for applicant owners and controlling interests, and provisions regarding a current and former default or delinquency. For example, Commission rules prohibit an individual from serving as an authorized bidder for more than one auction applicant.

12. Further, the interests of the applicant, and of any individual or entity with an attributable interest in the applicant, in other media of mass communications are considered as of the initial Form 175 filing deadline when determining an applicant's eligibility for a new entrant bidding credit. Events occurring after this filing deadline, however, may cause diminishment or loss of bidding credit eligibility, and must be reported immediately.

13. The description in the Filing Instructions Public Notice of the noncommercial education (NCE) status election included a warning that if an FCC Form 175 identifies the application's proposed FM translator as noncommercial educational and that NCE engineering proposal is mutually exclusive with any engineering proposal for a commercial station, the NCE engineering proposal (Form 349) will be returned as unacceptable for filing. Each prospective applicant should consider carefully if it wishes to propose NCE operation for any FM translator acquired in this auction. This NCE election cannot be reversed after the initial application filing deadline on August 2, 2017.

14. After the initial application filing deadline, an applicant will be permitted to make only minor modifications to its FCC Form 175 and major modifications are not permitted. For example, a claim of eligibility for a higher percentage of bidding credit will not be permitted after the initial application filing

deadline. Further information is provided in the Filing Instructions Public Notice.

15. Each applicant has a continuing obligation to maintain the accuracy and completeness of information furnished in its pending FCC Form 175, including any change that may cause a loss of or reduction in the percentage of bidding credit requested previously. An auction applicant must file additional or corrected information within five days after a significant occurrence or amend its FCC Form 175 no later than five days after the applicant becomes aware of the need for amendment. An applicant's obligation to make modifications to a pending FCC Form 175 continues after these five days. An applicant is obligated to amend its pending application even if a reported change is considered to be a major modification that may result in the dismissal of its application.

16. Prospective applicants should study carefully the explanations in the Filing Instructions Public Notice concerning prohibited communication by an auction applicant contained in sections 1.2105(c) and 73.5002. For example, an applicant is defined in section 1.2105(c) for purposes of these prohibitions to include each officer and each director of the applicant, each controlling interest of the applicant, and each holder of an ownership interest in the applicant of 10 percent or more. The Filing Instructions Public Notice provided further details concerning an impermissible communication, including a reminder of the duty to report immediately a communication that appears to violate section 1.2105(c). If mutual exclusivity (MX) is determined to exist for any engineering proposals submitted during this filing window, the Bureaus will announce a subsequent period during which this prohibition will be suspended for the purpose of resolving MX conflicts. Until such time, however, these prohibited communication rules remain in effect for Auction 99 from 6:00 p.m. on August 2, 2017, until the down payment deadline which will be announced in a future public notice.

17. If any FM translator engineering proposals filed during this announced window are determined to be MX and such MX is not resolved through a future opportunity for settlement or technical amendment, the Commission will resolve MX engineering proposals for commercial stations through competitive bidding.

Federal Communications Commission.

Sue McNeil,

Chief of Staff/Special Counsel, Wireless Telecommunications Bureau.

[FR Doc. 2017–15327 Filed 7–20–17; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 161017970–6999–02]

RIN 0648–XF550

Fisheries of the Northeastern United States; Summer Flounder Fishery; Commercial Quota Harvested for the Commonwealth of Massachusetts

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

ACTION: Temporary rule; closure.

SUMMARY: NMFS announces that the 2017 summer flounder commercial quota allocated to the Commonwealth of Massachusetts has been harvested. Vessels issued a commercial Federal fisheries permit for the summer flounder fishery may not land summer flounder in Massachusetts for the remainder of calendar year 2017, unless additional quota becomes available through a transfer from another state. Regulations governing the summer flounder fishery require publication of this notification to advise Massachusetts that the quota has been harvested and to advise vessel permit holders and dealer permit holders that no Federal commercial quota is available for landing summer flounder in Massachusetts.

DATES: Effective 0001 hours, July 20, 2017 through December 31, 2017.

FOR FURTHER INFORMATION CONTACT: Cynthia Hanson, (978) 281–9180, or *Cynthia.Hanson@noaa.gov.*

SUPPLEMENTARY INFORMATION: Regulations governing the summer flounder fishery are found at 50 CFR part 648. The regulations require annual specification of a commercial quota that is apportioned on a percentage basis among the coastal states from Maine through North Carolina. The process to set the annual commercial quota and the percent allocated to each state is described in § 648.102.

The initial commercial quota for summer flounder for the 2017 calendar year was set equal to 5,658,260 lb (2,566,544 kg) (81 FR 93842, December 22, 2016). The percent allocated to vessels landing summer flounder in Massachusetts is 6.82046 percent, resulting in a commercial quota of 385,988 lb (175,081 kg). Massachusetts has not received any quota transfers in 2017 that would cause the initial commercial quota to be adjusted.

The NMFS Administrator for the Greater Atlantic Region (Regional Administrator), monitors the state commercial landings and determines when a state's commercial quota has been harvested. NMFS is required to publish notification in the **Federal Register** advising and notifying commercial vessels and dealer permit holders that, effective upon a specific date, the state's commercial quota has been harvested and no commercial quota is available for landing summer flounder in that state. The Regional Administrator has determined, based upon dealer reports and other available information, that the 2017 Massachusetts commercial summer flounder quota will be harvested by July 19, 2017.

Section 648.4(b) provides that Federal permit holders agree, as a condition of the permit, not to land summer flounder in any state that the Regional Administrator has determined no longer has commercial quota available. Therefore, effective 0001 hours, July 20, 2017, landings of summer flounder in Massachusetts by vessels holding summer flounder commercial Federal fisheries permits are prohibited for the remainder of the 2017 calendar year, unless additional quota becomes available through a transfer and is announced in the **Federal Register**. Effective 0001 hours, July 20, 2017, federally permitted dealers are also notified that they may not purchase summer flounder from federally permitted vessels that land in Massachusetts for the remainder of the calendar year, or until additional quota becomes available through a transfer from another state.

Classification

This action is required by 50 CFR part 648 and is exempt from review under Executive Order 12866.

The Assistant Administrator for Fisheries, NOAA, finds good cause pursuant to 5 U.S.C. 553(b)(B) to waive prior notice and the opportunity for public comment because it would be contrary to the public interest. This action closes the commercial summer flounder fishery for Massachusetts until January 1, 2018, under current regulations. The regulations at § 648.103(b) require such action to

ensure that summer flounder vessels do not exceed quotas allocated to the states. If implementation of this closure was delayed to solicit prior public comment, the quota for this fishing year will be exceeded, thereby undermining the conservation objectives of the Summer Flounder Fishery Management Plan. The Assistant Administrator further finds, pursuant to 5 U.S.C. 553(d)(3), good cause to waive the 30-day delayed effectiveness period for the reason stated above.

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

Dated: July 17, 2017.

Emily H. Menashes,

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

[FR Doc. 2017–15298 Filed 7–18–17; 11:15 am]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 82, No. 139
Friday, July 21, 2017

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

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 986

[Doc. No. AMS–SC–17–0032, SC17–986–2 PR]

Pecans Grown in the States of Alabama, Arkansas, Arizona, California, Florida, Georgia, Kansas, Louisiana, Missouri, Mississippi, North Carolina, New Mexico, Oklahoma, South Carolina, and Texas; Establishment of Reporting Requirements and New Information Collection

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule.

SUMMARY: This proposed rule invites comments on the establishment of reporting requirements under the Federal marketing order for pecans (order). The American Pecan Council (Council) locally administers the order and is comprised of growers and handlers of pecans operating within the production area and a public member. This action would require all pecan handlers to submit two forms to the Council: One for inter-handler transfers and another that includes year-end inventory and pecans handled throughout the year. The Council would use this information to facilitate assessment collection and provide valuable reports to the industry, including the annual marketing policy required by the order. This proposal also announces the Agricultural Marketing Service's (AMS) intention to request approval from the Office of Management and Budget (OMB) of a new information collection.

DATES: Comments must be received by September 19, 2017. Pursuant to the Paperwork Reduction Act, comments on the information collection burden must be received by September 19, 2017.

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

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

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

SUPPLEMENTARY INFORMATION: This proposal is issued under Marketing Agreement and Order No. 986, (7 CFR part 986), regulating the handling of pecans grown in the states of Alabama, Arkansas, Arizona, California, Florida, Georgia, Kansas, Louisiana, Missouri, Mississippi, North Carolina, New Mexico, Oklahoma, South Carolina, and Texas, hereinafter referred to as the ''order.'' The order is effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), hereinafter referred to as the ''Act.''

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

This action falls within a category of regulatory actions that the Office of Management and Budget (OMB) has exempted from Executive Order 12866 review. Additionally, because this rule does not meet the definition of a significant regulatory action it does not trigger the requirements contained in Executive Order 13771. See OMB's Memorandum titled ''Interim Guidance Implementing Section 2 of the Executive Order of January 30, 2017 titled 'Reducing Regulation and Controlling Regulatory Costs' '' (February 2, 2017).

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. This proposed rule is not intended to have retroactive effect.

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

This proposed rule would establish reporting requirements under the order. This action would require all pecan handlers to submit to the Council reports of inter-handler transfers of pecans, inventory, and a summary of pecans handled. This information would be used to facilitate assessment collection and provide valuable reports to the industry, including the annual marketing policy required by the order. This proposal was unanimously recommended by the Council at its April 17, 2017, meeting.

Section 986.61 of the order requires all handlers warehousing pecans as of August 31 be identified as the handler of those pecans and pay the assessment rate accordingly. Section 986.62 provides the Council, with the approval of the Secretary, authority to establish methods and procedures, including

necessary reports, to maintain accurate records for inter-handler transfers. Sections 986.75, 986.76, and 986.77 provide authority to prescribe reports of handler inventory, merchantable pecans handled, and pecans received by handlers, respectively. Section 986.78 further provides the Council, with the approval of the Secretary, authority to collect other reports and information from handlers needed to enable the Council to perform its duties. This proposed rule would utilize these authorities to establish new §§ 986.162 and 986.175 under the rules and regulations of the order. These new sections would require handlers of pecans to report to the Council any inter-handler transfers, and the volume of shelled, inshell, and total volume of pecans handled each fiscal year by type using specific Council forms.

At its November 16, 2016 meeting, the first meeting following the order's promulgation, the Council discussed its initial budget, assessment rates, and necessary reporting requirements in order to set up a program that is efficient and responsive to industry needs. During these discussions, the Council established a Statistics and Reporting Committee (Committee) to develop reporting requirements.

Members of the Committee discussed the reporting needs of the industry, reviewed examples of reporting forms from other marketing orders, and met and worked with the staff of another marketing order in developing the proposed reporting requirements. The Committee also worked with USDA to ensure the recommended information collection would provide the information necessary to facilitate the administration of the order.

At its February 23, 2017 meeting, the Council reviewed drafts of seven reporting forms as developed and recommended by the Committee. The Council expressed its interest in having as much electronic reporting as possible, but recognized that many handlers may prefer a paper submission. The Council also considered the timing of when forms would be due and submission dates that would work for all parts of the industry. After a thorough review and some modifications, seven forms were approved by the Council.

At a meeting on April 17, 2017, the Council revisited the recommended reporting requirements and the accompanying forms. Acknowledging the industry was more than halfway through the fiscal year at that time, the Council took action to move forward with the minimum reports necessary to facilitate the collection of assessments and to provide the other information needed for the 2016–17 fiscal year. Specifically, the Council voted to utilize two forms for the current fiscal year, one focusing on inter-handler transfers, and one containing information regarding year-end inventory and pecans handled throughout the fiscal year. The Council agreed it still wanted to move forward with all seven forms for the 2017–18 fiscal year, but considered year-end reporting on two forms as the most viable option for this fiscal year. The remaining five forms will be proposed in a subsequent rulemaking action.

This proposed rule would add two new reporting requirements and two new forms to the rules and regulations under the order by adding §§ 986.162 and 986.175. The pecan industry includes a subset of handlers, defined in the order as accumulators, who compile pecans for the purpose of resale or transfer to another handler. Additionally, small handlers may also sell or transfer pecans to other handlers. During the formal rulemaking hearing, the industry expressed concern that it may be difficult to track pecans moved through accumulators or transferred between handlers. Further, some handlers and accumulators that are small operations may find reporting, recordkeeping, and paying assessments burdensome.

The report of inter-handler transfers would include information on the month of transfer, type of pecans transferred, the volume transferred, the amount of assessments owed on the pecans transferred, identification information and signatures of the two handlers involved, and whether the transferring handler or receiving handler would be responsible for reporting and paying the assessments. This report would help ensure that transferred pecans are not counted twice for volume reporting purposes and would help facilitate the collection of assessments. It would also allow receiving handlers to assume the reporting burden from smaller entities and ensure payment of corresponding assessments.

The Council selected the tenth day of the month following the month of transfer as the due date for reports of inter-handler transfers. Should the tenth day of the month fall on a weekend or holiday, reports would be due by the first business day following the tenth day of the month. However, given that the current season began October 1, 2016, for the 2016–17 fiscal year, all inter-handler transfer forms would need to be submitted by Monday, September 11, 2017. For subsequent fiscal years, reports of inter-handler transfers would be due on a monthly basis as specified above.

In order to correctly collect assessments, provide industry data, and complete a marketing policy for the coming fiscal year, the Council requires accurate reports of what has been handled and what is in inventory going into the next fiscal year. Based on Council discussions, it is also important for the industry to know the variety and form of the pecan in inventory. This information would be vital to the industry as it enters the next harvest, as the amount and type of inventory impacts prices of the new crop. Collection of this data was one of the industry's goals in promulgating the order, as currently there is no source for this type of information across the 15-state production area. This information would be captured in the year-end inventory report.

The year-end inventory report would include information on the handler submitting the form, total pounds by type of pecans inshell and shelled in inventory, inventory committed but not shipped for both export and domestic, and any uncommitted inventory. It would also include information on pecans handled throughout the year, as well as data for total inventory including both shelled and inshell, with shelled volume converted to an inshell basis using the conversion specified in the order (volume shelled $\times$ 2). In addition, it would include information regarding total assessments owed, assessments paid to date, and remaining assessments due for that handler.

The order specifies that on August 31 of each year, every handler warehousing inshell pecans shall be identified as the first handler of those pecans and shall be required to pay the required assessment rate. The order also specifies that the marketing policy include an estimate of the handler inventory as of August 31. Consequently, the Council selected September 10 as the due date for the year-end inventory report, or the first business day following the tenth of September should the tenth fall on a weekend or a holiday. The Council believes this would give all handlers sufficient time to submit the information to the Council after August 31. Further, handlers would be required to pay to the Council all remaining unpaid assessments by the due date of the year-end inventory report.

This action would require all pecan handlers to provide the Council with reports of any inter-handler transfers, year-end inventory, and pecans handled throughout the year. This information would facilitate assessment collections, provide valuable reports to the industry,

and allow the Council to complete the annual marketing policy required by the order.

The Council also recommended additional reporting requirements, which would be effective for the 2017–18 fiscal year. These requirements are being considered under a separate action.

Initial Regulatory Flexibility Analysis

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

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

There are approximately 2,500 growers of pecans in the production area and approximately 250 handlers subject to regulation under the marketing order. Small agricultural growers are defined by the Small Business Administration as those having annual receipts less than $750,000, and small agricultural service firms are defined as those whose annual receipts are less than $7,500,000 (13 CFR 121.201).

According to information from the National Agricultural Statistics Service (NASS), the average grower price for pecans during the 2015–16 season was $2.20 per pound and 254 million pounds were utilized. The value for pecans that year totaled $558.8 million ($2.20 per pound multiplied by 254 million pounds). Taking the total value of production for pecans and dividing it by the total number of pecan growers provides an average return per grower of $223,520. Using the average price and utilization information, and assuming a normal bell-curve distribution of receipts among growers, the majority of growers receive less than $750,000 annually.

Evidence presented at the formal rulemaking hearing indicates an average handler margin of $0.58 per pound. Adding this margin to the average grower price of $2.20 per pound of inshell pecans results in an estimated handler price of $2.78 per pound. With a total 2015 production of 254 million pounds, ($2.78 per pound multiplied by 254 million pounds) the total value of production in 2015 was $706.12 million. Taking the total value of production for pecans and dividing it by the total number of pecan handlers provides an average return per handler of $2,824,480. Using this estimated price, the utilization volume, number of handlers, and assuming a normal bell-curve distribution of receipts among handlers, the majority of handlers have annual receipts of less than $7,500,000. Thus, the majority (a substantial number) of growers and handlers of pecans grown in the states of Alabama, Arkansas, Arizona, California, Florida, Georgia, Kansas, Louisiana, Missouri, Mississippi, North Carolina, New Mexico, Oklahoma, South Carolina, and Texas may be classified as small entities.

This proposed rule would establish reporting requirements under the order. This action would require all pecan handlers to provide the Council with reports of any inter-handler transfers, year-end inventory, and pecans handled throughout the year. This information would facilitate the Council's collection of assessments and provide valuable reports to the industry. This rule would establish new §§ 986.162 and 986.175 under the rules and regulations of the order. The authority for this action is provided for in §§ 986.62, 986.75, 986.76, 986.77, and 986.78 of the order.

Requiring reports of transfers, handler inventory, and pecans handled throughout the year would impose an increase in the reporting burden on all pecan handlers. However, this data is already recorded and maintained by handlers as a part of their daily business. Handlers, regardless of size, should be able to readily access this information. Consequently, any additional costs associated with this change would be minimal (not significant) and apply equally to all handlers.

This action should also help the entire industry by providing comprehensive data on pecans handled and year-end inventory. Collection of this data was one of the industry's goals in promulgating the order as there is no other source for this type of data. This information would help with marketing and planning for the industry, as well as provide important information for the collection of assessments and in preparing the annual marketing policy required by the order. The benefits of this rule are expected to be equally available to all pecan growers and handlers, regardless of their size.

The Council discussed other alternatives to this action, including having additional reporting requirements, but determined that in order to efficiently carry out the objectives of the marketing order this first fiscal year, the information collected in these two reports would be sufficient. The Council also considered requiring the inter-handler transfer form to be submitted for each transfer. However, the Council determined that could be burdensome for some handlers and a monthly report would provide the necessary documentation. Therefore, the alternatives were rejected.

This proposal would establish two new reporting requirements and would require two new Council forms. Therefore, this proposed rule would impose an increase in the reporting burden for all handlers, which is discussed in the Paperwork Reduction Act section of this document.

As with all Federal marketing order programs, reports and forms are periodically reviewed to reduce information requirements and duplication by industry and public sector agencies. USDA has not identified any relevant Federal rules that duplicate, overlap, or conflict with this rule.

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

Further, the Council's meetings were widely publicized throughout the pecan industry and all interested persons were invited to attend the meetings and participate in Council deliberations on all issues. Additionally, the Council's Committee meetings held February 23, 2017, and April 17, 2017, were also public meetings and all entities, both large and small, were able to express views on this issue. Finally, interested persons are invited to submit comments on this proposed rule, including the regulatory and information collection impacts of this action on small businesses.

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

A 60-day comment period is provided to allow interested persons to respond to this proposal. All written comments

timely received will be considered before a final determination is made on this matter.

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35), this notice announces AMS's intent to request approval from the Office of Management and Budget (OMB) for a new information collection under OMB No. 0581—NEW. It will be merged with the forms currently approved under OMB No. 0581–0291 ''Federal Marketing Order for Pecans.''

Title: Pecans Grown in the States of Alabama, Arkansas, Arizona, California, Florida, Georgia, Kansas, Louisiana, Missouri, Mississippi, North Carolina, New Mexico, Oklahoma, South Carolina, and Texas; Marketing Order No. 986.

OMB Number: 0581—NEW.

Type of Request: New Collection.

Abstract: The information requirements in this request are essential to carry out the intent of the Act, to provide the respondents the type of service they request, and to administer the pecan marketing order program.

On April 17, 2017, the Council unanimously recommended that all pecan handlers covered under the order provide the Council with a record of any inter-handler transfers by type and volume. This form, titled ''Report of Inter-Handler Transfers of Pecans'', would be submitted directly to the Council by handlers by the tenth day of the month following the transfer(s).

This information collection would improve the accuracy of the Council's data collection by accounting for transferred pecans, and allow smaller handlers to transfer reporting and assessment obligations to another handler.

The Council also recommended that all handlers covered under the order submit an annual report of inventory held by type as well as a summary of pecans handled for the year. This form, titled ''Year End Inventory Report'', would be submitted directly to the Council by handlers by September 10. This information collection will facilitate the Council's collection of assessments needed to administer the program and provide necessary data for the industry on volume handled. It would also provide the volume in inventory going into the next fiscal year, which would assist with market planning and provide information for the marketing policy required by the order.

The information collected would only be used by authorized representatives of the USDA, including the AMS Specialty Crops Program regional and headquarters staff, and authorized employees of the Council. Authorized Council employees would be the primary users of the information, and the AMS would be the secondary users. The Council's staff would compile the information and utilize it to account for assessments due, to calculate total pecans handled, and to prepare a marketing policy as required under the order. All proprietary information would be kept confidential in accordance with the Act and the order.

The proposed request for new information collection under the order is as follows:

Report of Inter-Handler Transfer of Pecans

Estimate of Burden: Public reporting burden for this collection of information is estimated to be an average of 0.16 hours per response.

Respondents: Handlers of pecans in Alabama, Arkansas, Arizona, California, Florida, Georgia, Kansas, Louisiana, Missouri, Mississippi, North Carolina, New Mexico, Oklahoma, South Carolina, and Texas.

Estimated Number of Respondents: 30.

Estimated Number of Responses per Respondent: 12.

Estimated Total Annual Burden on Respondents: 60 hours.

Year End Inventory Report

Estimate of Burden: Public reporting burden for this collection of information is estimated to be an average of 0.33 hours per response.

Respondents: Handlers of pecans in Alabama, Arkansas, Arizona, California, Florida, Georgia, Kansas, Louisiana, Missouri, Mississippi, North Carolina, New Mexico, Oklahoma, South Carolina, and Texas.

Estimated Number of Respondents: 250.

Estimated Number of Responses per Respondent: 1.

Estimated Total Annual Burden on Respondents: 125 hours.

Comments are invited on: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information, 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 the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments should reference OMB No. 0581–NEW and the Marketing Order for Pecans Grown in the states of Alabama, Arkansas, Arizona, California, Florida, Georgia, Kansas, Louisiana, Missouri, Mississippi, North Carolina, New Mexico, Oklahoma, South Carolina, and Texas, and should be sent to the USDA in care of the Docket Clerk at the previously-mentioned address or at *http://www.regulations.gov.*

All responses to this notice will be summarized and included in the request for OMB approval. All comments received will become a matter of public record and will be available for public inspection during regular business hours at the address of the Docket Clerk or at *http://www.regulations.gov.*

If this proposed rule is finalized, this information collection will be merged with the forms currently approved under OMB No. 0581–0291 ''Federal Marketing Order for Pecans.''

List of Subjects in 7 CFR Part 986

Marketing agreements, Nuts, Pecans, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, 7 CFR part 986 is proposed to be amended as follows:

PART 986—PECANS GROWN IN THE STATES OF ALABAMA, ARKANSAS, ARIZONA, CALIFORNIA, FLORIDA, GEORGIA, KANSAS, LOUISIANA, MISSOURI, MISSISSIPPI, NORTH CAROLINA, NEW MEXICO, OKLAHOMA, SOUTH CAROLINA, AND TEXAS

■ 1. The authority citation for 7 CFR part 986 continues to read as follows:

Authority: 7 U.S.C. 601–674.

■ 2. Revise the heading ''Subpart B—[Reserved]'' to read ''Subpart—Rules and Regulations.''

■ 3. Add § 986.162 to subpart B to read as follows:

§ 986.162 Inter-handler transfers.

(a) Inter-handler transfers of inshell pecans, pursuant to § 986.62, shall be reported to the Council on APC Form 4. Handlers shall file reports by the tenth day of the month following the month of transfer. Should the tenth day of the month fall on a weekend or holiday, reports are due by the first business day following the tenth day of the month; Provided, that for the 2016–17 fiscal year, all inter-handler transfer forms

shall be submitted by Monday, September 11, 2017. The report shall contain the following information:

(1) Month of transfer;

(2) The type and weight of pecans transferred;

(3) The amount of assessments owed on the pecans transferred;

(4) The names and signatures for both the transferring and receiving handlers;

(5) Handler assuming the reporting and assessment obligations on the pecans transferred.

■ 4. Add § 986.175 to read as follows:

§ 986.175 Handler inventory.

(a) Handlers shall submit to the Council a year-end inventory report following August 31 each fiscal year. Handlers shall file such reports by September 10. Should September 10 fall on a weekend, reports are due by the first business day following September 10. Such reports shall be reported to the Council on APC Form 7 and include:

(1) The name and address of the handler;

(2) The total weight and type of inshell pecans in inventory, regardless of country of origin;

(3) The total weight and type of shelled pecans in inventory, regardless of country of origin;

(4) The total weight and type of inshell pecans committed, not shipped, for export and domestic shipments, and any uncommitted inventory, regardless of country of origin;

(5) The total weight and type of shelled pecans committed, not shipped, for export and domestic shipments, and any uncommitted inventory, regardless of country of origin;

(6) The combined total inventory for inshell and shelled pecans calculated on an inshell basis, and combined weight committed, not shipped, for exports and domestic shipments, and any uncommitted inventory;

(7) Total weight and type of domestic pecans handled for the fiscal year;

(8) Total assessments owed, assessments paid to date, and remaining assessments due to be paid by the due date of the year-end inventory report for the fiscal year.

Dated: July 17, 2017.

Bruce Summers,

Acting Administrator, Agricultural Marketing Service.

[FR Doc. 2017–15305 Filed 7–20–17; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2017–0354; Airspace Docket No. 17–ACE–8]

Proposed Amendment of Class E Airspace, Seward, NE

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to modify Class E airspace extending up to 700 feet above the surface at Seward Municipal Airport, Seward, NE., to accommodate new standard instrument approach procedures for instrument flight rules (IFR) operations at the airport. This action is necessary due to the decommissioning of the Seward non directional radio beacon (NDB), and cancellation of NDB approach, and would enhance the safety and management of IFR operations at the airport.

DATES: Comments must be received on or before September 5, 2017.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12–140, Washington, DC 20590; telephone (202) 366–9826, or 1–800–647–5527. You must identify FAA Docket No. FAA–2017–0354 and Airspace Docket No. 17–ACE–8, at the beginning of your comments. You may also submit comments through the Internet at *http://www.regulations.gov.* You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays.

FAA Order 7400.11A, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *http://www.faa.gov/air_traffic/publications/.* For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591; telephone: (202) 267–8783. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order 7400.11A at NARA, call (202) 741–6030, or go to *http://www.archives.gov/federal_register/code_of_federal-regulations/ibr_locations.html.*

FAA Order 7400.11A, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

FOR FURTHER INFORMATION CONTACT: Walter Tweedy (prepare by Ron Laster), Federal Aviation Administration, Operations Support Group, Central Service Center, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone (817) 222–5802.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. 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. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would amend controlled airspace in Class E.

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify both docket numbers and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. FAA–2017–0354/Airspace Docket No. 17–ACE–8.'' The postcard will be date/time stamped and returned to the commenter.

All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of the comments received. A

report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

An electronic copy of this document may be downloaded through the Internet at *http://www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's Web page at *http://www.faa.gov/air_traffic/publications/airspace_amendments/.*

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for the address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An informal docket may also be examined during normal business hours at the Federal Aviation Administration, Air Traffic Organization, Central Service Center, Operations Support Group, 10101 Hillwood Parkway, Fort Worth, TX 76177.

Availability and Summary of Documents Proposed for Incorporation by Reference

This document proposes to amend FAA Order 7400.11A, Airspace Designations and Reporting Points, dated August 3, 2016, and effective September 15, 2016. FAA Order 7400.11A is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.11A lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

The FAA is proposing an amendment to Title 14 Code of Federal Regulations (14 CFR) part 71 by modifying Class E airspace extending upward from 700 feet above the surface within a 6.5-mile radius of Seward Municipal Airport. The segments within 4 miles each side of the 166° bearing from the Seward NDB extending from the 6.4-mile radius to 14 miles southeast of the NDB, and within 4 miles each side of the 359° bearing from the Seward NDB extending from the 6.4-mile radius to 13 miles north of the NDB, would be modified due to the decommissioning of the Seward NDB and cancellation of the NDB approach. This action would enhance the safety and management of the standard instrument approach procedures for IFR operations at the airport.

Class E airspace designations are published in paragraph 6005 of FAA Order 7400.11A, dated August 3, 2016, and effective September 15, 2016, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in the Order.

Regulatory Notices and Analyses

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current, is non-controversial and unlikely to result in adverse or negative comments. It, therefore: (1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this proposed rule, when promulgated, would not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures'' prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.11A, Airspace Designations and Reporting Points, dated August 3, 2016, and effective September 15, 2016, is amended as follows:

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 feet or More Above the Surface of the Earth.

* * * * *

ACE NE E5 Seward, NE [Amended]

Seward Municipal Airport, NE
(Lat. 40°51′53″ N., long. 97°06′33″ W.)

The airspace extending upward from 700 feet above the surface within a 6.5-mile radius of Seward Municipal Airport.

Issued in Fort Worth, Texas, on July 11, 2017.

Walter Tweedy,

Acting Manager, Operations Support Group, ATO Central Service Center.

[FR Doc. 2017–15283 Filed 7–20–17; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2017–0536; Airspace Docket No. 17–ACE–10]

Proposed Amendment of Class E Airspace; Clarinda, IA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to modify Class E airspace extending upward from 700 feet above the surface at Schenck Field, Clarinda, IA. The FAA is proposing this action due to the decommissioning of the Clarinda non-directional radio beacon (NDB) and the cancellation of the associated instrument approach procedures. This action would enhance the safety and management of instrument flight rules (IFR) operations at this airport.

DATES: Comments must be received on or before September 5, 2017.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12–140, Washington, DC 20590; telephone (202) 366–9826, or 1–800–647–5527. You must identify FAA Docket No. FAA–2017–0536; Airspace Docket No. 17–ACE–10 at the beginning of your comments. You may also submit comments through the Internet at *http://www.regulations.gov.* You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays.

FAA Order 7400.11A, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *http://www.faa.gov/air_traffic/publications/.* For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591; telephone: (202) 267–8783. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order 7400.11A at NARA, call (202) 741–6030, or go to *http://www.archives.gov/federal_register/code_of_federal-regulations/ibr_locations.html.*

FAA Order 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

FOR FURTHER INFORMATION CONTACT: Jeffrey Claypool, Federal Aviation Administration, Operations Support Group, Central Service Center, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone (817) 222–5711.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. 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. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would amend Class E airspace extending upward from 700 feet above the surface at Schenck Field, Clarinda, IA, to support IFR operations at this airport.

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify both docket numbers and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. FAA–2017–0536/Airspace Docket No. 17–ACE–10.'' The postcard will be date/time stamped and returned to the commenter.

All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of the comments received. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

An electronic copy of this document may be downloaded through the Internet at *http://www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's Web page at *http://www.faa.gov/air_traffic/publications/airspace_amendments/.*

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for the address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An informal docket may also be examined during normal business hours at the Federal Aviation Administration, Air Traffic Organization, Central Service Center, Operations Support Group, 10101 Hillwood Parkway, Fort Worth, TX 76177.

Availability and Summary of Documents Proposed for Incorporation by Reference

This document proposes to amend FAA Order 7400.11A, Airspace Designations and Reporting Points, dated August 3, 2016, and effective September 15, 2016. FAA Order 7400.11A is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.11A lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

The FAA is proposing an amendment to Title 14, Code of Federal Regulations (14 CFR) part 71 by modifying the Class E airspace extending upward from 700 feet above the surface at Schenck Field, Clarinda, IA, by removing the Clarinda NDB from the legal description; removing the extension south of the airport; and updating the geographic coordinates of the airport to coincide with the FAA's aeronautical database.

Airspace reconfiguration is necessary due to the decommissioning of the Clarinda NDB, the cancellation of the associated instrument approach procedures, and to bring the airspace in compliance with FAA Order JO 7400.2L, Procedures for Handling Airspace Matters. Controlled airspace is necessary for the safety and management of standard instrument approach procedures for IFR operations at this airport.

Class E airspace designations are published in paragraph 6005 of FAA Order 7400.11A, dated August 3, 2016, and effective September 15, 2016, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in the Order.

Regulatory Notices and Analyses

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current, is non-controversial and unlikely to result in adverse or negative comments. It, therefore: (1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this proposed rule, when promulgated, would not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures'' prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal

Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.11A, Airspace Designations and Reporting Points, dated August 3, 2016, and effective September 15, 2016, is amended as follows:

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

* * * * *

ACE IA E5 Clarinda, IA [Amended]

Clarinda, Schenck Field, IA
(Lat. 40°43′20″ N., long. 95°01′36″ W.)

That airspace extending upward from 700 feet above the surface within a 6.5-mile radius of Schenck Field.

Issued in Fort Worth, Texas, on July 12, 2017.

Walter Tweedy,

Acting Manager, Operations Support Group, ATO Central Service Center.

[FR Doc. 2017–15275 Filed 7–20–17; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2016–9274; Airspace Docket No. 15–ASW–18]

Proposed Establishment of Class E Airspace; Augusta, AR

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to establish Class E airspace at Augusta, AR. Controlled airspace is necessary to accommodate new special instrument approach procedures developed at Woodruff County Airport, for the safety and management of instrument flight rules (IFR) operations at the airport.

DATES: Comments must be received on or before September 5, 2017.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590; telephone (202) 366–9826, or (800) 647–5527. You must identify FAA Docket No. FAA–2016–9274; Airspace Docket No. 15–ASW–18, at the beginning of your comments. You may also submit comments through the Internet at *http://www.regulations.gov.* You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office between 9:00 a.m. and 5:00 p.m., Monday through Friday, except Federal holidays.

FAA Order 7400.11A, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *http://www.faa.gov/air_traffic/publications/.* For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591; telephone: (202) 267–8783. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order 7400.11A at NARA, call (202) 741–6030, or go to *http://www.archives.gov/federal_register/code_of_federal-regulations/ibr_locations.html.*

FAA Order 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

FOR FURTHER INFORMATION CONTACT: Rebecca Shelby, Federal Aviation Administration, Operations Support Group, Central Service Center, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone (817) 222–5857.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. 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. This rulemaking is promulgated under the authority described in Subtitle VII, Part, A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would establish Class E airspace extending up to and including 700 feet above the surface at Woodruff County Airport, Augusta, AR, to support special instrument approach procedures for IFR operations at the airport.

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify both docket numbers and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. FAA–2016–9274/Airspace Docket No. 15–ASW–18.'' The postcard will be date/time stamped and returned to the commenter.

Availability of NPRMs

An electronic copy of this document may be downloaded through the Internet at *http://www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's Web page at *http://www.faa.gov/air_traffic/publications/airspace_amendments/.*

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for the address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An informal docket may also be examined during normal business hours at the Federal Aviation Administration, Air Traffic Organization, Central Service Center, Operations Support Group, 10101 Hillwood Parkway, Fort Worth, TX 76177.

All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of the comments received. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability and Summary of Documents Proposed for Incorporation by Reference

This document proposes to amend FAA Order 7400.11A, Airspace Designations and Reporting Points, dated August 3, 2016, and effective September 15, 2016. FAA Order 7400.11A is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.11A lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

The FAA is proposing an amendment to Title 14 Code of Federal Regulations (14 CFR) part 71 by establishing Class E airspace extending upward from 700 feet above the surface within a 6.4-mile radius of Woodruff County Airport, Augusta, AR, to accommodate new special instrument approach procedures. Controlled airspace is needed for the safety and management of IFR operations at the airport.

Class E airspace designations are published in paragraph 6005 of FAA Order 7400.11A, dated August 3, 2016, and effective September 15, 2016, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in the Order.

Regulatory Notices and Analyses

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current, is non-controversial and unlikely to result in adverse or negative comments. It, therefore: (1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, would not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures'' prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.11A, Airspace Designations and Reporting Points, dated August 3, 2016, and effective September 15, 2016, is amended as follows:

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

* * * * *

ASW AR E5 Augusta, AR [New]

Woodruff County Airport, AR
(Lat. 35°16′19″ N., long. 091°16′13″ W.)

That airspace extending upward from 700 feet above the surface within a 6.4-mile radius of Woodruff County Airport.

Issued in Fort Worth, TX, on July 12, 2017.

Walter Tweedy,

Acting Manager, Operations Support Group, ATO Central Service Center.

[FR Doc. 2017–15285 Filed 7–20–17; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2016–0384; Airspace Docket No. 17–ASO–14]

Proposed Amendment of Class D and Class E Airspace, Elizabeth City, NC

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to remove the Notice to Airmen (NOTAM) part-time status from the legal description of the Class E airspace area designated as an extension at Elizabeth City CGAS/Regional Airport, Elizabeth City, NC, and add NOTAM part-time language information to Class E surface area airspace. This proposal would bring the airspace descriptions in line with the airspace hours listed in the applicable Chart Supplement. This action also would update the geographic coordinates of the airport and the Woodville non-directional radio beacon (NDB) in the associated Class D and E airspace. Also, an editorial change would be made to the Class D and E surface area airspace legal descriptions replacing Airport/Facility Directory with the term Chart Supplement.

DATES: Comments must be received on or before September 5, 2017.

ADDRESSES: Send comments on this proposal to: U.S. Department of Transportation, Docket Operations, 1200 New Jersey Avenue SE., West Bldg. Ground Floor Rm. W12–140, Washington, DC 20590; Telephone: 1–800–647–5527, or 202–366–9826. You must identify the Docket No. FAA–2016–0384; Airspace Docket No. 17–ASO–14, at the beginning of your comments. You may also submit and review received comments through the Internet at *http://www.regulations.gov.* You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office between 9:00 a.m. and 5:00 p.m., Monday through Friday, except Federal holidays.

FAA Order 7400.11A, Airspace Designations and Reporting Points, and subsequent amendments can be viewed on line at *http://www.faa.gov/air_traffic/publications/.* For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591; telephone: 202–267–8783. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order 7400.11A at NARA, call 202–741–6030, or go to *http://www.archives.gov/federal_register/code_of_federal-regulations/ibr_locations.html.*

FAA Order 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

FOR FURTHER INFORMATION CONTACT: John Fornito, Operations Support Group, Eastern Service Center, Federal Aviation Administration, P.O. Box 20636, Atlanta, Georgia 30320; telephone 404 305–6364.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. 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. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would amend Class D and Class E airspace at Elizabeth City CGAS/Regional Airport, Elizabeth City, NC, to ensure the efficient use of airspace within the National Airspace System.

Comments Invited

Interested persons are invited to comment on this rule by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal.

Communications should identify both docket numbers and be submitted in triplicate to the address listed above. You may also submit comments through the Internet at *http://www.regulations.gov.*

Persons wishing the FAA to acknowledge receipt of their comments on this action must submit with those comments a self-addressed stamped postcard on which the following statement is made: ''Comments to Docket No. FAA–2016–0384; Airspace Docket No. 17–ASO–14.'' The postcard will be date/time stamped and returned to the commenter.

All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of the comments received. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

An electronic copy of this document may be downloaded from and comments submitted through *http://www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's Web page at *http://www.faa.gov/air_traffic/publications/airspace_amendments/.*

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except Federal Holidays. An informal docket may also be examined between 8:00 a.m. and 4:30 p.m., Monday through Friday, except Federal Holidays at the office of the Eastern Service Center, Federal Aviation Administration, Room 350, 1701 Columbia Avenue, College Park, Georgia 30337.

Availability and Summary of Documents for Incorporation by Reference

This document proposes to amend FAA Order 7400.11A, Airspace Designations and Reporting Points, dated August 3, 2016, and effective September 15, 2016. FAA Order 7400.11A is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.11A lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

The FAA is considering an amendment to Title 14, Code of Federal Regulations (14 CFR) part 71 by eliminating the NOTAM information that reads, ''This Class D airspace is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Airport/Facility Directory.'' from the regulatory text of Class E airspace designated as an extension to Class D, Elizabeth City CGAS/Regional Airport, Elizabeth City, NC.

This proposal also would add NOTAM part-time status information to the regulatory text in Class E surface area airspace. This would bring the airspace descriptions in Order 7400.11A in line with the airspace hours listed in the applicable Chart Supplement. Additionally, the geographic coordinates of the airport and Woodville NDB would be adjusted to coincide with the FAAs aeronautical database.

Class D and Class E airspace designations are published in paragraph 5000, 6002, 6004, and 6005, respectively, of FAA Order 7400.11A, dated August 3, 2016, and effective September 15, 2016, which is incorporated by reference in 14 CFR 71.1. The Class D and E airspace designations listed in this document will be published subsequently in the Order.

Regulatory Notices and Analyses

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore: (1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this proposed rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

This proposal would be subject to an environmental analysis in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures'' prior to any FAA final regulatory action.

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.11A, Airspace Designations and Reporting Points, dated August 3, 2016, effective September 15, 2016, is amended as follows:

Paragraph 5000 Class D Airspace.

* * * * *

ASO NC D Elizabeth City, NC [Amended]

Elizabeth City CGAS/Regional Airport, NC
(Lat. 36°15′38″ N., long. 76°10′28″ W.)

That airspace extending upward from the surface to and including 2,500 feet within a 4.1-mile radius of Elizabeth City CGAS/Regional Airport. This Class D airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Chart Supplement.

Paragraph 6002 Class E Surface Area Airspace.

* * * * *

ASO NC E2 Elizabeth City, NC [Amended]

Elizabeth City CGAS/Regional Airport, NC
(Lat. 36°15′38″ N., long. 76°10′28″ W.)

Within a 4.1-mile radius of Elizabeth City CGAS/Regional Airport. This Class E airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Chart Supplement.

Paragraph 6004 Class E Airspace Designated as an Extension to a Class D Surface Area.

* * * * *

ASO NC E4 Elizabeth City, NC [Amended]

Elizabeth City CGAS/Regional Airport, NC
(Lat. 36°15′38″ N., long. 76°10′28″ W.)
Elizabeth City VOR/DME
(Lat. 36°15′27″ N., long. 76°10′32″ W.)
Woodville NDB
(Lat. 36°15′47″ N., long. 76°17′53″ W.)

That airspace extending upward from the surface within 1.6 miles each side of Elizabeth City VOR/DME 189° radial, extending from the 4.1-mile radius of Elizabeth City CGAS/Regional Airport to 9.5 miles south of the VOR/DME; within 3.3 miles each side of Elizabeth City VOR/DME 357° radial, extending from the 4.1-mile radius of Elizabeth City CGAS/Regional Airport to 7 miles north of the VOR/DME; within 1.2 miles each side of the 079° bearing from the Woodville NDB, extending from 4.1-mile radius of the airport to the NDB.

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

* * * * *

ASO NC E5 Elizabeth City, NC [Amended]

Elizabeth City CGAS/Regional Airport, NC
(Lat. 36°15′38″ N., long. 76°10′28″ W.)
Elizabeth City VOR/DME
(Lat. 36°15′27″ N., long. 76°10′32″ W.)

That airspace extending upward from 700 feet above the surface within a 7-mile radius of Elizabeth City CGAS/Regional Airport, and within 8 miles east and 4 miles west of Elizabeth City VOR/DME 189° radial, extending from the VOR/DME to 9.5 miles south of the VOR/DME.

Issued in College Park, Georgia, on July 10, 2017.

Ryan W. Almasy,

Manager, Operations Support Group, Eastern Service Center, Air Traffic Organization.

[FR Doc. 2017–15288 Filed 7–20–17; 8:45 am]

BILLING CODE 4910–13–P

SECURITIES AND EXCHANGE COMMISSION

17 CFR Part 230

[Release No. 33–10390; File No. S7–06–17]

RIN 3235–AM07

Covered Securities Pursuant to Section 18 of the Securities Act of 1933

AGENCY: Securities and Exchange Commission.

ACTION: Proposed rule.

SUMMARY: The Securities and Exchange Commission (''Commission'') proposes for comment an amendment to Rule 146 under Section 18 of the Securities Act of 1933 (''Securities Act''), as amended, to designate certain securities on Investors Exchange LLC (''IEX'' or ''Exchange'') as covered securities for purposes of Section 18(b) of the Securities Act. Covered securities under Section 18(b) of the Securities Act are exempt from state law registration requirements.

DATES: Comments should be received on or before August 21, 2017.

ADDRESSES: Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/proposed.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number S7–06–17 on the subject line.
- Use the Federal eRulemaking Portal (*http://www.regulations.gov*). Follow the instructions for submitting comments.

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 S7–06–17. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/proposed.shtml*). Comments are also 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. 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. Studies, memoranda or other substantive items may be added by the Commission or staff to the comment file during this rulemaking. A notification of the inclusion in the comment file of any such materials will be made available on the Commission's Web site. To ensure direct electronic receipt of such notifications, sign up through the ''Stay Connected'' option at *www.sec.gov* to receive notifications by email.

FOR FURTHER INFORMATION CONTACT: Richard Holley III, Assistant Director; Edward Cho, Special Counsel; or Michael Ogershok, Attorney-Adviser, Office of Market Supervision, at (202) 551–5777, Division of Trading and Markets, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–7010.

SUPPLEMENTARY INFORMATION:

I. Introduction

In 1996, Congress amended Section 18 of the Securities Act to exempt from state registration requirements securities listed, or authorized for listing, on the New York Stock Exchange LLC (''NYSE''), the American Stock Exchange LLC (''Amex'') (now known as NYSE American LLC),[1] or the National

[1] On October 1, 2008, NYSE Euronext acquired The Amex Membership Corporation (''AMC'') pursuant to an Agreement and Plan of Merger, dated January 17, 2008 (''Merger''). In connection with the Merger, NYSE Amex's predecessor, Amex, a subsidiary of AMC, became a subsidiary of NYSE Euronext called NYSE Alternext US LLC (''NYSE Alternext''). *See* Securities Exchange Act Release No. 58673 (September 29, 2008), 73 FR 57707 (October 3, 2008) (SR–NYSE–2008–60 and SR–Amex 2008–62) (approving the Merger). In 2009, NYSE Alternext changed its name to NYSE Amex LLC (''NYSE Amex''). *See* Securities Exchange Act Release No. 59575 (March 13, 2009), 74 FR 11803 (March 19, 2009) (SR–NYSEALTR–2009–24) (approving the name change). In 2012, NYSE Amex changed its name from NYSE Amex LLC to NYSE MKT LLC (''NYSE MKT''). *See* Securities Exchange Act Release No. 67037 (May 21, 2012), 77 FR 31415 (May 25, 2012) (SR–NYSEAmex–2012–32) (publishing notice of the name change to NYSE MKT LLC). Effective July 24, 2017, NYSE MKT intends to change its name from NYSE MKT LLC to NYSE American LLC (''NYSE American''). *See* Securities Exchange Act Release No. 80283 (March

Continued

Market System of The Nasdaq Stock Market LLC (''Nasdaq/NGM'')[2] (collectively, ''Named Markets''), or any national securities exchange designated by the Commission to have ''substantially similar'' listing standards to those of the Named Markets.[3] Specifically, Section 18(a) of the Securities Act provides that ''no law, rule, regulation, or order, or other administrative action of any State . . . requiring, or with respect to, registration or qualification of securities . . . shall directly or indirectly apply to a security that—(A) is a covered security. . . .''[4] Covered securities are defined in Section 18(b)(1) of the Securities Act to include those securities listed, or authorized for listing, on the Named Markets, or securities listed, or authorized for listing, on a national securities exchange (or tier or segment thereof) that has listing standards that the Commission determines by rule are ''substantially similar'' to those of the Named Markets (''Covered Securities'').[5]

In 1998, the Chicago Board Options Exchange, Incorporated (''CBOE''), the Pacific Exchange, Inc. (''PCX'') (now known as NYSE Arca, Inc.), the Philadelphia Stock Exchange, Inc. (''Phlx'') (now known as NASDAQ PHLX LLC),[6] and the Chicago Stock Exchange, Inc. (''CHX'') each petitioned the Commission to determine by rule that specified portions of the exchanges' listing standards were substantially similar to the listing standards of the Named Markets.[7] In response to the petitions, and after extensive review of the petitioners' listing standards, the Commission adopted Rule 146(b) pursuant to Section 18(b)(1)(B) of the Securities Act, having determined that the listing standards of CBOE, Tier 1 of PCX, and Tier 1 of Phlx were substantially similar to those of the Named Markets, and thus securities listed pursuant to those standards are deemed Covered Securities.[8]

Accordingly, Rule 146(b) lists those national securities exchanges, or segments or tiers thereof, that the Commission has determined to have listing standards that are ''substantially similar'' to those of the Named Markets and thus securities listed on such exchanges are deemed Covered Securities.[9]

The Commission has since amended Rule 146(b) several times in response to petitions after having determined that the listing standards for securities listed, or authorized for listing, on the petitioning markets were substantially similar to those of the Named Markets and, accordingly, that such securities listed pursuant to such listing standards qualified as Covered Securities for purposes of Section 18(b) of the Securities Act.[10]

II. Petition From IEX

In June 2016, the Commission granted the application of IEX to become a registered national securities exchange.[11] IEX's exchange registration application included a rulebook, which contained a complete set of listing rules and standards that were based on those of Nasdaq/NGM.[12] When the Commission granted IEX's exchange registration it stated, among other things, that it believed IEX's proposed initial and continuing listing standards are consistent with the requirements of the Securities Exchange Act of 1934 (''Exchange Act'').[13]

Subsequent to its exchange registration, IEX petitioned the Commission to amend Rule 146(b) and determine that the listing standards for securities listed on IEX are substantially similar to those of the Named Markets, such that IEX listed securities would be Covered Securities under Section 18(b) of the Securities Act.[14]

For the reasons discussed below, the Commission preliminarily believes that IEX's listing standards are substantially similar to those of the Named Markets and, therefore, securities listed, or authorized for listing, on IEX would be eligible to be designated as Covered Securities under Rule 146(b)(1) under the Securities Act, which, as described above, are exempt from state law registration requirements. The

21, 2017), 82 FR 15244 (March 27, 2017) (SR–NYSEMKT–2017–14). *See also* NYSE Trader Update, NYSE Group—Pillar Migration Update (April 13, 2017), *available at https://www.nyse.com/publicdocs/nyse/notifications/trader-update/Pillar%20Migration%20Update.pdf* (providing notification of the expected implementation date of the name change).

[2] As of July 1, 2006, the National Market System of The Nasdaq Stock Market LLC is known as the Nasdaq Global Market (''NGM''). *See* Securities Exchange Act Release Nos. 53799 (May 12, 2006), 71 FR 29195 (May 19, 2006) and 54071 (June 29, 2006), 71 FR 38922 (July 10, 2006).

[3] *See* National Securities Markets Improvement Act of 1996, Public Law 104–290, 110 Stat. 3416 (October 11, 1996).

[4] 15 U.S.C. 77r(a).

[5] 15 U.S.C. 77r(b)(1)(A) and (B). In addition, securities of the same issuer that are equal in seniority or senior to a security listed on a Named Market or national securities exchange designated by the Commission as having substantially similar listing standards to a Named Market are covered securities for purposes of Section 18(b) of the Securities Act. *See* 15 U.S.C. 77r(b)(1)(C).

[6] On July 24, 2008, The NASDAQ OMX Group, Inc. acquired Phlx and renamed it ''NASDAQ OMX PHLX LLC.'' *See* Securities Exchange Act Release Nos. 58179 (July 17, 2008), 73 FR 42874 (July 23, 2008) (SR–Phlx–2008–31); and 58183 (July 17, 2008), 73 FR 42850 (July 23, 2008) (SR–NASDAQ–2008–035). *See also* Securities Exchange Act Release No. 62783 (August 27, 2010), 75 FR 54204 (September 3, 2010) (SR–Phlx–2010–104). NASDAQ OMX PHLX LLC subsequently changed its name to ''NASDAQ PHLX LLC.'' *See* Securities Exchange Act Release No. 76654 (December 15, 2015), 80 FR 79396 (December 21, 2015) (SR–Phlx–2015–105).

[7] *See* Letter from David P. Semak, Vice President, Regulation, PCX, to Arthur Levitt, Jr., Chairman, Commission, dated November 15, 1996; Letter from Alger B. Chapman, Chairman, CBOE, to Jonathan G. Katz, Secretary, Commission, dated November 18, 1996; Letter from J. Craig Long, Esq., Foley & Lardner, Counsel to CHX, to Jonathan G. Katz, Secretary, Commission, dated February 4, 1997; and Letter from Michele R. Weisbaum, Vice President and Associate General Counsel, Phlx, to Jonathan G. Katz, Secretary, Commission, dated March 31, 1997.

[8] *See* Securities Exchange Act Release No. 39542 (January 13, 1998), 63 FR 3032 (January 21, 1998) (determining that the listing standards of CBOE, Tier 1 of PCX, and Tier 1 of Phlx were substantially similar to those of the Named Markets). The Commission did not include Tier 1 of CHX in Rule 146 because of ''concerns regarding the CHX's listing and maintenance procedures.'' *Id.* at 3032.

[9] 17 CFR 230.146(b).

[10] In 2004, the Commission amended Rule 146(b) to designate options listed on the International Securities Exchange, Inc. (''ISE'') (now known as Nasdaq ISE, LLC) as Covered Securities for purposes of Section 18(b) of the Securities Act. *See* Securities Act Release No. 8442 (July 14, 2004), 69 FR 43295 (July 20, 2004). The Commission notes that, in March 2017, ISE changed its name from International Securities Exchange, LLC to ''Nasdaq ISE, LLC.'' *See* Securities Exchange Act Release No. 80325 (March 29, 2017), 82 FR 16445 (April 4, 2017) (SR–ISE–2017–25) (publishing notice of the name change to Nasdaq ISE, LLC). In 2007, the Commission amended Rule 146(b) to designate securities listed on the Nasdaq Capital Market (''NCM'') as Covered Securities for purposes of Section 18(b) of the Securities Act. *See* Securities Act Release No. 8791 (April 18, 2007), 72 FR 20410 (April 24, 2007). In 2012, the Commission amended Rule 146(b) to designate securities listed on Tiers I and II of BATS Exchange, Inc. (''BATS'') as Covered Securities for purposes of Section 18(b) of the Securities Act. *See* Securities Act Release No. 9295 (January 20, 2012), 77 FR 3590 (January 25, 2012). The Commission notes that, in March 2016, BATS changed its name from BATS Exchange, Inc. to ''Bats BZX Exchange, Inc.'' *See* Securities Exchange Act Release No. 77307 (March 7, 2016), 81 FR 12996 (March 11, 2016) (SR–BATS–2016–25) (publishing notice of the name change to Bats BZX Exchange, Inc.).

[11] *See* Securities Exchange Act Release No. 78101 (June 17, 2016), 81 FR 41142 (June 23, 2016) (File No. 10–222) (order granting IEX's exchange registration).

[12] *See* Securities Exchange Act Release No. 75925 (September 15, 2015), 80 FR 57261 (September 22, 2015) (File No. 10–222) (Notice of Filing of Application of IEX). *See also* Securities Exchange Act Release Nos. 77406 (March 18, 2016), 81 FR 15765 (March 24, 2016) (File No. 10–222) (Notice of Filing of Amendment Nos. 2, 3, and 4 to, and Order Instituting Proceedings To Determine Whether To Grant or Deny, and Notice of Designation of Longer Period for Commission Action on Proceedings To Determine Whether To Grant or Deny, an Application for Registration as a National Securities Exchange Under Section 6 of the Securities Exchange Act of 1934, as Modified by Amendment Nos. 1, 2, 3, and 4 Thereto).

[13] *See* Securities Exchange Act Release No. 78101 (June 17, 2016), 81 FR 41142, 41136 (June 23, 2016) (File No. 10–222) (order granting IEX's exchange registration).

[14] *See* Letter from Sophia Lee, General Counsel, IEX, to Brent J. Fields, Secretary, Commission, dated September 22, 2016 (''IEX Petition'').

Commission notes that, as provided in Rule 146(b)(2) under the Securities Act, the designation of IEX's listed securities as Covered Securities under Rule 146(b)(1) would be conditioned on IEX maintaining listing standards for equity securities that continue to be substantially similar to those of the Named Markets.[15]

III. Discussion

Under Section 18(b)(1)(B) of the Securities Act,[16] the Commission has the authority to determine that the listing standards of an exchange, or tier or segment thereof, are substantially similar with those of the NYSE, NYSE American, or Nasdaq/NGM. The Commission has compared IEX's listing standards with these Named Markets.[17] In addition, as it has done previously, the Commission has interpreted the ''substantially similar'' standard to require listing standards at least as comprehensive as those of the Named Markets.[18] If a petitioner's listing standards are higher than the Named Markets, then the Commission may still determine that the petitioner's listing standards are substantially similar to those of the Named Markets.[19] Finally, the Commission notes that differences in language or approach would not necessarily lead to a determination that the listing standards of the petitioner are not substantially similar to those of any Named Market.[20]

The Commission has reviewed the listing standards for securities to be listed and traded on IEX and, for the reasons discussed below, preliminarily believes that the standards are substantially similar to those of the Named Markets.[21]

A. IEX Quantitative Listing Standards

The Commission preliminarily believes that IEX's initial and continued quantitative listing standards for its securities are substantively identical to, and thus substantially similar to, the initial and continued quantitative listing standards for securities listed on Nasdaq/NGM.[22] Therefore, the Commission preliminarily believes that IEX's quantitative listing standards are substantially similar to a Named Market.

The Commission requests comment on whether IEX's quantitative listing rules are ''substantially similar'' to Nasdaq/NGM's listing rules.

B. IEX Qualitative Listing Standards

The Commission preliminarily believes that IEX's initial and continued qualitative listing standards for its securities are substantively identical to, and thus substantially similar to, the qualitative listing standards for securities listed on Nasdaq/NGM, with the exception of IEX Rule 14.201 (Confidential Pre-Application Review of Eligibility), discussed below, which is substantively similar to rules of NYSE and NYSE American, and IEX Rule 14.414 (Internal Audit Function), also discussed below, which is substantively similar to a rule of NYSE.[23]

With respect to the standards relating to the listing and delisting of companies, including prerequisites for initial and continued listing on IEX, obligations of security issuers listed on IEX, as well as rules describing the application and qualification process,[24] IEX's listing rules for securities are virtually identical to, and thus the Commission preliminarily believes they are substantially similar to, those of Nasdaq/NGM.[25] With respect to IEX Rule 14.201, which relates to confidential pre-application review for listing eligibility, the Commission preliminarily believes that this rule is substantially similar to the corresponding rules of NYSE and NYSE American.[26] This rule requires a company seeking the initial listing of one or more classes of securities to participate in a free, confidential pre-application eligibility review to determine whether the company meets the applicable listing criteria and, if, upon completion of this review, IEX determines that a company is eligible for listing, IEX will notify that company in writing that it has been cleared to submit an original listing application.[27]

The Commission also notes that IEX's corporate governance standards in connection with securities to be listed and traded on IEX are virtually identical to, and thus the Commission preliminarily believes they are substantially similar to, the current rules of Nasdaq/NGM and NYSE.[28] With respect to IEX Rule 14.414, concerning the internal audit function for a listed issuer, the Commission preliminarily

[15] *See* 17 CFR 240.146(b)(2). In response to recent proposed rule changes made by Nasdaq to its NGM listing standards since IEX first adopted its listing standards as part of its Form 1 exchange application, IEX submitted several proposed rule changes to conform its listing standards to those recent changes made by Nasdaq. *See, e.g.,* Securities Exchange Act Release Nos. 79652 (December 21, 2016), 81 FR 95664 (December 28, 2016) (SR–IEX–2016–21) (incorporating substantially similar changes concerning substitution listing events in response to changes made by Nasdaq); and 80905 (June 12, 2017), 82 FR 27748 (June 16, 2017) (SR–IEX–2017–14) (incorporating substantially similar continued listing requirements approved for Nasdaq).

[16] 15 U.S.C. 77r(b)(1)(B).

[17] Specifically, the Commission compared IEX's listing standards with those of Nasdaq/NGM, upon which IEX based almost all of its listing rules. If, as discussed further below, a particular listing standard was not substantially similar to the standards of that market, the Commission compared IEX's listing standard to one of the other two Named Markets. This approach is consistent with the approach that the Commission has previously taken. *See, e.g.,* Securities Act Release No. 7494 (January 13, 1998), 63 FR 3032 (January 21, 1998).

[18] *See id.*

[19] *See id.*

[20] *See id.*

[21] *See generally* IEX Rules Chapters 14 (IEX Listing Rules) and 16 (Other Securities). *See also* Securities Exchange Act Release No. 75925, *supra* note 12, 80 FR 57261. In making its preliminary determination of substantial similarity, as discussed in detail below, the Commission compared IEX's qualitative listing standards to Nasdaq/NGM's qualitative listing standards and, with respect to the rules relating to the listing application process and internal audit function, with NYSE's and NYSE American's applicable qualitative listing standards; IEX's quantitative listing standards with Nasdaq/NGM's quantitative listing standards; and IEX's listing standards for other securities, including portfolio depository receipts, index fund shares, and managed fund shares, with the corresponding listing standards of Nasdaq/NGM.

[22] Quantitative listing standards relate to, among other things, the requirements for bid price, number of publicly held shares, number of shareholders, market value of publicly held shares, and market capitalization. *Compare* IEX Rules 14.300 series *with* Nasdaq/NGM Rule 5300 and 5400 series (providing for identical rules concerning initial listing and maintenance standards for units, primary equity securities, preferred stock and secondary classes of common stock, rights, warrants, and convertible debt on IEX and Nasdaq/NGM).

[23] Qualitative listing standards relate to, among other things, the number of independent directors required, conflicts of interest, composition of the audit committee, executive compensation, shareholder meeting requirements, voting rights, quorum, code of conduct, proxies, shareholder approval of certain corporate actions, and the annual and interim reports requirements. *Compare* IEX Rules 14.200 and 14.400 series *with* Nasdaq/NGM Rule 5200 and 5600 series (providing for virtually identical rules concerning procedures and prerequisites for initial and continued listing, obligations of security issuers, the application and qualification process, and corporate governance standards on IEX and Nasdaq/NGM).

[24] *See* IEX Rule 14.200 series. The Commission notes that, while IEX Rule 14.201 is substantially similar to the equivalent NYSE and NYSE American rules (all of which relate to the confidential pre-application review for eligibility for companies seeking to list on the Exchange), IEX's rule contains an additional provision stating that a company deemed eligible for listing will be provided with written notification valid for nine months that it has been cleared to submit an original listing application. *See* IEX Rule 14.201. *See also* NYSE Listed Company Manual Sections 101 and 104; NYSE American Company Guide Section 201.

[25] *See* Nasdaq/NGM Rule 5200 series.

[26] *See* IEX Rule 14.201; NYSE Listed Company Manual Sections 101 and 104; and NYSE American Company Guide Section 201.

[27] IEX represents that an issuer that does not clear the pre-application eligibility review process or receive a timely response as part of that process on IEX after the confidential pre-application eligibility review would be permitted to appeal such determination under the procedures set forth in IEX Rule Series 9.500. *See* IEX Petition, *supra* note 14, at 5.

[28] *Compare* IEX Rule 14.400 series with Nasdaq/NGM Rule 5600 series.

believes that this rule is substantially similar to the corresponding rule of NYSE.[29] Therefore, the Commission preliminarily believes that IEX's qualitative listing standards are substantially similar to a Named Market.

The Commission requests comment on whether IEX's qualitative listing standards are ''substantially similar'' to Nasdaq/NGM's and NYSE's listing standards.

C. Other Securities, Including Securities of Exchange-Traded Funds and Other Exchange-Traded Derivative Securities Products

IEX has listing standards for other types of securities and exchange-traded derivative securities products, including, for example, portfolio depository receipts; index fund shares; securities linked to the performance of indexes, commodities, and currencies; index-linked exchangeable notes; partnership units; trust units; and managed fund shares.[30] The Commission notes that IEX's listing rules for these other securities are virtually identical to, and thus the Commission preliminarily believes they are substantially similar to, those of Nasdaq/NGM.[31] Therefore, the Commission preliminarily believes that IEX's standards for these other securities are substantially similar to those of a Named Market.

The Commission requests comment on whether IEX's listing standards relating to other securities are ''substantially similar'' to Nasdaq/NGM's listing standards.

D. Other Proposed Amendments to Rule 146

Paragraphs (b)(1) and (b)(2) of Rule 146 use the term ''NYSE Amex'' to refer to the national securities exchange formerly known as the American Stock Exchange LLC. As noted above, in 2012, NYSE Amex changed its name from NYSE Amex LLC to NYSE MKT LLC, and, in 2017, NYSE MKT LLC intends to change its name to NYSE American LLC.[32] In addition, paragraph (b)(1) of Rule 146 refers to Tier I of the NASDAQ OMX PHLX LLC. As noted above, in December 2015, NASDAQ OMX PHLX LLC changed its name to NASDAQ PHLX LLC.[33] In addition, paragraph (b)(1) of Rule 146 refers to Tier I and Tier II of BATS Exchange, Inc. As noted above, in March 2016, BATS Exchange, Inc. changed its name to Bats BZX Exchange, Inc.[34] Lastly, paragraph (b)(1) of Rule 146 refers to Options listed on the International Securities Exchange, LLC. As noted above, in March 2017, the International Securities Exchange, LLC changed its name to Nasdaq ISE, LLC.[35] This proposed rule includes changes to Rule 146(b) to account for these name changes.

E. Comments

To date, the Commission has not received any comment letters on the IEX Petition.

IV. Solicitation of Comments

The Commission seeks comment generally on amending Rule 146(b) to include securities listed, or authorized for listing, on IEX. As discussed above, based on its review of IEX's listing standards, the Commission preliminarily believes that the initial and continued listing standards for IEX are substantially similar to those of the Named Markets. In addition to the questions posed above, commenters are welcome to offer their views on any other matter raised by the proposed amendment to Rule 146(b).

V. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 does not apply because the proposed amendment to Rule 146(b) does not impose recordkeeping or information collection requirements or other collection of information, which require the approval of the Office of Management and Budget under 44 U.S.C. 3501 *et seq.*

VI. Economic Analysis

The Commission is sensitive to the economic consequences of its rules, including the benefits, costs, and effects on efficiency, competition, and capital formation. As noted above, the Commission preliminarily believes that the overall listing standards for securities to be listed and traded on IEX are substantially similar to those of a Named Market. As such, the Commission proposes to amend Rule 146 under Section 18 of the Securities Act, as amended, to designate securities listed, or authorized for listing, on IEX as Covered Securities. The following analysis considers the economic effects that may result from the proposed amendment.

Where possible, the Commission has quantified the economic effects of the proposed amendment; however, as explained further below, the Commission is unable to quantify all of the economic effects because it lacks the information necessary to provide reasonable estimates. In some cases, quantification depends heavily on factors outside of the control of the Commission, particularly due to the flexibility that an issuer has when choosing if and where to list and the flexibility of a registered national securities exchange to tailor its policies and rules to the nature of its business and technology. These factors make it difficult to quantify the changes in market share of Named and Designated Markets that may result from the proposed amendment. In addition, the incumbent Named and Designated Markets and IEX each may react to the proposed amendments with respect to listing fees and services. These reactions are also difficult to quantify or predict, which further complicates quantification of changes to market share, and also makes quantification of the economic effects of the proposed amendment difficult. Therefore, some of the discussions below are qualitative in nature. The Commission encourages commenters to provide data and information to help quantify the costs, benefits, and the potential impacts on efficiency, competition, and capital formation of the proposed amendment.

A. Baseline

We compare the economic effects of the proposed rule, including benefits, costs, and effects on efficiency, competition, and capital formation, to a baseline that consists of the existing regulatory framework and market structure.

[29] Compare NYSE Listed Company Manual Section 303A.07(c) (requiring listed companies to maintain an internal audit function to provide management and the audit committee with ongoing assessments of the listed company's risk management processes and system of internal control) with IEX Rule 14.414.

[30] *See generally* IEX Rules Chapter 16 (Other Securities). *See also* IEX Rule 16.105(a) (Portfolio Depository Receipts); Rule 16.105(b) (Index Fund Shares); Rule 16.110 (Securities Linked to the Performance of Indexes and Commodities (Including Currencies); Rule 16.111(a) (Index-Linked Exchangeable Notes); Rule 16.111(b) (Equity Gold Shares); Rule 16.111(c) (Trust Certificates); Rule 16.111(d) (Commodity-Based Trust Shares); Rule 16.111(e) (Currency Trust Shares); Rule 16.111(f) (Commodity Index Trust Shares); Rule 16.111(g) (Commodity Futures Trust Shares); Rule 16.111(h) (Partnership Units); Rule 16.111 (i) (Trust Units); Rule 16.111 (j) (Managed Trust Securities); Rule 16.113 (Paired Class Shares); Rule 16.115 (Selected Equity-linked Debt Securities (''SEEDS'')); Rule 16.120 (Trust Issued Receipts); Rule 16.125 (Index Warrants); Rule 16.130 (Listing Requirements for Securities Not Otherwise Specified (Other Securities)); and Rule 16.135 (Managed Funds Shares).

[31] *See* Nasdaq/NGM Rule 5700 series.

[32] *See supra* note 1 and accompanying text.

[33] *See supra* note 6 and accompanying text.

[34] *See supra* note 10 and accompanying text.

[35] *See id.*

1. Regulatory Framework and Affected Parties

The listing standards of Named and Designated Markets are quantitative and qualitative requirements that issuers must satisfy before they may list on these markets. Securities listed on a Named or Designated Market are Covered Securities, which are exempt from complying with state securities law registration and qualification requirements. As mentioned above,[36] subsequent to its exchange registration, IEX petitioned the Commission to amend Rule 146(b) and determine that the listing standards for securities listed on IEX are substantially similar to those of the Named Markets.

Pursuant to unlisted trading privileges (''UTP''), a national securities exchange such as IEX currently can trade securities that are listed on other exchanges.[37] While IEX may offer to list securities for trading, currently, those securities would not be Covered Securities. Issuers of securities that are not Covered Securities must comply with state securities law registration and qualification requirements, which generally require the issuer to register such securities in each state or jurisdiction in which the issuer will offer or sell its securities. State registration and qualification requirements generally vary across the 54 U.S. jurisdictions, comprising the 50 states, the District of Columbia, and the three U.S. territories of Puerto Rico, the Virgin Islands, and Guam.[38] These requirements typically include: (1) Filing state administrative forms and other paperwork necessary for compliance with state registration requirements; (2) adherence to disclosure standards; and (3) in some states, requirements based upon the merits of the offering or issuer.[39]

The Commission lacks comprehensive, independent data to precisely estimate the total time, registration and compliance costs associated with state registration and qualification. Moreover, those total costs may vary widely for issuers depending on how many states an issuer needs to register in. To provide some information about potential costs for state registration, we list examples of Blue Sky registration filing fees for several states below in Table 1.

TABLE 1—EXAMPLES OF BLUE SKY REGISTRATION FILING FEES[40]

State	Filing fee
California	$200 plus ⅕ of 1 percent of the aggregate value of the securities proposed to be sold, with a maximum fee of $2,500.
Florida	$1,000.
Illinois	1/20 of 1 percent of the aggregate offering in Illinois, with a minimum fee of $500 and a maximum fee of $2,500.
New York	Based on total offerings: $500,000 or less: $300 More than $500,000: $1,200.
Texas	$100 filing fee, plus examination fee of 1/10 of 1 percent of the aggregate amount of securities sold in Texas.

The issuer of a non-Covered Security in multiple jurisdictions would have more compliance obligations than the issuer of a Covered Security, including the potential for considerable additional costs and legal fees associated with reviews of offering-related materials at the state level.[41] Additionally, as discussed above, many state securities regulators also review securities offerings based upon the merits of the offering and/or the issuer of the securities, which can further increase an issuer's compliance obligations and associated costs.[42] In addition, the Commission notes that one commenter estimated that an issuer seeking state registration in 50 states would incur $50,000 to $70,000 in filing fees and $80,000 to $100,000 in legal fees.[43] The Commission encourages commenters to provide additional information on the costs associated with complying with Blue Sky laws.[44]

In addition, the Commission preliminarily believes that the state registration and qualification requirements applicable to non-Covered Securities also impose costs on broker-dealers. Specifically, broker-dealers may incur costs to ensure that they are

[36] *See supra* notes 11–14 and accompanying text.

[37] *See* 15 U.S.C. 781(f) and Rule 12f–2.

[38] *See* Office of Investor Education and Advocacy, ''Blue Sky Laws'' (2014), *available at https://www.sec.gov/fast-answers/answers-blueskyhtm.html.*

[39] *See, e.g.,* Stuart R. Cohn, *Securities Counseling for Small and Emerging Companies* § 12:8 (2016) (describing merit review as ''the authority of state administrators to deny, suspend or revoke an offering because the administrator believes that the offering has substantive weaknesses in structure, financial strength or fairness to investors''). Typical elements of merit review include: Offering expenses, including underwriter's compensation, issuer capitalization requirements, dilution, financial condition of the issuer, cheap stock held by insiders, types of offering (*e.g.,* blind pool offerings), the quantity of securities subject to options and warrants, loans to insiders, and the price at which the securities will be offered. *See id.* The North American Securities Administrators Association (NASAA), an association of state and provincial securities regulators composed of the securities administrators from each state, Mexico, and 13 Canadian provinces, has issued guidelines intended to provide uniformity among state merit review standards. *See* NASAA Statements of Policy, *available at http://www.nasaa.org/regulatory-activity/statements-of-policy/.* Some exchange listing standards impose merit regulation on issuers.

[40] *See* CA Corp Code § 25608(e) for California filing fees; *http://www.leg.state.fl.us/Statutes/index.cfm?App_mode=Display_Statute&Search_String=&URL=0500-0599/0517/Sections/0517.081.html* for Florida filing fees; *http://www.cyberdriveillinois.com/departments/securities/sellingsec.html* for Illinois filing fees; *https://ag.ny.gov/investor-protection/broker-dealer-and-securities-registration-information-sheet* for New York filing fees; and *https://www.ssb.texas.gov/texas-securities-act-board-rules/fee-schedule#one* for Texas filing fees.

[41] For a discussion of state securities law registration and qualification requirements, the obligations of issuers with respect to such requirements, and developments in coordinated state securities law review programs for offerings in multiple jurisdictions, *see generally* Securities Act Release No. 9741 (March 25, 2015), 80 FR 21806 (April 20, 2015) (Amendments for Small and Additional Issues Exemptions under the Securities Act (Regulation A), at Section II.H.3 (''Regulation A Release'').

[42] *See id. See also Factors that May Affect Trends in Regulation A Offerings,* GAO–12–839 (July 2012) (discussing the varying standards and degrees of stringency applied during the qualification and review process in merit review states), *available at http://www.gao.gov/assets/600/592113.pdf.*

[43] *See* Regulation A Release, *supra* note 41; and Letter from Michael L. Zuppone, Paul Hastings LLP, to Commission, dated November 26, 2013, at 2 (further noting the ''significant costs and uncertainties associated with 'Blue Sky' law compliance''). *See also* Regulation A Release, *supra* note 41, at n.1024 and accompanying text. The commenter did not address whether these estimated costs vary by the size of the offering. Also, we note that the estimate concerns the initial costs associated with registration. The Commission believes that the ongoing costs of compliance that the issuer bears will be lower than these initial costs.

[44] *See* Regulation A Release, *supra* note 41; and Letter from Daniel Zinn, General Counsel, OTC Markets Group Inc., to Elizabeth M. Murphy, Secretary, Commission, dated March 24, 2014 (''OTC Markets Group Letter''), at 4–5 (describing the costs for issuers associated with Blue Sky laws).

complying with applicable state laws governing non-Covered Securities in each state in which they are transacting in those securities on behalf of their customers or providing advice or other information to customers related to those securities. For example, broker-dealers could incur costs associated with maintaining a compliance program to verify an issuer's state registration status and comply with any state requirements applicable to broker-dealers that transact in non-Covered Securities, which could vary depending on where the customer resides and the transaction occurs. In addition, the types and content of communications broker-dealers may have with their customers regarding non-Covered securities may be subject to regulation under Blue Sky laws, so broker-dealers may incur costs to ensure they are compliant with such requirements in each state in which they advising customers.[45] While some portion of these costs may be passed on to a broker-dealer's customers—*i.e.,* the investors that transact through the broker-dealer in non-Covered Securities—through commissions or transaction fees, the Commission preliminarily believes that the compliance costs associated with Blue Sky requirements may lead some broker-dealers to only offer their services for Covered Securities.[46] However, the Commission lacks the data necessary to quantify the costs that broker-dealers and their customers face, and encourages commenters to provide information on these costs and the extent to which the Blue Sky requirements affect the services broker-dealers offer for non-Covered Securities.

The proposed amendment, which would make IEX a Designated Market, would preempt the application of state securities law registration and qualification requirements for securities that are listed or authorized for listing on IEX, and would impact (1) issuers who currently list their securities on a Named or Designated Market; (2) issuers with securities not currently listed on any incumbent Named or Designated Market but who would consider listing on IEX, or on an incumbent Named or Designated Market, as a result of the competition from IEX if IEX enters the listing market; and (3) issuers with securities not currently listed on any incumbent Named or Designated Market and would eventually list on a Named or Designated Market, regardless of IEX's entry into the market. Given that issuers who meet the listing standards of IEX are likely to meet the listing standards of other Named or Designated Markets, the number of issuers that would list on a Named or Designated Market solely as a result of the proposed amendment (*i.e.,* those in category (ii) above) may be small. The proposed amendment would also affect IEX and the existing trading venues for securities that IEX would be able to list.[47]

2. Current Practices in the Market for Listings

Issuers of public securities make several considerations when deciding on which exchange to list their securities. These considerations include, among other things, the visibility and publicity provided by the exchange, the listing services and fees, and the exchange's listing standards. The Named and Designated Markets may provide issuers of Covered Securities with additional visibility over that of securities traded over the counter, which may, in turn, increase the pool of potential investors for an issuer and thereby improve an investor's access to capital. In addition, the Named and Designated Markets provide listing services for their listed issuers, which can include monitoring, communication, and regulatory compliance services. These services may help issuers by reducing the cost of raising capital and the costs associated with going or remaining public. However, many issuers that list for the first time do so as part of an initial public offering, which can include considerations not related to listing on an exchange, such as SEC reporting obligations, as well as legal, accounting, and other expenses (both for the initial offering and the ongoing requirements of remaining public), as well as the benefits of going public, such as increased access to capital and providing investors with a signal of an issuer's ability to meet obligations, such as reporting requirements, that apply to public companies. In this case, the decision of which exchange to list on is made along with the decision about whether or not to go public.

Issuers must pay listing fees and meet listing standards to list on a Named or Designated Market. Listing fees may include an initial application fee as well as an ongoing annual fee, and may vary by the number of shares in the initial offering or be a fixed fee. However, listing fees typically represent a small portion of the overall cost of an initial public offering or the ongoing costs of remaining public,[48] and thus may not be a significant factor that issuers consider when deciding (1) whether to list on a Named or Designated Market; and (2) which Named or Designated market to list on. Listing exchanges also impose listing standards on issuers, which can include corporate governance standards as well as quantitative requirements such as minimum income, market capitalization, and operating history requirements. While an exchange's listing standards may prevent potential issuers who do not meet those standards from listing on the exchange, the stringency of an exchange's listing standards may provide a valuable signal to investors about the quality of issuers that are able to list, which may improve the issuers' access to capital.[49]

3. Competitive Landscape

Because securities listed on the Named or Designated Markets are Covered Securities, being a Named Market or achieving status as a Designated Market permits exchanges to compete to provide listing services to issuers of Covered Securities.[50] Because Covered Securities are exempt from state securities registration laws, issuers of Covered Securities are not subject to costs from state securities registration laws and the costs associated with complying with state securities registration laws are lower for broker-dealers that transact on behalf of their customers in Covered Securities.

Furthermore, as described below in SectionVI.A.3.b, evidence that the

[45] *See* OTC Markets Group Letter, *supra* note 44, at 4 (describing impact of Blue Sky laws on broker-dealers).

[46] The OTC Markets letter also notes that broker-dealers may have increased ''rescission risk'' for failing to comply with each jurisdiction's Blue Sky requirements, which OTC Markets argues ''may chill some broker-dealers' willingness to allow their customers to transact in those securities at all, including securities of SEC reporting companies.'' *See* OTC Markets Group letter, *supra* note 44, at 4.

[47] The Commission preliminarily believes that the proposed amendment may also impact exchanges that are not Named or Designated Markets indirectly as explained below.

[48] Listing fees for equity securities can range from $55,000 (NYSE American) to $295,000 (NYSE). *See* NYSE MKT Company Guide at Sec. 140, *available at http://wallstreet.cch.com/MKTtools/PlatformViewer.asp?SelectedNode=chp_1_1_1&manual=/MKT/CompanyGuide/mkt-company-guide/;* and NYSE Listed Company Manual at 902.02, *available at http://nysemanual.nyse.com/LCMTools/bookmark.asp?id=sx-ruling-nyse-policymanual_902.02&manual=/lcm/sections/lcm-sections/. See also supra* notes 40–44 and accompanying text, which discusses the overall costs of state securities registration. See also Proskauer Rose LLP, 2016 IPO Study, at 52, *available at http://www.proskauer.com/files/uploads/Proskauer-2016-IPO-Study.pdf,* which examined 258 IPOs from 2013 to 2015 and found that the average total IPO expense, excluding underwriting fees, was $4.15 million.

[49] See *infra* Section VI.A.3, for further discussion of listing standards and signaling to investors.

[50] The Commission views the term ''listing exchange'' as equivalent to the term ''Named or Designated Market,'' for purposes of this release.

listing status and listing designation (*i.e.,* whether a security is a Covered Security and where it is listed) of securities are related to where and how the securities trade leads the Commission to believe that the proposed rule could also impact the market for trading services. In this section, we discuss competition between Named and Designated Markets for listings, as well as competition between Named and Designated Markets and other trading platforms for trading services.

(a) Competition for Listings

Listing exchanges compete with each other on many dimensions for listing securities, including, but not limited to, listing fees, listing standards, and listing services. When issuers choose which listing exchange to list on, issuers compare the listing fees and the costs of compliance with listing standards against the quality of listing services across listing exchanges. Although issuers may incur costs to meet an exchange's listing standards, high listing standards may also yield benefits as they may serve as a positive signal to investors of an issuer's ability to satisfy high qualitative and quantitative listing requirements. Investors may interpret the reputation of listing exchanges and their listing standards as a credible signal of the quality of listed security, and the reputation of an exchange is one of the factors that issuers consider when choosing which listing exchange to list on.[51]

Currently, there are three Named Markets under Section 18(b)(1)(A) of the Securities Act: NYSE, NYSE American, and Nasdaq/NGM. In addition, there are currently six Designated Markets: (1) Tier I of the NYSE Arca, Inc.; (2) Tier I of the NASDAQ OMX PHLX LLC; (3) CBOE; (4) options listed on ISE; (5) The Nasdaq Capital Market; and (6) Tier I and Tier II of BATS. As of June 2, 2017, NYSE listed 3,172, Nasdaq listed 3,183, NYSE Arca listed 1,529, NYSE American listed 359, and BATS listed 176.[52]

While the number of equities listed on an exchange may be informative about the general size of exchanges, the market shares for recent equity issue listings may provide a better picture of the nature of competition between exchanges and the size of the new listings market. In Table 2, we show the number of new equity issue listings from 2008 to 2016.[53]

TABLE 2—NEW EQUITY LISTINGS IN NAMED AND DESIGNATED MARKETS, 2008–2016

	NYSE	Nasdaq	NYSE American	NYSE ARCA	BATS
2008	68	142	53	68	0
2009	76	115	33	20	0
2010	141	156	31	12	0
2011	130	132	34	14	0
2012	148	135	19	9	17
2013	178	201	26	13	6
2014	178	278	23	12	5
2015	101	220	15	13	31
2016	81	163	5	12	85

As shown in Table 2, two listing exchanges—NYSE and Nasdaq—captured 71% of all new equity listings on Named and Designated Markets in 2016, which is evidence of a highly concentrated listing market.[54] In addition, when BATS entered the market in 2012, it gained only 17 new listings, which was 5.2% of all new equity listings of 2012, which suggests that the number of issuers that remain unlisted but would list with an entrant is likely to be small.[55]

A highly concentrated market may be the result of barriers to entry, which limit competition, and can include economies of scale, reputation, legal barriers to entry, and network externalities. Listing exchanges may exhibit economies of scale because an exchange with a large number of listings can spread the fixed costs of listing equities over a greater number of issuers. The larger these fixed costs are, the greater will be the scale economies of larger listing exchanges. Entrant exchanges can also face barriers to entry related to reputation. Exchanges that enter the market may not be able to quickly establish a strong reputation for high quality listings, which may adversely affect their ability to compete with incumbent exchanges. This lack of reputation may discourage both investors and issuers from transacting or listing on an entrant exchange, which may reinforce an entrant exchange's lack of reputation.

Legal barriers to entry could also apply because exchanges are self-regulatory organizations overseen by the Commission. The governing statute and regulations establish legal barriers of entry for an entity becoming an exchange as well as for an exchange becoming a Designated Market. As discussed, the fact that an exchange must be designated by the Commission to become a Designated Market, which enables such an exchange to effectively compete for the listing business of Covered Securities, imposes legal barriers to entry.

In addition, the market for listing exhibits positive network externalities: Issuers may prefer to be listed on exchanges where other similar issuers

[51] *See, e.g.,* Thomas J. Chemmanur & Paolo Fulghieri, *Competition and Cooperation Among Exchanges: A Theory of Cross-listing and Endogenous Listing Standards,* 82 J. Fin. Econ. 455–89 (2006), *available at http://www.sciencedirect.com/science/article/pii/S0304405X06001139.*

[52] These estimates of listed equities include equity securities reported to a securities information processor, and do not include options or corporate debt securities. The estimates also include multiple securities from the same issuer, which means the total number of securities may differ from the total number of issuers potentially affected by this rulemaking. Listing information is from the master files of the daily trade and quotation data (''TAQ Data'').

[53] The listings data for NYSE, Nasdaq, NYSE American, and NYSE Arca were taken from Compustat Merged © 2016 Center for Research in Securities Prices (''CRSP''), The University of Chicago Booth School of Business. As CRSP does not have BATS listings data, BATS listings are from TAQ Data. *See supra* note 52.

[54] The Herfindahl-Hirschman Index (HHI) measure for listing exchanges is 0.321, calculated as the sum of squared market shares, or (2,552/7,217)∧2 + (2,863/7,217)∧2 + (1,377/7,217)∧2 + (339/7,217)∧2 + (86/7,217)∧2 = 0.321. See Campbell McConnell, Stanley Brue & Sean Flynn, Microeconomics: Principles, Problems, & Policies 218, 219, 225, 226 (2014). An HHI close to 0 indicates low concentration while an HHI of 1 indicates total concentration or monopoly.

[55] See *infra* SectionVI.B.2, for further discussion about how this may affect currently unlisted issuers.

are listed because of increased visibility. This indicates that, all else being equal, large exchanges (in terms of listings) may tend to be favored over smaller ones.

Issuers also may face switching costs associated with moving their listing from one exchange to another. These switching costs would not only include the fixed costs associated with a listing on an new exchange such as the exchange's application fee, and the legal and accounting expenses associated with ensuring that the issuer satisfies the listing standards of the new exchange, but would also include the costs associated with communicating with investors, including about the move to the new exchange. Thus, an issuer that is considering moving from one exchange would compare the relatively lower annual listing fee of their current exchange with the relatively high costs of moving its listing to a new exchange, which places the new exchange at a disadvantage and creates a barrier to entry for a potential entrant. Even if an entrant exchange prices its listing fees and services competitively compared to the incumbent exchanges for new issuers, the switching costs for issuers that are already listed may prevent the entrant from gaining market share.

Table 3 shows estimates of the probability that an issuer would change its listing market in a given year, based on issuer switching behavior for equities over the period 2008 to 2016. As an example, during this period, if an equity security was listed on NYSE, there was a 99.33% chance that it would still be listed on NYSE the following year and a 0.04% chance it would be listed on AMEX the following year, a 0.34% chance it would be listed on Nasdaq the following year, and a 0.08% chance it would be listed on ARCA the following year. More generally, equities listed on NYSE and Nasdaq had a greater than 99% chance of remaining listed on that exchange the following year, which suggests that issuers were unlikely to switch their listings away from the two exchanges with the highest market shares.

TABLE 3—CONDITIONAL PROBABILITY OF TRANSITION FOR LISTINGS, 2008–2016 [56]

Original exchange	NYSE (%)	NYSE American (%)	Nasdaq (%)	NYSE ARCA (%)	BATS (%)	Not trading [57] (%)
Status in the Following Year						
NYSE	99.33	0.04	0.34	0.08	0.00	0.20
NYSE Amer	1.80	93.47	2.80	1.39	0.00	0.54
Nasdaq	0.38	0.07	99.11	0.01	0.00	0.42
NYSE ARCA	1.50	0.47	1.13	90.81	0.00	6.10
BATS	0.00	0.00	0.00	0.00	94.40	5.60

(b) Competition for Trading Services

Trading in Covered Securities is segmented from trading in securities that are not covered (''OTC trading''). In addition to trading on Named or Designated Markets, Covered Securities can also trade on 12 other registered national securities exchanges or off-exchange either on 35 alternative trading systems (''ATSs'') or by broker-dealers who internalize orders. The market to trade Covered Securities on Named and Designated Markets as well as other trading platforms is more liquid than OTC trading of securities that are not Covered Securities due to, among other things, the search costs associated with finding buyers and sellers in OTC markets.[58]

Covered Securities can trade on exchanges and other markets that do not ''list'' the security. This flexibility allows trading platforms to compete with each other by offering better trading services or innovative trading mechanisms to attract order flow for securities, even if they do not list such securities. The order flow from these securities, through the application of transaction fees, can generate revenue for an exchange. Exchanges also receive revenue from the sale of SIP data, determined, in part, from an exchange's share of transaction volume.[59] Listing exchanges currently enjoy a larger trading market share in their listed securities.[60]

Despite the historical advantages listing exchanges enjoy in the market for trading services, the success of listing exchanges when competing for equity issue listings by offering better trading services or innovative trading mechanisms has declined over the past decade.[61] During this time, the increase in fragmentation in the market for trading services resulted in a significant shift in the market share of trading volume in Covered Securities across trading venues. For example, the two exchanges historically with the highest trading volume, NYSE and Nasdaq, have each experienced a sharp decline in market share of trading volume in securities they list. The market share of the NYSE in NYSE-listed stocks fell from approximately 80% in 2005 to 20% in 2013; for Nasdaq-listed stocks, Nasdaq's market share of Nasdaq-listed stocks fell by approximately half, from 50% in 2005 to 25% in 2013.[62]

The competition for trading services is not limited to exchanges. Over the past decade, greater trading volume has been executed on other venues, including ATSs. Since the third quarter of 2009, the number of ATSs that trade NMS stocks has increased from 32 to 34, while the share of trading volume of Covered Securities that trade on ATSs

[56] The listings data for NYSE, Nasdaq, NYSE American, and NYSE Arca were taken from CRSP. BATS listings are from TAQ Data. *See supra* note 52.

[57] For the exchanges in the CRSP data (NYSE, NYSE American, Nasdaq, and NYSE Arca), this category (Not Trading) includes listings that were halted, suspended, not trading, or whose listing status was not known in the following year. For the exchange from the TAQ data (BATS), this column includes listings that were not in the TAQ master file in the following year.

[58] *See, e.g.,* Ulff Brüggemann, Aditya Kaul, Christian Leuz & Ingrid M. Werner, *The Twilight Zone: OTC Regulatory Regimes and Market Quality,* (Nat'l Bureau of Econ. Research, Working Paper No. 19358, 2013), *available at https://ideas.repec.org/p/nbr/nberwo/19358.html.*

[59] *See* Securities Exchange Act Release No. 61358 (January 14, 2010), 75 FR 3594, 3600–01 (January 21, 2010) (Concept Release on Equity Market Structure) (Commission concept release discussing the revenues and expenses from data fees at that point in time).

[60] For the purposes of this rulemaking, staff examined TAQ Data for the time period of November through December 2014. Staff observed that exchanges tend to enjoy more than 15% higher market share in the securities they list compared to the securities they do not list, on average, and they tend to enjoy about 20% higher market share in the securities they list compared to the market share of others' trading in those securities, on average.

[61] *See* James Angel, Lawrence Harris & Chester Spatt, Equity Trading in the 21st Century: An Update (2013), *available at http://www.q-group.org/wp-content/uploads/2014/01/Equity-Trading-in-the-21st-Century-An-Update-FINAL1.pdf.*

[62] *See id.* at 20–21.

has increased from 7.9% to 13.0%.[63] This suggests that the importance of ATSs for trading services has increased relative to Named and Designated Markets, and that the listing exchange of a security may be less important in determining the location of trading activity.

B. Impact on Efficiency, Competition, and Capital Formation

Securities Act Section 2(b)[64] requires the Commission, when engaging in rulemaking that requires it to consider or determine whether an action is necessary or appropriate in the public interest, to consider, in addition to the protection of investors, whether the action will promote efficiency, competition, and capital formation.

1. Efficiency

By listing on IEX, security issuers that otherwise would have not listed their securities on a Named or Designated Market would be able to avoid the duplicative costs of securities registration in multiple jurisdictions and thus reduce the impediments to listing on exchanges, which in turn can improve market efficiency. To the extent that the proposed amendment results in increased listing activity, then it may improve the allocative efficiency of securities markets by allowing investors to better diversify financial risks by investing in newly-listed securities.

However, these two impacts may be mitigated by the extent to which issuers' abilities to list on a Named or Designated Market are constrained by other factors, such as their ability to satisfy listing standards and the attendant costs from doing so. For example, issuers may face increased disclosure costs associated with becoming an SEC reporting company if they are not already an SEC reporting company because issuers must be an SEC reporting company to list on a national securities exchange.[65] Moreover, issuers that are able to meet the listing standards of IEX are likely to be able to meet the listing standards of other Named or Designated Markets, so the entry of IEX would not necessarily increase the pool of securities eligible for listing. As a result, the Commission preliminarily believes that the number of issuers that would list on IEX, where, in the absence of the proposed amendment, would not have listed at all, is likely to be small.[66]

2. Capital Formation

As noted in Section VI.A, a reason issuers list on a Named or Designated Market is improved access to capital. Listing on a Named or Designated Market may improve access to capital, which can promote capital formation, in several ways. First, listing on a Named or Designated Market may credibly signal to investors that a firm is of higher quality because firms that list on these exchanges must meet certain minimum standards for governance and disclosure set by listing on these exchanges. Like listed issuers on the Named and Designated Markets, IEX's listed issuers might benefit from the signal of quality that comes from listing on a Named or Designated Market compared to issuers that do not list. The reputational benefits that come from listing on a Named or Designated Market may make investors more willing to invest in such issuers, which may improve the issuers' access to capital, and promote capital formation.

Second, listing on a Named or Designated Market may provide additional liquidity for equities relative to OTC trading, due in part to potential frictions to liquidity imposed by OTC search costs.[67] If investors demand a liquidity risk premium,[68] the enhanced liquidity could facilitate capital formation by reducing the size of the premium that issuers would otherwise incur when issuing new securities. Additionally, listing on a Named or Designated Market may promote access to capital by reducing the costs associated with broker-dealers ensuring their compliance with state securities laws in multiple jurisdictions, which would be borne by broker-dealers and potentially shared with investors, thus attracting broker-dealers and investors to transact in securities that list on a Named or Designated Market.[69] Investors in securities that list on IEX as a result of the proposed amendment would have easier access to invest in those securities and to further diversify their investment portfolios, which may promote capital formation by improving allocative efficiency.[70]

Whether IEX entering the listing market promotes capital formation depends on the extent to which issuers previously unable or unwilling to list on a Named or Designated Market subsequently do so. Some issuers may, as a result of improved services and/or decreased fees stemming from the increased competition between listing exchanges, be induced to list on an exchange where, in the absence of the proposed amendment, they would not have. If so, then the entrance of IEX could provide issuers with lower cost access to capital.

3. Competition

The proposed amendment to Rule 146(b) would likely increase competition among the Named and Designated Markets that compete to list securities. By determining that IEX has ''substantially similar'' listing standards to the Named and other Designated Markets, the proposed amendment permits IEX to compete with other Named and Designated Markets to list securities that are exempt from state registration requirements. This would reduce the costs associated with complying with state securities laws in multiple jurisdictions that are borne by broker-dealers and such a reduction would potentially be shared with customers. As mentioned earlier, the Named and Designated Markets compete with each other on many dimensions, including listing standards, listing fees, and listing services. Besides permitting IEX to compete to list securities as a Designated Market, IEX's entry as a listing market might also provide incumbent listing markets with incentives to change how they compete with each other.[71]

Generally, there are two ways that increased competition can affect how listing markets compete with each other. The first involves how the Named or

[63] *See* 17 CFR 242.600(b)(47) (definition of NMS Stock) (''*NMS stock* means any NMS security other than an option.'') and 17 CFR 242.600(46) (definition of NMS security) (''*NMS security* means any security or class of securities for which transaction reports are collected, processed, and made available pursuant to an effective transaction reporting plan, or an effective national market system plan for reporting transactions in listed options.''). The estimates of ATSs that trade NMS stocks and ATS trade volume share was developed using weekly summaries of trade volume collected from ATSs pursuant to FINRA Rule 4552. *See also* Securities Exchange Act Release No. 76474 (November 18, 2015), 80 FR 80998, 81109 (December 28, 2015) (Regulation of NMS Stock Alternative Trading Systems). The estimates in this release were done in the same manner as in the cited release. *See also OTC (ATS & Non-ATS) Transparency,* FINRA, *http://www.finra.org/Industry/Compliance/MarketTransparency/ATS/.*

[64] *See* 15 U.S.C. 77b(b).

[65] *See* 15 U.S.C. 78(*l*)(b).

[66] See *supra* SectionVI.A.3.a, for further discussion.

[67] *See* Darrell Duffie, Nicolae Garleanu & Lasse Heje Pedersen, *Over-the-Counter Markets,* 73 Econometrica 1815 (2005).

[68] Liquidity risk premia are the extra returns that investors demand because of the risks associated with investing in illiquid assets.

[69] *See supra* Section VI.A.1.

[70] *See, e.g.,* John Heaton & Deborah J. Lucas, *Evaluating the Effects of Incomplete Markets on Risk Sharing and Asset Pricing,* 104 J. Pol. Econ. 443 (1996).

[71] *See, e.g.,* Thierry Foucault & Christine A. Parlour, *Competition for Listing,* 35 Rand J. Econ. 329 (2004) (describing how, in equilibrium, competing exchanges obtain positive expected profits by offering different execution costs and different listing fees). *See also supra* note 61 and accompanying text.

Designated Markets compete to provide better services and value for listing issuers. For example, listing markets could reduce fees, improve services, or reduce compliance burdens associated with their listing standards.[72] If an additional entrant competes by providing better listing and monitoring services or lower costs for issuers, incumbent listing exchanges may decide to follow suit.

The Named and Designated Markets also may compete to provide better services by increasing their level of specialization with respect to securities listings. As noted below, as in the case of BATS, some Named and Designated Markets may develop reputations for specializing in specific types of issues by catering to specific types of issuers. An increase in competitive pressures may cause the Named and Designated Markets to more closely cater to specific types of issuers. Specialization may reduce the cost of providing listing services or may promote innovation in the provision of listing services. To the extent that specialization improves the services provided to issuers or reduces the costs of these services, this competitive response may improve the efficiency of the market for listing services.

The second way that increased competition can affect how the Named and Designated Markets compete with each other is through their role as intermediaries. The Named and Designated Markets serve as information and reputation intermediaries partly through their listing standards. Because issuers cannot perfectly signal their quality, the reputation of a Named or Designated Market for strict listing standards may be informative to an investor and serve as a signal of the quality of an issuer.[73] Issuers that are able to meet the listing standards of a Named or Designated Market can signal their ability to do so by listing on them. However, because complying with these listing standards may be costly for issuers, issuers weigh the benefits of higher quality signaling through stronger listing standards against the costs of compliance with these standards. The Named and Designated Markets thus balance the competitive incentives to cater to two different groups of market participants—issuers and investors.

Because the Named and Designated Markets serve as information and reputation intermediaries between issuers and investors, the impact of increased competition on listing standards is ambiguous. The Named and Designated Markets may respond to increased competition by increasing listing standards to provide additional signaling and attract investors. Alternatively, the Named and Designated Markets could instead respond to increased competition by decreasing listing standards to attract additional listings. The intermediaries' opposing incentives to cater to these two groups of market participants make predicting the impact of competition on listing standards difficult.

The Named and Designated Markets' ability to lower standards would be constrained by the fact that 1. any proposed listing standards or proposed changes to existing listing standards must be filed with the Commission pursuant to Section 19(b) of the Exchange Act and must meet statutory and rule requirements to become effective,[74] and 2. an exchange with lower listing standards that are not substantially similar to those of a Named Market may lose its status as a Designated Market.[75] The requirement that the listing standards of a Designated Market be substantially similar to those of a Named Market means that the listing standards of the Named Markets serve as a lower bound for the extent to which competition may drive down listing standards for the other exchanges.

Despite the potential for increased competition, some of the features of the market for listings that inhibit competition, as discussed above, may also mitigate the effects of IEX's entry on competition. Specifically, some of the barriers to entry discussed in the baseline—economies of scale and network externalities—may make it difficult for IEX to effectively compete with incumbent exchanges for listings.[76] For example, if a new entrant does not attract enough initial listings, the fixed cost of operations may make it difficult to keep its listing fees competitive. In addition, new entrants may not have established a sufficient reputation as a listing exchange to credibly certify the quality of its new issues. Thus, the structure of the market for listings may mitigate some of the potential effects of increased competition between Named and Designated Markets.

The latest example of an entrant into the market for listings is BATS BZX, which became a Designated Market in 2012.[77] Table 2 in Section VI.A.3.a shows that the number of new listings on BATS decreased each year until 2015, but has increased more recently. While the growth in new listings by BATS may be indicative of the barriers to entry that entrants such as IEX face, circumstances specific to BATS may have impacted its ability during that period to attract listings.[78]

Table 3 in Section VI.A.3.a shows that almost none of the new listings on BATS arrived as transfers from another exchange, but were instead the first listing for each issuer that listed on BATS. This evidence is consistent with the argument that switching costs may also have had an impact on BATS' ability to gain market share, and may be a factor that also shapes IEX's entry. Moreover, the vast majority of BATS-listed securities are exchange-traded products. This is consistent with the idea that despite barriers to entry, BATS was able to enter by competing for one segment of the market and specializing in listing exchange-traded products.

C. Analysis of Benefits and Costs

If the Commission amends Rule 146(b) to include IEX, then securities listed, or authorized for listing, on IEX would be eligible to be designated as Covered Securities under Rule 146(b)(1) under the Securities Act, which, as described above, are exempt from state law registration requirements.[79] In this

[72] *See infra* note 74 (discussing the Exchange Act filing requirements necessary for any revision to exchange listing standards and noting that such listing standards and changes to such listing standards are subject to the requirements of the Exchange Act and the rules and regulations thereunder).

[73] See Stewart C. Myers & Nicholas S. Majluf, *Corporate Financing and Investment Decisions When Firms Have Information That Investors Do Not Have,* 13 J. Fin. Econ. 187 (1984), *available at http://www.sciencedirect.com/science/article/pii/0304405X84900230,* for a discussion of the role of asymmetric information in corporate finance. See also Nathalie Dierkens, *Information Asymmetry and Equity Issues,* 26 J. Fin. & Quantitative Analysis 181 (1991), *available at www.jstor.org/stable/2331264,* for empirical evidence of asymmetric information in the equity issue process.

[74] Any revision to exchange listing standards must be filed in accordance with Section 19(b) of the Exchange Act and Rule 19b–4 thereunder and is subject to the requirements of the Exchange Act and the rules and regulations thereunder. *See* 15 U.S.C. 78s(b) and 17 CFR 240.19b–4.

[75] *See* 17 CFR 230.146(b)(2).

[76] *See supra* Section VI.A.

[77] *See* Securities Act Release No. 9295 (January 20, 2012), 77 FR 3590 (January 25, 2012).

[78] As BATS noted in its registration statement filed with the Commission on December 15, 2015, ''[O]n March 23, 2012, we experienced a serious technical failure on BZX, forcing us to cancel our planned IPO. . . . These technical failures damaged our reputation and resulted in increased regulatory scrutiny of the event by the SEC and other governmental authorities.''

[79] Rule 146 and Section 18 have no effect on Federal registration requirements, which are addressed by Section 5 of the Exchange Act. *See* 15 U.S.C. 78e. Section 18 of the Securities Act states that no law, rule, regulation, or order, or other administrative action of any State or any political subdivision thereof requiring, or with respect to, registration or qualification of securities, or registration or qualification of securities

section, we discuss the benefits and costs of the proposed amendment, which stem from its two major effects: (1) The exemption from Blue Sky laws provided to any issuers that would not list in the absence of the proposed amendment; and (2) the entry of IEX into the market for listings as a Designated Market.

As noted above, the Commission is unable to quantify all of the economic effects of the proposed amendment because it lacks the information necessary to provide reasonable estimates. The Commission seeks comment on any information on these factors or information that would help it directly quantify the economic effects of the rule.

1. Benefits of the Proposed Amendment

The proposed amendment could provide benefits, flowing from the exemption from Blue Sky laws, to currently unlisted issuers that do not currently list on an existing Named or Designated Market but would choose to list on IEX.[80] Specifically, the proposed amendment permits these issuers of Covered Securities that list on IEX to avoid the potentially duplicative costs of complying with multiple state securities regulations. As mentioned previously, these duplicative costs could include both a fixed cost of registration and ongoing compliance costs. An unlisted issuer needs to register in each of the jurisdictions it wants to transact in, so if the proposed amendments increase the number of issuers that list, such issuers save these costs. To the extent that IEX attracts previously unlisted issuers, IEX may benefit as a result of revenue from listing fees, trading fees, and data fees associated with the new issuers. In addition, absent the proposed amendment, the heterogeneity in state securities regulations generates ongoing costs for broker-dealers and investors transacting in multiple jurisdictions.[81] However, the overall magnitude of these benefits depends on the number of currently unlisted issuers that choose to list on IEX as a result of the proposed amendment, and the Commission preliminarily believes this number is likely to be small because any unlisted issuer able to meet the listing standards of IEX is likely to be able to meet the listing standards of the other Named and Designated Markets.[82]

More generally, by making IEX a Designated Market, the proposed amendment would benefit IEX by allowing it to compete in the listing market for Covered Securities on a more level playing field with similarly situated national securities exchanges.[83] Specifically, being able to list Covered Securities would allow IEX to more effectively compete with the incumbent Named and Designated Markets that also are able to offer Covered Securities status. This would also benefit issuers that choose to list securities on a Named or Designated Market by providing them with another alternative venue on which to list. Furthermore, adding IEX as an entrant into this market would increase the number of competitors in the market for listings. To the extent that the existing Named and Designated Markets respond to this increased competition by reducing listing fees or improving listing services, as discussed above, currently listed issuers and their investors may benefit from the improved quality of listing services, reduced listing fees or reduced compliance costs. In addition, to the extent that the entry of IEX increases the specialization of incumbent Named and Designated Markets, issuers may benefit from listing services that are more tailored to their needs.

Although the direct effect of the proposed amendment may reduce the costs associated with registering in multiple jurisdictions, the Commission notes that issuers already have other Named and Designated Markets as options to list, and are likely to be able to meet the listing standards of these other markets if they would be able to list on IEX. IEX's entry into the market for listings may have a larger impact on issuers by increasing the amount of competition between Named and Designated Markets, rather than through the direct provision of Covered Securities status provided to securities that list on IEX. An increased amount of competition between Named and Designated Markets may improve listing services, reduce listing fees, and issuer specialization, which may benefit issuers.[84]

Last, issuers that choose to list on a Named or Designated Market because of IEX's entry may impact the trading of those issuers' securities on markets that are not Named or Designated Markets. As noted in the baseline, securities that list on a Named or Designated Market may also trade on exchanges that are not Named or Designated Markets, which may bring them additional revenue from trades.[85] Exchanges that are not Named or Designated Markets may thus benefit from the entry of IEX into the market for listings, even if these exchanges do not directly compete with IEX or the Named or Designated Markets for listings business.

2. Costs of the Proposed Amendment

The Commission notes that the overall magnitude of costs associated with the loss of state oversight depends on the number of unlisted issuers that choose to list as a result of the proposed amendment, and the Commission preliminarily believes this number is likely to be small, if any, for the reasons noted above.[86] For unlisted issuers that choose to list on IEX as a result of the proposed amendment, listing on IEX may entail costs from a loss of state oversight and compliance costs arising from new reporting obligations from IEX's listing standards. However, we note that these issuers would only choose to list on IEX and bear these costs if they decided that the benefits of listing on IEX justified the costs.

The Commission preliminarily believes that any costs to investors from a loss of state oversight for such issuers would be mitigated by federal regulations and oversight of IEX and the other Named and Designated Markets and the requirement to meet their respective listing standards. Indeed, Congress, in Section 18, has already determined that federal regulation is sufficient for those issuers that meet the high listing standards of a Named/Designated Market. Furthermore, the Commission preliminarily believes that other regulatory protections (*e.g.,* market surveillance, investigation and enforcement) already imposed on previously unlisted issuers who choose to list on IEX will mitigate these potential costs.

Issuers who currently list on an existing Named or Designated Market that would switch to IEX would not experience potential costs from a loss of state oversight or compliance costs arising from new reporting obligations. However, any previously listed issuers that decide to change their listing from a Named or Designated Market to IEX

transactions, shall directly or indirectly apply to a covered security. *See* 15 U.S.C. 77r(a)(1)(A).

[80] Data to estimate the number of such issuers does not exist, but the Commission preliminarily believes that the numbers of such issuers is likely to be small, as any issuers that can meet the listing standards of IEX are likely to be able to meet the listing standards of the incumbent Named or Designated Markets.

[81] *See supra* Sections VI.A.1 and VI.B.1.

[82] *See* Table 2, *supra* Section VI.A.3.a, and accompanying text.

[83] The Commission acknowledges that this benefit to IEX may come at the expense of the existing Named and Designated Markets, who may lose a portion of their current share to a new entrant. *See infra* Section VI.D.

[84] *See supra* Section VI.B.3.

[85] *See supra* Section VI.A.1.

[86] *See* Table 2, *supra* Section VI.A.3.a, and accompanying text.

would incur costs to switch their listing.[87] Still, the issuers could choose whether or not to incur this cost and likely would do so only if the benefits of switching their listing exceed their switching costs.

D. Other Effects of the Proposed Amendment

Some of the effects of the proposed amendments to IEX, incumbent Named and Designated Markets, and issuers involve transfers from one party to another. For example, the listing fees collected by IEX from previously-listed issuers may accompany a related loss of the listing fees collected by other Named or Designated Markets. Issuers that list on Named and Designated Markets may also enjoy savings from listing fee reductions as a result of increased listing exchange competition, which would also accompany a loss of listing fees collected by Named or Designated Markets.

Additionally, as a result of changes to competition in the market for listings, the volume of trade in trading venues may shift, to the advantage of some venues and to the detriment of others. Changes to the Named or Designated Markets' shares of the market for listings may affect the distribution of trading volumes across Named and Designated Markets, as well as other trading venues. Commission staff estimates that an exchange captures an average of about 20% higher share of volume in the securities listed by that exchange compared to the market share of other exchanges trading the same securities.[88] This result suggests that changes to listings driven by increased competition may alter the market share of trades distributed across each venue, even if the number of listed securities does not change, by about 20% of the volume in such securities. Any shifts in the market share of trading could result in gains and losses in transaction fees collected and the share of data fees split between exchanges. Although these gains and losses are relevant potential economic effects of the proposed amendment, the Commission preliminarily does not consider these transfers to be a benefit or cost of the proposed amendment, but rather a consequence of increased competition between listings.[89]

E. Request for Comment

The Commission seeks comment and supporting information as to the costs and benefits associated with this rule amendment, including identification and assessments of any costs and benefits not discussed in this analysis, and the effects on efficiency, capital formation and competition. We solicit comments on the usefulness of the rule amendment to investors, reporting persons, registrants, and the marketplace at large. We encourage commentators to identify, discuss, analyze, and supply relevant data, information, or statistics regarding any such costs or benefits, as well as any costs and benefits not already defined. We also request qualitative feedback on the nature of the benefits and costs described above. Additionally, we request comment on the extent of any costs that may be attributable to any loss of protections that currently are afforded by the state registration process, such as any merit-based requirements imposed by states on issuers. In particular, the Commission seeks comment on the following:

1. Has the Commission accurately described the baseline for the economic analysis? What are the typical costs of registering securities in multiple states? In how many states do issuers that qualify or are close to qualifying to list register? What are the typical attorney fees and other costs for registering securities in multiple states?

2. Has the Commission accurately described the competitive landscape for the market for listing Covered Securities? Has the Commission accurately described the competitive landscape for the market for trading services?

3. Does the proposing release discuss all relevant markets and forms of competition? If not, which additional markets or forms of competition could the proposal impact and what is the current competitive landscape in those markets?

4. Has the Commission accurately identified all market participants that would be affected by the proposed amendments to Rule 146? Which market participants do commenters believe would be affected by the proposed amendments but have not been included in the analysis?

5. Has the Commission accurately identified the potential impacts on efficiency, competition, and capital formation?

6. Has the Commission accurately identified and explained the costs and benefits of the proposed amendments to Rule 146?

a. Has the Commission accurately described the benefits to issuers and investors that would choose to list on IEX should IEX become a Designated Market?

b. Has the Commission accurately described the benefits to investors, IEX and other Designated Markets as a result of IEX becoming a Designated Market?

c. Has the Commission accurately described the costs to investors in securities of issuers that will choose to list on IEX should IEX become a Designated Market?

d. Has the Commission accurately described the costs to issuers of securities that will choose to list on IEX should IEX become a Designated Market?

e. Has the Commission accurately described the costs to IEX and other Designated Markets as a result of IEX becoming a Designated Market?

7. Are there benefits or costs that could be quantified or otherwise monetized? The Commission encourages commenters to provide specific estimates or data.

8. In light of the relevant statutory language and in the context of this particular proposed rulemaking, are there reasonable alternatives to this proposal to designate securities listed on IEX as covered securities?

VII. Regulatory Flexibility Act Certification

Section 603(a) of the Regulatory Flexibility Act[90] requires the Commission to undertake an initial regulatory flexibility analysis of the proposed amendment to Rule 146 on small entities, unless the Commission certifies that the proposed amendment, if adopted, would not have a significant economic impact on a substantial number of small entities.[91] For purposes of Commission rulemaking in connection with the Regulatory Flexibility Act, an issuer is a small business if its ''total assets on the last day of its most recent fiscal year were $5 million or less.''[92] In addition, an exchange is a small entity if it is an exchange that is exempt from the reporting requirements of Rule 601 under Regulation NMS, and is not

[87] See *supra* Section VI.A.3.a, for a discussion of the sources of switching costs.

[88] *See supra* note 60. Using TAQ data, Commission staff estimates that listing exchanges have around 28.8% of the dollar volume in the securities they list compared to other exchanges' average of about 3.3% of the dollar volume. Staff observed that each listing exchange enjoys a higher market share of dollar volume in its listed securities than any other exchange trading the listing exchange's listed securities. Staff also observed that these differences were not only economically large, but that they were also statistically significant.

[89] In light of the relevant statutory language and in the context of this particular proposed rulemaking, we do not believe there are reasonable alternatives to this proposal to designate securities listed on IEX as covered securities.

[90] 5 U.S.C. 603(a).

[91] 5 U.S.C. 605(b).

[92] 17 CFR 230.157. *See also* 17 CFR 240.0–10(a).

affiliated with any person (other than a natural person) that is not a small business or small organization.[93]

The Commission preliminarily believes that the proposal to amend Rule 146(b) would not affect a substantial number of small entities because IEX is not a small entity. Further, to list its securities on IEX, an issuer's aggregate market value of publicly held shares would be required to be at least $5 million. If an entity's market value of publicly held shares were at least $5 million, it is reasonable to believe that its assets generally would be worth more than $5 million. Therefore, an entity seeking to list securities on IEX pursuant to IEX's listing standards generally would have assets with a market value of more than $5 million and thus would not be a small entity.

Accordingly, the Commission hereby certifies, pursuant to Section 605(b) of the Regulatory Flexibility Act,[94] that amending Rule 146(b) as proposed would not have a significant economic impact on a substantial number of small entities. The Commission encourages written comments regarding this certification. The Commission solicits comment as to whether the proposed amendment to Rule 146(b) could have an effect that has not been considered. The Commission requests that commenters describe the nature of any impact on small entities and provide empirical data to support the extent of such impact.

VIII. Small Business Regulatory Enforcement Fairness Act of 1996

For purposes of the Small Business Enforcement Fairness Act of 1996, a rule is ''major'' if it results or is likely to result in:

1. An annual effect on the economy of $100 million or more;

2. a major increase in costs or prices for consumers or individual industries; or

3. significant adverse effects on competition, investment, or innovation.[95]

The Commission requests comment regarding the potential impact of the proposed amendment on the economy on an annual basis. Commenters should provide empirical data to support their views to the extent possible.

[93] 17 CFR 240.0–10(e).

[94] 5 U.S.C. 605(b).

[95] Public Law 104–121, Title II, 110 Stat. 857 (1996) (codified in various sections of 5 U.S.C., 15 U.S.C., and as a note to 5 U.S.C. 601).

IX. Statutory Authority and Text of the Proposed Rule

The Commission is proposing an amendment to Rule 146 pursuant to the Securities Act of 1933,[96] particularly Sections 18(b)(1)(B) and 19(a).[97]

List of Subjects in 17 CFR Part 230

Securities.

For the reasons set forth in the preamble, the Commission proposes to amend Title 17, Chapter II of the Code of Federal Regulations as follows:

PART 230—GENERAL RULES AND REGULATIONS, SECURITIES ACT OF 1933

■ 1. The authority citation for part 230 continues to read, in part, as follows:

Authority: 15 U.S.C. 77b, 77b note, 77c, 77d, 77f, 77g, 77h, 77j, 77r, 77s, 77z–3, 77sss, 78c, 78d, 78j, 78*l*, 78m, 78n, 78o, 78o–7 note, 78t, 78w, 78*ll*(d), 78mm, 80a–8, 80a–24, 80a–28, 80a–29, 80a–30, and 80a–37, and Pub. L. 112–106, sec. 201(a), sec. 401, 126 Stat. 313 (2012), unless otherwise noted.

* * * * *

■ 2. Amend § 230.146 by revising paragraphs (b)(1) and (b)(2) to read as follows:

§ 230.146 Rules under section 18 of the Act.

* * * * *

(b) * * *

(1) For purposes of Section 18(b) of the Act (15 U.S.C. 77r), the Commission finds that the following national securities exchanges, or segments or tiers thereof, have listing standards that are substantially similar to those of the New York Stock Exchange (''NYSE''), the NYSE American LLC (''NYSE American''), or the National Market System of the Nasdaq Stock Market (''Nasdaq/NGM''), and that securities listed, or authorized for listing, on such exchanges shall be deemed covered securities:

(i) Tier I of the NYSE Arca, Inc.;

(ii) Tier I of the NASDAQ PHLX LLC;

(iii) The Chicago Board Options Exchange, Incorporated;

(iv) Options listed on Nasdaq ISE, LLC;

(v) The Nasdaq Capital Market;

(vi) Tier I and Tier II of Bats BZX Exchange, Inc.; and

(vii) Investors Exchange LLC.

(2) The designation of securities in paragraphs (b)(1)(i) through (vii) of this section as covered securities is conditioned on such exchanges' listing standards (or segments or tiers thereof) continuing to be substantially similar to those of the NYSE, NYSE American, or Nasdaq/NGM.

By the Commission.

Dated: July 14, 2017.

Brent J. Fields,

Secretary.

[FR Doc. 2017–15216 Filed 7–20–17; 8:45 am]

BILLING CODE 8011–01–P

[96] 15 U.S.C. 77a *et seq.*

[97] 15 U.S.C. 77r(b)(1)(B) and 77s(a).

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R04–OAR–2016–0656; FRL–9965–13–Region 4]

Air Plan Approval; Florida: Unnecessary Rule Removal

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve a revision to the Florida State Implementation Plan submitted by the Florida Department of Environmental Protection on February 20, 2013. The revision removes unnecessary and superseded rules from the Florida State Implementation Plan. Specifically, this revision removes non-regulatory introductory language, as well as a regulation that has been superseded by more stringent federal regulations. This action is being taken pursuant to the Clean Air Act.

DATES: Written comments must be received on or before August 21, 2017.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R04–OAR–2016–0656 at *http://www.regulations.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. 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. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.* on the Web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on

making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Sean Lakeman, Air Regulatory Management Section, Air Planning and Implementation Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW., Atlanta, Georgia 30303–8960. Mr. Lakeman can be reached via telephone at (404) 562–9043 or via electronic mail at *lakeman.sean@epa.gov.*

SUPPLEMENTARY INFORMATION: In the Final Rules Section of this **Federal Register**, EPA is approving the State's implementation plan revision as a direct final rule without prior proposal because the Agency views this as a noncontroversial submittal and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no adverse comments are received in response to this rule, no further activity is contemplated. If EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period on this document. Any parties interested in commenting on this document should do so at this time.

Dated: July 7, 2017.

V. Anne Heard,

Acting Regional Administrator, Region 4.

[FR Doc. 2017–15267 Filed 7–20–17; 8:45 am]

BILLING CODE 6560–50–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

41 CFR Part 51–11

RIN 3037–AA04

Touhy Regulations

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Committee for Purchase From People Who Are Blind or Severely Disabled (Committee) is proposing procedures to use in responding to subpoenas or other official demands for information and testimony served upon itself or its employees.

DATES: Comments must be received by September 19, 2017.

ADDRESSES: You may submit comments, identified by docket number and/or Regulatory Information Number (RIN) and title, to the Federal Rulemaking Portal at: *http://www.regulations.gov.*

All submissions received must include the agency name and docket number or RIN for this document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: Timi Kenealy, (703) 603–2100, Email: *CMTEFedReg@AbilityOne.gov.*

SUPPLEMENTARY INFORMATION:

Background

The Committee, operating as the U.S. AbilityOne Commission, administers the AbilityOne Program pursuant to the authority of 41 U.S.C. 8501. Through this program, employment opportunities are provided to people who are blind or severely disabled through the provisions of products and services to the Federal Government.

Pursuant to 5 U.S.C. 301, the head of an Executive department or military department may prescribe regulations for the government of his department, the conduct of its employees, the distribution and performance of its business, and the custody, use, and preservation of its records, papers, and property. The part does not authorize withholding information from the public or limiting the availability of records to the public.

The United States Supreme Court held in *United States ex rel. Touhy* v. *Ragen,* 340 U.S. 462 (1951), that the head of a federal agency may make the determination on his/her sole authority to produce documents and authorize employee's testimony in response to a subpoena or other demand for information.

This proposed regulation will govern the Committee's procedures for authorizing or denying such demands. In addition to updating this section for the Touhy case, the Committee is taking this opportunity to make technical corrections to include changes to the mailing address and changing ''JWOD'' to ''AbilityOne'' the operating name of the agency since 2010. Changes to this section of the CFR were last made in 1994.

Regulatory Analysis

Executive Order 12866, Regulatory Planning and Review, and Executive Order 13563, Improving Regulation and Regulatory Review

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, distribute impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule benefits the public and the United States Government by providing clear procedures for members of the public and Government employees to follow when official testimony or official documents, records, files or information are sought from the Committee or from Committee personnel in connection with legal proceedings. This rule has not been designated a significant regulatory action.

Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1532) requires agencies to 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 rule will not mandate any requirements for State, local, or tribal governments, nor will it affect private sector costs.

Public Law 96–354, Regulatory Flexibility Act

The Committee certifies this proposed rule is not subject to the Regulatory Flexibility Act (5 U.S.C. Ch. 6) because it would not, if promulgated, have a significant economic impact on a substantial number of small entities. This rule will provide clarity to U.S. Government personnel and outside counsel on the proper rules and procedures to serve process on U.S. Government officials in their official capacity and to obtain official U.S. Government testimony or documents for use in legal proceedings. Therefore, the Regulatory Flexibility Act, as amended, does not require the Committee to prepare a regulatory flexibility analysis.

Executive Order 13132, Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. This rule will not have a substantial effect 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.

Public Law 96–511, Paperwork Reduction Act

It has been determined that this rule does not impose reporting or record keeping requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35).

List of Subjects in 41 CFR Part 51–11

Administrative practices and procedures, Courts, Disclosure, Exemptions, Government employees, Subpoenas, Records, Testimony.

■ For the reasons set forth above, the Committee proposes to amend chapter 51 of title 41 by adding part 51–11 to read as follows:

PART 51–11—PRODUCTION OR DISCLOSURE IN FEDERAL AND STATE PROCEEDINGS

Sec.
51–11.1 Scope and purpose.
51–11.2 Applicability.
51–11.3 Definitions.
51–11.4 General prohibition.
51–11.5 Service of demand.
51–11.6 Filing requirements for demand for documents or testimony.
51–11.7 Factors the Committee will consider.
51–11.8 Processing demands.
51–11.9 Final determination.
51–11.10 Restrictions that apply to testimony.
51–11.11 Restrictions that apply to released records.
51–11.12 Procedure when a decision is not made prior to the time a response is required.
51–11.13 Procedure in the event of an adverse ruling.
51–11.14 Fees.
51–11.15 Penalties.

Authority: 41 U.S.C. 85039d.

PART 51–11—PRODUCTION OR DISCLOSURE IN FEDERAL AND STATE PROCEEDINGS

§ 51–11.1 Scope and purpose.

(a) This part sets forth policies and procedures of the Committee for Purchase From People Who Are Blind or Severely Disabled (Committee) regarding the testimony of current and former employees as witnesses and the production or disclosure of Committee documents or information:

(1) In all federal and state proceedings in which the United States is a party; and

(2) In all federal and state proceedings in which the United States is not a party, when a demand pursuant to a subpoena, order or request (collectively referred to in this part as a ''demand'') of a court or other authority is issued for such material, testimony, or information.

(b) The Committee intends these provisions to:

(1) Promote economy and efficiency in its programs and operations;

(2) Minimize the possibility of involving the Committee in controversial issues not related to its functions;

(3) Prevent the misuse of the Committee's employees as involuntary expert witnesses for private interests or as inappropriate expert witnesses as to the state of the law;

(4) Maintain the Committee's impartiality among private litigants where neither the Committee nor any other Federal entity is a named party; and

(5) Protect sensitive, confidential information and the deliberative processes of the Committee.

(c) In providing for these requirements, the Committee does not waive the sovereign immunity of the United States.

(d) This part provides guidance for the internal operations of the Committee. The procedures specified in this part, or the failure of any Committee employee to follow the procedures specified in this part, are not intended to, do not, and may not be relied upon to create a right or benefit, substantive or procedural, enforceable at law by a party against the United States.

§ 51–11.2 Applicability.

This part applies to demands and requests to employees of the Committee in legal proceedings, for factual or expert testimony relating to official information or for production of official records or information. However, it does not apply to:

(a) Demands for a current Committee employee to testify as to facts or events that are unrelated to his or her official duties or that are unrelated to the functions of the Committee;

(b) Demands for a former Committee employee to testify as to matters in which the former employee was not directly or materially involved while at the Committee;

(c) Requests for the release of non-exempt records under the Freedom of Information Act, 5 U.S.C. 552 (41 CFR part 51–8), or the Privacy Act, 5 U.S.C. 552(a) (41 CFR part 51–9); and

(d) Congressional or Government Accountability Office (GAO) demands and requests for testimony or records.

§ 51–11.3 Definitions.

As used in this part:

Committee means the Committee for Purchase From People Who Are Blind or Severely Disabled.

Committee employee or *employee* means:

(1) Any current or former officer or employee of the Committee;

(2) Any other individual hired through contractual agreement by or on behalf of the Committee or who has performed or is performing services under such an agreement for the Committee; and

(3) Any individual who served or is serving in any consulting or advisory capacity to the Committee, whether formal or informal.

(4) Provided, that this definition does not include persons who are no longer employed by the Committee and who are retained or hired as expert witnesses or who agree to testify about general matters available to the public, or matters with which they had no specific involvement or responsibility during their employment with the Committee.

Demand means a subpoena, request, or an order or other command of a court or other competent authority, for the production, disclosure, or release of records or information related to, for the appearance and testimony of a Committee employee that is issued in a legal proceeding.

General Counsel means Committee General Counsel or Committee employee to whom the General Counsel has delegated authority to act under this part.

Legal proceeding means any matter before a court of law, administrative board or tribunal, commission, administrative law judge, hearing officer, or other body that conducts a legal or administrative proceeding. Legal proceeding includes all phases of discovery, litigation and informal requests by attorneys or others involved in legal proceedings seeking interviews or the like.

Records or *official records and information* mean all documents and materials, however stored, that is in the custody and control of the Committee, relating to information in the custody and control of the Committee, or acquired by a Committee employee in the performance of his or her official

duties or because of his or her official status, while such individual was employed.

Request means any informal request, by whatever method, for the production of records and information or for testimony which has not been ordered by a court or other competent authority.

Testimony means any written or oral statements, including depositions, answers to interrogatories, affidavits, declarations, recorded interviews, and statements made by an individual in connection with a legal proceeding.

§ 51–11.4 General prohibition.

(a) In any federal or state case or matter in which the United States is not a party, no employee or former employee of the Committee shall, in response to a demand, produce any record contained in the files of the Committee, or disclose any information relating to or based upon record contained in the files of the Department, or disclose any information or produce any record acquired as part of the performance of that person's official duties or because of that person's official status without prior written approval of the General Counsel in accordance with § 51–11.9.

(1) Whenever a demand is made upon an employee or former employee as described in paragraph (a) of this section, the employee shall immediately notify the General Counsel. The General Counsel shall follow procedures set forth in § 51–11.8.

(2) If oral testimony is sought by a demand in any case or matter in which the United States is not a party, an affidavit, or, if that is not feasible, a statement by the party seeking the testimony or by his attorney, setting forth a summary of the testimony sought and its relevance to the proceeding, must be furnished to the General Counsel. Any authorization for testimony by a present or former employee of the Committee shall be limited to the scope of the demand as summarized in such statement.

(3) When information other than oral testimony is sought by a demand, the General Counsel shall request a summary of the information sought and its relevance to the proceeding.

(b) In any federal or state case or matter in which the United States is a party, the General Counsel is authorized to reveal and furnish to any person, including an actual or prospective witness, a grand jury, counsel, or a court, either during or preparatory to a proceeding, such testimony, and relevant unclassified material, documents, or information secured by the employee or former employee of the Committee, as the General Counsel shall deem necessary or desirable to the discharge of the attorney's official duties: *Provided,* Such an attorney shall consider, with respect to any disclosure, the factors set forth in § 51–11.7.

(1) If oral testimony is sought by a demand in a case or matter in which the United States is a party, an affidavit, or, if that is not feasible, a statement by the party seeking the testimony or by the party's attorney setting forth a summary of the testimony sought must be furnished to the agency attorney handling the case or matter.

(2) [Reserved]

(c) In appropriate cases, the General Counsel shall notify the United States Department of Justice (DOJ) of the demand and coordinate with the DOJ to file any appropriate motions or other pleadings.

§ 51–11.5 Service of demand.

(a) Written demands directed to the Committee or requests for official records, information or testimony shall be served in accordance with the requirements of the Federal Rules of Civil or Criminal Procedure, or applicable State procedures, as appropriate. If the demand is served by U.S. mail, it should be addressed to the General Counsel, Committee for Purchase From People Who Are Blind or Severely Disabled, 1401 S. Clark Street, Suite 715, Arlington, VA 22202. The Committee's acceptance of service of a demand shall not constitute an admission or waiver of any objection with respect to the propriety of jurisdiction, service of process, venue or any other defense in law or equity available under applicable law.

(b) If any doubt exists, whether a demand relates to purely personal matters or arises out of the performance of official duties, copies of the demand may be delivered to the General Counsel for such determination.

§ 51–11.6 Filing requirements for demands for documents or testimony.

Compliance with the following requirements is required when issuing demands or requests for official records, information or testimony.

(a) Requests must be in writing and must be submitted to the General Counsel. If a subpoena is served on the Committee or a Committee employee before submitting a written request and receiving a final determination, the Committee will object to the subpoena on grounds that it was not submitted in accordance with this part.

(b) Written requests must contain the following information:

(1) The caption of the legal proceeding, docket number, and name and address of the court or other authority involved;

(2) A copy of the complaint or equivalent document setting forth the assertions in the case and any other pleading or document necessary to show the relevance of the information sought;

(3) A detailed description of how the information sought is relevant to the issues in the legal proceeding, and a specific description of the substance of the testimony or records sought;

(4) A statement as to how the need for the information outweighs the need to maintain any confidentiality of the information and outweighs the burden on the Committee to produce the records or provide testimony;

(5) A statement indicating that the information sought is not available from another source, from other persons or entities, or from the testimony of someone other than a Committee employee, such as a retained expert;

(6) If testimony is requested, the intended use of the testimony, a general summary of the desired testimony, and a showing that no document could be provided and used in lieu of testimony;

(7) A description of all prior decisions, orders, or pending motions in the case that bear upon the relevance of the requested records or testimony;

(8) The name, address, and telephone number of counsel to each party in the case; and

(9) An estimate of the amount of time that the requester and other parties will require with each Committee employee for time spent by the employee to prepare for testimony, in travel, and for attendance at the legal proceeding.

(c) The Committee reserves the right to require additional information to complete any request where appropriate.

(d) Requests should be submitted at least 45 calendar days before the date that records or testimony is required. Requests submitted in less than 45 calendar days before records or testimony is required must be accompanied by a written explanation stating the reasons for the late request and the reasons for expedited processing.

(e) Failure to cooperate in good faith to enable the General Counsel to make an informed decision may serve as the basis for a determination not to comply with the request.

§ 51–11.7 Factors the Committee will consider.

The General Counsel in his or her sole discretion, may grant an employee permission to testify on matters relating to official information, or produce

official records and information, in response to an appropriate demand or request. Among the relevant factors that the General Counsel may consider in making this decision are whether:

(a) The purposes of this part are met;

(b) Allowing such testimony or production of records would be necessary to prevent a miscarriage of justice;

(c) The Committee has an interest in the decision that may be rendered in the legal proceeding;

(d) Allowing such testimony or production of records would assist or hinder the Committee in performing its statutory duties or use the Committee resources in a way that will interfere with the ability of the Committee employees to do their regular work;

(e) Allowing such testimony or production of records would be in the best interest of the Committee or the United States;

(f) The records or testimony can be obtained from other sources;

(g) The demand or request is unduly burdensome or otherwise inappropriate under the applicable rules of discovery or the rules of procedure governing the case or matter in which the demand or request arose;

(h) Disclosure would violate a statute, Executive order or regulation;

(i) Disclosure would reveal confidential, sensitive, or privileged information, trade secrets or similar, confidential commercial or financial information, otherwise protected information, or would otherwise be inappropriate for release;

(j) Disclosure would impede or interfere with an ongoing law enforcement investigation or proceedings, or compromise constitutional rights;

(k) Disclosure would result in the Committee appearing to favor one private litigant over another private litigant;

(l) Disclosure relates to documents that originate from another agency;

(m) A substantial Government interest is implicated;

(n) The demand or request is within the authority of the party making it;

(o) The demand improperly seeks to compel a Committee employee to serve as an expert witness for a private interest;

(p) The demand improperly seeks to compel a Committee employee to testify as to a matter of law; and/or

(q) The demand or request is sufficiently specific to be answered.

§ 51–11.8 Processing demands or requests.

(a) After service of a demand or request, the General Counsel will review the demand or request and, in accordance with the provisions of this part, determine whether, or under what conditions, to authorize an employee to testify on matters relating to Committee records and/or produce records.

(b) The Committee will process requests in the order in which they are received. Absent exigent or unusual circumstances, the Committee will respond within 45 calendar days from the date of receipt. The time for response will depend upon the scope of the request.

(c) The General Counsel may grant a waiver of any procedure described by this part where a waiver is considered necessary to promote a significant interest of the Committee or the United States or for other good cause.

§ 51–11.9 Final determination.

The General Counsel makes the final determination on demands and requests for production of official records and information or testimony. All final determinations are within the sole discretion of the General Counsel. The General Counsel will notify the requester and the court or other authority of the final determination, the reasons for the grant or denial of the demand or request, and any conditions that the General Counsel may impose on the release of records or information, or on the testimony of a Committee employee.

§ 51–11.10 Restrictions that apply to testimony.

(a) Conditions or restrictions may be imposed on the testimony of the Committee employees including, for example, limiting the areas of testimony or requiring the requester and other parties to the legal proceeding to agree that they will seek to file the transcript of the testimony under seal and that it will be used or made available only in the particular legal proceeding for which testimony was requested. The General Counsel may also require a copy of the transcript or testimony be provided to the Committee at the requester's expense.

(b) The Committee may offer the employee's written declaration in lieu of testimony.

(c) If authorized to testify pursuant to this part, an employee may testify as to facts within his or her personal knowledge, but, unless specifically authorized to do so by the General Counsel, the employee shall not:

(1) Disclose confidential or privileged information;

(2) Testify as to any information outside the scope of the General Counsel's authorization (*see* § 51–11.7); or

(3) For a current Committee employee, testify as an expert or opinion witness with regard to any matter arising out of the employee's official duties or the functions of the Committee unless testimony is being given on behalf of the United States whether or not the United States is a party.

§ 51–11.11 Restrictions that apply to released records.

(a) The General Counsel may impose conditions or restrictions on the release of official records and information, including the requirement that parties to the proceeding obtain a protective order or execute a confidentiality agreement to limit access and any further disclosure. The terms of the protective order or of a confidentiality agreement must be acceptable to the General Counsel. In cases where protective orders or confidentiality agreements have already been executed, the Committee may condition the release of official records and information on an amendment to the existing protective order or confidentiality agreement.

(b) If the General Counsel so determines, original Committee records may be presented for examination in response to a demand or request, but they are not to be presented as evidence or otherwise used in a manner by which they could lose their identity as official Committee records, and they are not to be marked or altered. In lieu of the original records, certified copies will be presented for evidentiary purposes.

§ 51–11.12 Procedure when a decision is not made prior to the time a response is required.

If a response to a demand or request is required before the General Counsel can make the determination previously referred to, the General Counsel when necessary, will provide the court or other competent authority with a copy of this part, inform the court or other competent authority that the demand or request is being reviewed, and seek a stay of the demand or request pending a final determination.

§ 51–11.13 Procedure in the event of an adverse ruling.

If the court or other competent authority fails to stay the demand, the employee upon whom the demand or request is made, unless otherwise advised by the General Counsel, will appear at the stated time and place, produce a copy of this part, state that the employee has not been authorized to provide the requested testimony or produce documents, and respectfully

decline to comply with the demand, citing *United States ex rel. Touhy* v. *Ragen,* 340 U.S. 462 (1951). A written response may be offered to a request, or to a demand, if permitted by the court or other competent authority.

§ 51–11.14 Fees.

(a) *Generally.* The General Counsel may condition the production of records or appearance for testimony upon advance payment of a reasonable estimate of the costs to the Committee.

(b) *Fees for records.* Fees for producing records will include fees for searching, reviewing, and duplicating records, costs of attorney time spent in reviewing the demand or request, and expenses generated by materials and equipment used to search for, produce, and copy the responsive information. Costs for employee time will be calculated on the basis of the hourly pay of the employee (including all pay, allowance, and benefits). Fees for duplication will be the same as those charged by the Committee in its Freedom of Information Act regulations at 41 CFR part 51–8.

(c) *Witness fees.* Fees for attendance by a witness will include fees, expenses, and allowances prescribed by the court's rules. If no such fees are prescribed, witness fees will be determined based upon the rule of the Federal district court closest to the location where the witness will appear. Such fees will include cost of time spent by the witness to prepare for testimony, travel time and expenses, and for attendance in the legal proceeding.

(d) *Payment of fees.* Witness fees for current Committee employees and any records certification fees shall be paid by check or money order presented to the Committee made payable to the United States Department of Treasury. Applicable fees for former Committee employees' testimony must be paid directly to the former employee in accordance with 28 U.S.C. 1821 or other applicable statutes.

(e) *Certification (authentication) of copies of records.* The Committee Records Manager may certify that records are true copies in order to facilitate their use as evidence. Certification requests require 45 calendar days for processing and a fee of $15.00 for each document certified.

(f) *Waiver or reduction of fees.* The General Counsel, in his or her sole discretion, may, upon a showing of reasonable cause, waive or reduce any fees in connection with the testimony, production, or certification of records.

(g) *De minimis fees.* Fees will not be assessed if the total charge would be $10.00 or less.

§ 51–11.15 Penalties.

(a) An employee who discloses official records or information or gives testimony relating to official information, except as expressly authorized by the Committee, or as ordered by a Federal court after the Committee has had the opportunity to be heard, may face the penalties provided in 18 U.S.C. 641 and other applicable laws. Additionally, former Committee employees are subject to the restrictions and penalties of 18 U.S.C. 207 and 216.

(b) A current Committee employee who testifies or produces official records and information in violation of this part may be subject to disciplinary action.

Patricia Briscoe,

Deputy Director, Business Operations Pricing and Information Management.

[FR Doc. 2017–15357 Filed 7–20–17; 8:45 am]

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FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 64

[CG Docket Nos. 10–51 and 03–123; DA 17–656]

Petition for Partial Reconsideration, or in the Alternative, Suspension of Action in Rulemaking Proceeding

AGENCY: Federal Communications Commission.

ACTION: Petition for partial reconsideration or suspension.

SUMMARY: A Petition for Partial Reconsideration, or in the Alternative Suspension of Compliance Deadline (Petition), has been filed in the Commission's rulemaking proceeding by Sorenson Communications, LLC.

DATES: Comments to the Petition must be filed on or before August 7, 2017. Reply Comments must be filed on or before July 31, 2017.

ADDRESSES: Federal Communications Commission, 445 12th Street SW., Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Eliot Greenwald, Consumer and Governmental Affairs Bureau, email: *Eliot.Greenwald@fcc.gov;* phone: (202) 418–2235.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's document DA 17–656, released July 7, 2017. The full text of the Petition is available for viewing and copying at the FCC Reference Information Center, 445 12th Street SW., Room CY–A257, Washington, DC 20554 or may be accessed online via the Commission's Electronic Comment Filing System at: *https://ecfsapi.fcc.gov/file/10530218217172/2017-05-30%20Sorenson%20Petition%20for%20Reconsideration%20re%20RUE%20Profile.pdf.* The Commission will not send a Congressional Review Act (CRA) submission to Congress or the Government Accountability Office Pursuant to the CRA, 5 U.S.C. because no rules are being adopted by the Commission.

Subject: Structure and Practices of the Video Relay Service Program; Telecommunications Relay Services and Speech-to-Speech Services for Individuals with Hearing and Speech Disabilities, Report and Order, DA 17–76, published at 82 FR 19322, April 27, 2017, in CG Docket Nos. 10–51 and 03–123. This document is being published pursuant to 47 CFR 1.429(e). *See also* 47 CFR 1.4(b)(1) and 1.429(f), (g).

Number of Petitions Filed: 1.

Federal Communications Commission.

Karen Peltz Strauss,

Deputy Chief, Consumer and Governmental Affairs Bureau.

[FR Doc. 2017–15302 Filed 7–20–17; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 64

[CC Docket No. 91–281; FCC 17–76]

Calling Number Identification Service—Caller ID

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: In this document, the Commission proposes to amend its Caller ID rules to allow carriers to disclose blocked Caller ID information in the limited case of threatening calls as an aid to law enforcement investigations. Media and law enforcement reports indicate that the number of threatening calls targeting schools, religious organizations, and other entities appears to be increasing dramatically. In many cases, the perpetrators block the Caller ID information, making it difficult to trace the threatening calls. The Commission's current rules require that carriers not reveal blocked Caller ID information or use that information to allow the called party to contact the caller. Recognizing that threatening callers do not have a legitimate privacy interest in having

blocked Caller ID protected from disclosure, the Commission seeks to amend its Caller ID rules to permit carriers to disclose blocked Caller ID information in the limited case of threatening calls as an aid to law enforcement investigations.

DATES: Comments are due on or before August 21, 2017, and reply comments are due on or before September 19, 2017.

ADDRESSES: You may submit comments identified by CC Docket No. 91–281 and/or FCC Number 17–76, by any of the following methods:

• *Electronic Filers:* Comments may be filed electronically using the Internet by accessing the Commission's Electronic Comment Filing System (ECFS), through the Commission's Web site: *http://apps.fcc.gov/ecfs/*. Filers should follow the instructions provided on the Web site for submitting comments. For ECFS filers, in completing the transmittal screen, filers should include their full name, U.S. Postal service mailing address, and CC Docket No. 91–281.

• *Mail:* Parties who choose to file by paper must file an original and one copy of each filing. Filings can be sent by hand or messenger delivery, by commercial overnight courier, or by first-class or overnight U.S. Postal Service mail (although the Commission continues to experience delays in receiving U.S. Postal Service mail). All filings must be addressed to the Commission's Secretary, Office of the Secretary, Federal Communications Commission.

For detailed instructions for submitting comments and additional information on the rulemaking process, see the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Nellie Foosaner, Consumer Policy Division, Consumer and Governmental Affairs Bureau (CGB), at: (202) 418–2925, email: *Nellie.Foosaner@fcc.gov.*

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Notice of Proposed Rulemaking, document FCC 17–76, adopted on June 22, 2017, and released on June 22, 2017. The full text of document FCC 17–76 will be available for public inspection and copying via ECFS, and during regular business hours at the FCC Reference Information Center, Portals II, 445 12th Street SW., Room CY–A257, Washington, DC 20554. A copy of document FCC 17–76 and any subsequently filed documents in this matter may also be found by searching ECFS at: *http://apps.fcc.gov/ecfs/* (insert CC Docket No. 91–281 into the Proceeding block).

Pursuant to 47 CFR 1.415, 1.419, interested parties may file comments and reply comments on or before the dates indicated on the first page of this document. Comments may be filed using ECFS. *See Electronic Filing of Documents in Rulemaking Proceedings,* 63 FR 24121 (1998).

• All hand-delivered or messenger-delivered paper filings for the Commission's Secretary must be delivered to FCC Headquarters at 445 12th Street SW., Room TW–A325, Washington, DC 20554. All hand deliveries must be held together with rubber bands or fasteners. Any envelopes must be disposed of before entering the building.

• Commercial Mail sent by overnight mail (other than U.S. Postal Service Express Mail and Priority Mail) must be sent to 9300 East Hampton Drive, Capitol Heights, MD 20743.

• U.S. Postal Service first-class, Express, and Priority mail should be addressed to 445 12th Street SW., Washington, DC 20554.

Pursuant to § 1.1200 of the Commission's rules, 47 CFR 1.1200, this matter shall be treated as a ''permit-but-disclose'' proceeding in accordance with the Commission's *ex parte* rules. Persons making oral *ex parte* presentations are reminded that memoranda summarizing the presentations must contain summaries of the substances of the presentations and not merely a listing of the subjects discussed. More than a one or two sentence description of the views and arguments presented is generally required. *See* 47 CFR 1.1206(b). Other rules pertaining to oral and written *ex parte* presentations in permit-but-disclose proceedings are set forth in § 1.1206(b) of the Commission's rules, 47 CFR 1.1206(b).

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 CGB at: (202) 418–0530 (voice), or (202) 418–0432 (TTY). Document FCC 17–76 can also be downloaded in Word or Portable Document Format (PDF) at: *https://www.fcc.gov/document/fcc-proposes-rules-aid-investigation-threatening-calls.*

Initial Paperwork Reduction Act of 1995 Analysis

Document FCC 17–76 seeks comment on proposed rule amendments that may result in modified information collection requirements. If the Commission adopts any modified information collection requirements, the Commission will publish another notice in the **Federal Register** inviting the public to comment on the requirements, as required by the Paperwork Reduction Act. Public Law 104–13; 44 U.S.C. 3501–3520. In addition, pursuant to the Small Business Paperwork Relief Act of 2002, the Commission seeks comment on how it might further reduce the information collection burden for small business concerns with fewer than 25 employees. Public Law 107–198, 116 Stat. 729; 44 U.S.C. 3506(c)(4).

SYNOPSIS

1. In the document FCC 17–76, the Commission proposes to amend its Caller ID rules to enable called parties and/or law enforcement to obtain blocked Caller ID information in connection with threatening calls. For purposes of document FCC 17–76, the Commission defines a ''threatening call'' as any call that includes a threat of serious and imminent unlawful action posing a substantial risk to property, life, safety, or health.

2. Based on reports of widespread and increasing numbers of threatening calls that have targeted schools, religious organizations and other entities, the Commission proposes amending § 64.1601 of its rules, which provides that ''[n]o common carrier subscribing to or offering any service that delivers [the Calling Party Number (CPN)] may override the privacy indicator associate with an interstate call,'' to ensure that all parties who receive threatening calls are not hindered by the Commission's rules in gaining timely access to CPN information that may allow them to identify threatening callers. Amending the Commission's Caller ID rules to permit threatened parties, law enforcement and security personnel of threatened entities to gain access to the CPN of threatening callers could promote public safety and provide administrative efficiencies over the current process, which necessitates addressing individual waiver requests on a case-by-case basis. Even when threatening calls prove to be a hoax, they can often result in substantial disruption and expenditure of public resources by law enforcement. The Commission therefore proposes to amend its rules to recognize an exemption from the privacy protections contained in § 64.1601(b) of its rules in the limited case of threatening calls. The Commission seeks additional comment on ways to facilitate the ability of law enforcement and security personnel to investigate and identify threatening callers while protecting the legitimate privacy interests of non-threatening callers. In that regard, the Commission seeks comment on how to define the term ''security personnel'' to ensure that

only the appropriate personnel responsible for the safety of any threatened entity has access to the information they require to perform their duties.

3. Section 64.1601(b) of the Commission's rules requires that carriers must act in accordance with the customer's privacy request that CPN not be passed on interstate calls. The Commission has recognized, however, certain exemptions to this requirement. The Commission has concluded, for example, that to the extent CPN-based services are used to deliver emergency services, privacy requirements should not apply to delivery of CPN to a public agency's emergency lines, a poison control line, or in conjunction with 911 emergency services. In these instances, the Commission concluded that Caller ID blocking mechanisms could jeopardize emergency services and therefore pose a serious threat to the safety of life and property. The Commission believes that threatening calls present equally compelling circumstances in which the need to ensure public safety, in accordance with the Commission's fundamental statutory mission, outweighs the threatening caller's interest in maintaining the privacy of his or her CPN.

4. Specifically, the Commission proposes amending § 64.1601 of its rules to recognize an exemption to § 64.1601(b)'s of its rules prohibition on overriding a privacy indicator associated with an interstate call when such call contains a threat of a serious nature. For purposes of this context, the Commission proposes defining a ''threatening call'' as any call that includes a threat of serious and imminent unlawful action posing a substantial risk to property, life, safety, or health. The Commission seeks comment on this definition and on any alternatives. Accordingly, the Commission proposes adding an exemption in § 64.1601(d) of its rules to exclude threatening calls from the privacy protections afforded by § 64.1601(b) of its rules.

5. In this context, the Commission seeks comment on how evaluations should be made to determine whether a threat meets the proposed definition of a threatening call, including who should make that evaluation. Should the Commission require, for example, that otherwise restricted CPN be made available only after a law enforcement agency confirms that it constitutes a threat of a serious and imminent unlawful action posing a substantial risk to property, life, safety, or health? Would this approach provide sufficient privacy safeguards to ensure that blocked CPN is released only in those limited situations? Conversely, to what extent would involving law enforcement in this process hinder the ability of threatened parties to gain timely access to the CPN of threatening callers?

6. The Commission seeks comment on this proposal and any additional options that might aid law enforcement and threatened parties in obtaining the information they need to identify threatening callers. In addition, the Commission seeks comment on how to facilitate the provision of CPN to threatened entities in a manner that minimizes administrative burdens on carriers while ensuring that such information is provided to the threatened party and law enforcement in a timely manner. How are carriers burdened today when law enforcement uses lawful processes to compel disclosure of call details? In particular, the Commission seeks comment on the potential burdens on small providers that may be asked to disclose information upon a report of a threatening call, including measures that could mitigate those burdens. The Commission recognizes that telecommunications systems utilized by threatened entities and relationships with their carriers may vary widely. The Commission therefore seeks the input of carriers on how best to facilitate the process of providing CPN information in a timely manner to parties that report a threatening call. Given the existing exemption for public agencies that deliver emergency services as noted above, the Commission also seeks comment on whether it should extend that exemption to non-public entities that provide emergency services such as private ambulance companies.

7. *Privacy.* In proposing this amendment to the Caller ID rules, the Commission endeavors to ensure that this exemption is not abused and that the legitimate privacy interests of non-threatening callers are not infringed, particularly when the calling party has a higher need for CPN blocking protections to mitigate the risk of personal injury, such as in the case of calls made from domestic violence agencies. When the Commission adopted the rule in 1994, it concluded based on an extensive record that ''the calling public has an interest in exercising a measure of control over the dissemination of telephone numbers that must be reflected in federal policies governing caller ID services.'' As a result, the Commission adopted a rule requiring carriers to offer per-call blocking of Caller ID and allowed carriers to continue offering per-line blocking as long as they also provided per-call unblocking. Because of this recognized privacy interest, the Commission seeks comment on whether it should require anyone reporting a threatening call for purposes of obtaining otherwise restricted CPN to do so in conjunction with a law enforcement agency, so as to provide some assurance that the called party is not attempting to circumvent the privacy obligations of the rule by reporting a false threat. Should access to restricted CPN be limited only to law enforcement authorities? Would the risk of abuse be further reduced by limiting application of this exemption only to non-residential entities such as schools, religious organizations, and other public and private business and governmental entities? Would excluding private individuals who are not typically the target of mass phone threats limit the potential for abuse of this exemption? The Commission notes, for example, that petitions seeking waivers on the basis of a pattern of threatening calls, including most press reports, relate to threatening calls that target entities such as these rather than private individuals. Finally, how would a carrier's obligations under section 222 of the Communications Act of 1934 (the Act) be affected? Is CPN that a caller intends to block protected by section 222 of the Act, and would a rule that requires or allows carriers to divulge blocked CPN conflict with section 222 of the Act?

8. Are there other means to ensure that legitimate privacy protections are not infringed should the Commissions exempt threatening calls from the privacy requirements of § 64.1601(b) of its rules? The Commission notes, for example, that CGB, in granting waivers of the Commission's rule, has imposed certain conditions and obligations on entities granted waivers of § 64.1601(b) of its rules in the past to ensure that restricted CPN information is disclosed only to authorized personnel for purposes of investigating threatening calls, and hence, any legitimate expectation of privacy by non-threatening callers is adequately protected. These conditions typically include: (1) The CPN on incoming restricted calls not be passed on to the line called; (2) any system used to record CPN be operated in a secure way, limiting access to designated telecommunications and security personnel; (3) telecommunications and security personnel may access restricted CPN data only when investigating phone calls of a threatening and serious nature, and shall document that access as part of the investigative report; (4) transmission of restricted CPN

information to law enforcement agencies must occur only through secure communications; (5) CPN information must be destroyed in a secure manner after a reasonable retention period; and (6) any violation of these conditions must be reported promptly to the Commission. The Commission seeks comment on whether similar conditions should be imposed on any party that obtains restricted CPN pursuant to the proposed exemption. The Commission seeks comment on these and any other proposals to achieve the Commission's objective in assisting threatened parties and law enforcement officials in identifying threatening callers in a timely manner.

9. The Commission seeks comment on whether circumstances have changed since the Commission originally adopted § 64.1601 of its rules. At the time, the Commission rejected arguments that parts of the rule would infringe on callers' expectations of privacy and anonymity. This was in part because the rule would allow callers to choose to block passage of CPN by choosing either per-call or per-line blocking. Would this logic hold true if the Commission were to allow call recipients to demand that CPN be revealed by asserting that the call contained a threat? In concluding that compelling the transmission of CPN would not violate any privacy rights under the Fourth Amendment, the Commission reasoned that callers have no reasonable expectation of privacy in their phone numbers because those numbers are voluntarily exposed to the telephone company's equipment. Does this hold true today, and would it be true if callers intending to block CPN delivery could have it unblocked by a called party's assertion that a call contained a threat?

The JCC Temporary Waiver

10. Based on the large numbers of recent threats phoned in to the JCCs and the record compiled in this matter, the Commission confirms that good cause continues to exist to maintain the temporary waiver of § 64.1601(b) of its rules granted to JCCs and the carriers who serve them for disclosure of CPN associated with threatening calls to JCCs.

11. In the event the Commission amends its rules to recognize an exemption for threatening calls as proposed herein, this waiver, along with other similar prior waivers, will be encompassed within the protections afforded by that exemption. In the meantime, this temporary waiver ensures that JCCs are afforded certainty that they will continue to have the necessary protections from threatening calls.

Initial Regulatory Flexibility Act Analysis

12. As required by the Regulatory Flexibility Act (RFA), the Commission has prepared an Initial Regulatory Flexibility Analysis (IRFA) of the possible significant economic impact on small entities by the policies and rules proposed in document FCC 17–76. Written public comments are requested on the IRFA. Comments must be identified as responses to the IRFA and must be filed by the deadlines for comments specified in the **DATES** section. The Commission will send a copy of document FCC 17–76, including the IRFA to the Chief Counsel for Advocacy of the Small Business Administration (SBA).

Need for, and Objectives of, the Proposed Rules

13. In recent years, media and law enforcement reports indicate that the number of threatening calls appears be increasing dramatically. In the past the Commission has addressed such situations on a case-by-case basis via a waiver process at the request of individual entities that report receiving threatening calls. In document FCC 17–76, the Commission takes steps to amend the Caller ID rules to ensure that law enforcement and threatened parties are not hindered in their ability to investigate and respond to threatening phone calls. The Commission recognizes the privacy interests of non-threatening callers that may have valid reasons to block their telephone numbers by limiting the proposal strictly to those situations that involve threatening calls of a serious and imminent nature while further limiting access to such restricted CPN information in the case of threatening calls only to those parties responsible for safety and security of the threatened party. The Commission proposes to amend the current process that necessitates addressing individual waiver requests on a case-by-case basis. The Commission proposes and seeks additional comment on ways to facilitate the ability of law enforcement and security personnel to investigate and identify callers while protecting the legitimate privacy interests of non-threatening callers.

14. Specifically, the Commission proposes to amend § 64.1601(d)(4)'s of its rules current list of exemptions by adding a new section (iv) to read: (4) CPN delivery—''(iv) Is made in connection with a threatening call. Upon report of such a threatening call, the carrier will provide any CPN of the calling party to the called party and/or law enforcement for the purpose of identifying the responsible party.'' The Commission proposes defining a ''threatening call'' as any called that includes a threat of serious and imminent unlawful action posing a substantial risk to property, life, safety, or health. In addition, the Commission seeks comment on how to facilitate the provision of CPN to threatened entities in a manner that minimizes administrative burdens on carriers while ensuring that such information is provided to the threatened party and law enforcement in a timely manner.

15. For privacy purposes, the Commission seeks comment on whether it should require anyone reporting a threatening call for purpose of obtaining otherwise restricted CPN to do so in conjunction with a law enforcement agency to provide some assurance that the called party is not attempting to circumvent the privacy obligations of the rule by reporting a false threat. The Commission also inquiries into the possibility of excluding private individuals, who are not typically the target of mass phone threats, from this exemption in order to limit the potential for abuse. The Commission notes, for example, that CGB has imposed certain conditions and obligations on entities granted waivers of § 64.1601(b) of its rules in the past to ensure that restricted CPN information is disclosed only to authorized personnel for purposes of investigating threatening calls, and hence, any legitimate expectation of privacy by non-threatening callers is adequately protected. The Commission seeks comment on whether similar conditions should be imposed on any party that obtains restricted CPN pursuant to the proposed exemption.

Legal Basis

16. The proposed and anticipated rules are authorized under sections 1–4 and 201 of the Act, as amended, 47 U.S.C. 151–154, and 201.

Description and Estimate of the Number of Small Entities To Which the Proposed Rules Will Apply

17. The RFA directs agencies to provide a description of, and where feasible, an estimate of the number of small entities that will be affected by the proposed rules, if adopted. The RFA generally defines the term ''small entity'' as having the same meaning as the terms ''small business,'' ''small organization,'' and ''small governmental jurisdiction.'' In addition, the term ''small business'' has the same meaning as the term ''small business concern''

under the Small Business Act. Under the Small Business Act, a ''small business concern'' is one that: (1) Is independently owned and operated; (2) is not dominant in its field of operation; and (3) meets any additional criteria established by the SBA. Nationwide, there are a total of approximately 28.8 million small businesses, according to the SBA.

Wireline Carriers

18. *Wired Telecommunications Carriers.* The U.S. Census Bureau defines this industry as ''establishments primarily engaged in operating and/or providing access to transmission facilities and infrastructure that they own and/or lease for the transmission of voice, data, text, sound, and video using wired communications networks. Transmission facilities may be based on a single technology or a combination of technologies. Establishments in this industry use the wired telecommunications network facilities that they operate to provide a variety of services, such as wired telephony services, including voice over Internet protocol (VoIP) services, wired (cable) audio and video programming distribution, and wired broadband internet services. By exception, establishments providing satellite television distribution services using facilities and infrastructure that they operate are included in this industry.'' The SBA has developed a small business size standard for Wired Telecommunications Carriers, which consists of all such companies having 1,500 or fewer employees. Census data for 2012 shows that there were 3,117 firms that operated that year. Of this total, 3,083 operated with fewer than 1,000 employees. Thus, under this size standard, the majority of firms in this industry can be considered small.

19. *Local Exchange Carriers (LECs).* Neither the Commission nor the SBA has developed a small business size standard specifically for local exchange services. The closest applicable size standard under SBA rules is for the category Wired Telecommunications Carriers. The U.S. Census Bureau defines this industry as ''establishments primarily engaged in operating and/or providing access to transmission facilities and infrastructure that they own and/or lease for the transmission of voice, data, text, sound, and video using wired communications networks. Transmission facilities may be based on a single technology or a combination of technologies. Establishments in this industry use the wired telecommunications network facilities that they operate to provide a variety of services, such as wired telephony services, including VoIP services, wired (cable) audio and video programming distribution, and wired broadband internet services. By exception, establishments providing satellite television distribution services using facilities and infrastructure that they operate are included in this industry.'' Under that size standard, such a business is small if it has 1,500 or fewer employees. Census data for 2012 show that there were 3,117 firms that operated that year. Of this total, 3,083 operated with fewer than 1,000 employees. Consequently, the Commission estimates that most providers of local exchange service are small businesses.

20. *Incumbent Local Exchange Carriers (Incumbent LECs).* Neither the Commission nor the SBA has developed a small business size standard specifically for incumbent local exchange services. The closest applicable size standard under SBA rules is for the category Wired Telecommunications Carriers. The U.S. Census Bureau defines this industry as ''establishments primarily engaged in operating and/or providing access to transmission facilities and infrastructure that they own and/or lease for the transmission of voice, data, text, sound, and video using wired communications networks. Transmission facilities may be based on a single technology or a combination of technologies. Establishments in this industry use the wired telecommunications network facilities that they operate to provide a variety of services, such as wired telephony services, including VoIP services, wired (cable) audio and video programming distribution, and wired broadband internet services. By exception, establishments providing satellite television distribution services using facilities and infrastructure that they operate are included in this industry.'' Under that size standard, such a business is small if it has 1,500 or fewer employees. Census data for 2012 show that there were 3,117 firms that operated that year. Of this total, 3,083 operated with fewer than 1,000 employees. Consequently, the Commission estimates that most providers of incumbent local exchange service are small businesses.

21. *Competitive Local Exchange Carriers (Competitive LECs), Competitive Access Providers (CAPs), Shared-Tenant Service Providers, and Other Local Service Providers.* Neither the Commission nor the SBA has developed a small business size standard specifically for these service providers. The appropriate size standard under SBA rules is for the category Wired Telecommunications Carriers. The U.S. Census Bureau defines this industry as ''establishments primarily engaged in operating and/or providing access to transmission facilities and infrastructure that they own and/or lease for the transmission of voice, data, text, sound, and video using wired communications networks. Transmission facilities may be based on a single technology or a combination of technologies. Establishments in this industry use the wired telecommunications network facilities that they operate to provide a variety of services, such as wired telephony services, including VoIP services, wired (cable) audio and video programming distribution, and wired broadband internet services. By exception, establishments providing satellite television distribution services using facilities and infrastructure that they operate are included in this industry.'' Under that size standard, such a business is small if it has 1,500 or fewer employees. Census data for 2012 show that there were 3,117 firms that operated that year. Of this total, 3,083 operated with fewer than 1,000 employees. Consequently, the Commission estimates that most providers of competitive local exchange service, competitive access providers, Shared-Tenant Service Providers, and other local service providers are small entities.

22. The Commission has included small incumbent LECs in the RFA analysis. As noted above, a ''small business'' under the RFA is one that, *inter alia,* meets the pertinent small business size standard (*e.g.,* a telephone communications business having 1,500 or fewer employees), and ''is not dominant in its field of operation.'' The SBA's Office of Advocacy contends that, for RFA purposes, small incumbent LECs are not dominant in their field of operation because any such dominance is not ''national'' in scope. The Commission has therefore included small incumbent LECs in the RFA analysis, although it emphasizes that the RFA action has no effect on Commission analyses and determinations in other, non-RFA contexts.

23. *Interexchange Carriers (IXCs).* Neither the Commission nor the SBA has developed a small business size standard specifically for providers of interexchange services. The appropriate size standard under SBA rules is for the category Wired Telecommunications Carriers. The U.S. Census Bureau defines this industry as ''establishments primarily engaged in operating and/or providing access to transmission facilities and infrastructure that they

own and/or lease for the transmission of voice, data, text, sound, and video using wired communications networks. Transmission facilities may be based on a single technology or a combination of technologies. Establishments in this industry use the wired telecommunications network facilities that they operate to provide a variety of services, such as wired telephony services, including VoIP services, wired (cable) audio and video programming distribution, and wired broadband internet services. By exception, establishments providing satellite television distribution services using facilities and infrastructure that they operate are included in this industry.'' Under that size standard, such a business is small if it has 1,500 or fewer employees. Census data for 2012 show that there were 3,117 firms that operated that year. Of this total, 3,083 operated with fewer than 1,000 employees. Consequently, the Commission estimates that the majority of IXCs are small entities.

24. *Other Toll Carriers.* Neither the Commission nor the SBA has developed a size standard for small businesses specifically applicable to Other Toll Carriers. This category includes toll carriers that do not fall within the categories of interexchange carriers, operator service providers, prepaid calling card providers, satellite service carriers, or toll resellers. The closest applicable size standard under SBA rules is for Wired Telecommunications Carriers. The U.S. Census Bureau defines this industry as ''establishments primarily engaged in operating and/or providing access to transmission facilities and infrastructure that they own and/or lease for the transmission of voice, data, text, sound, and video using wired communications networks. Transmission facilities may be based on a single technology or a combination of technologies. Establishments in this industry use the wired telecommunications network facilities that they operate to provide a variety of services, such as wired telephony services, including VoIP services, wired (cable) audio and video programming distribution, and wired broadband internet services. By exception, establishments providing satellite television distribution services using facilities and infrastructure that they operate are included in this industry.'' Under that size standard, such a business is small if it has 1,500 or fewer employees. Census data for 2012 show that there were 3,117 firms that operated that year. Of this total, 3,083 operated with fewer than 1,000 employees. Thus, under this category and the associated small business size standard, the majority of Other Toll Carriers can be considered small.

Wireless Carriers

25. *Wireless Telecommunications Carriers (except Satellite).* Since 2007, the Census Bureau has placed wireless firms within this new, broad, economic census category. Under the present and prior categories, the SBA has deemed a wireless business to be small if it has 1,500 or fewer employees. For the category of Wireless Telecommunications Carriers (except Satellite), Census data for 2012 show that there were 967 firms that operated for the entire year. Of this total, 955 firms had fewer than 1,000 employees. Thus under this category and the associated size standard, the Commission estimates that the majority of wireless telecommunications carriers (except satellite) are small entities. Similarly, according to internally developed Commission data, 413 carriers reported that they were engaged in the provision of wireless telephony, including cellular service, Personal Communications Service (PCS), and Specialized Mobile Radio (SMR) services. Of this total, an estimated 261 have 1,500 or fewer employees. Thus, using available data, the Commission estimates that the majority of wireless firms can be considered small.

26. *Satellite Telecommunications Providers.* The category of Satellite Telecommunications ''comprises establishments primarily engaged in providing telecommunications services to other establishments in the telecommunications and broadcasting industries by forwarding and receiving communications signals via a system of satellites or reselling satellite telecommunications.'' This category has a small business size standard of $32.5 million or less in average annual receipts, under SBA rules. For this category, Census Bureau data for 2012 show that there were a total of 333 firms that operated for the entire year. Of this total, 299 firms had annual receipts of under $25 million. Consequently, the Commission estimates that the majority of Satellite Telecommunications firms are small entities.

27. *All Other Telecommunications.* All Other Telecommunications comprises, *inter alia,* ''establishments primarily engaged in providing specialized telecommunications services, such as satellite tracking, communications telemetry, and radar station operation. This industry also includes establishments primarily engaged in providing satellite terminal stations and associated facilities connected with one or more terrestrial systems and capable of transmitting telecommunications to, and receiving telecommunications from, satellite systems. Establishments providing Internet services or VoIP services via client-supplied telecommunications connections are also included in this industry.'' For this category, Census Bureau data for 2012 show that there were a total of 1,442 firms that operated for the entire year. Of this total, 1,400 had annual receipts below $25 million per year. Consequently, the Commission estimates that the majority of All Other Telecommunications firms are small entities.

Resellers

28. *Toll Resellers.* The Commission has not developed a definition for Toll Resellers. The closest NAICS Code Category is Telecommunications Resellers. The Telecommunications Resellers industry comprises establishments engaged in purchasing access and network capacity from owners and operators of telecommunications networks and reselling wired and wireless telecommunications services (except satellite) to businesses and households. Establishments in this industry resell telecommunications; they do not operate transmission facilities and infrastructure. Mobile virtual network operators (MVNOs) are included in this industry. The SBA has developed a small business size standard for the category of Telecommunications Resellers. Under that size standard, such a business is small if it has 1,500 or fewer employees. Census data for 2012 show that 1,341 firms provided resale services during that year. Of that number, 1,341 operated with fewer than 1,000 employees. Thus, under this category and the associated small business size standard, the majority of these resellers can be considered small entities. According to Commission data, 881 carriers have reported that they are engaged in the provision of toll resale services. Of this total, an estimated 857 have 1,500 or fewer employees. Consequently, the Commission estimates that the majority of toll resellers are small entities.

29. *Local Resellers.* The SBA has developed a small business size standard for the category of Telecommunications Resellers. The Telecommunications Resellers industry comprises establishments engaged in purchasing access and network capacity from owners and operators of telecommunications networks and reselling wired and wireless

telecommunications services (except satellite) to businesses and households. Establishments in this industry resell telecommunications; they do not operate transmission facilities and infrastructure. MVNOs are included in this industry. Under that size standard, such a business is small if it has 1,500 or fewer employees. Census data for 2012 show that 1,341 firms provided resale services during that year. Of that number, all operated with fewer than 1,000 employees. Thus, under this category and the associated small business size standard, the majority of these prepaid calling card providers can be considered small entities.

30. *Prepaid Calling Card Providers.* The SBA has developed a small business size standard for the category of Telecommunications Resellers. The Telecommunications Resellers industry comprises establishments engaged in purchasing access and network capacity from owners and operators of telecommunications networks and reselling wired and wireless telecommunications services (except satellite) to businesses and households. Establishments in this industry resell telecommunications; they do not operate transmission facilities and infrastructure. MVNOs are included in this industry. Under that size standard, such a business is small if it has 1,500 or fewer employees. Census data for 2012 show that 1,341 firms provided resale services during that year. Of that number, all operated with fewer than 1,000 employees. Thus, under this category and the associated small business size standard, the majority of these prepaid calling card providers can be considered small entities.

Description of Projected Reporting, Recordkeeping, and Other Compliance Requirements

31. As indicated above, document FCC 17–76 seeks comment on a proposed amendment to the rules to require carriers to make available, upon report of a threatening call from the called party, any CPN of the calling party to the called party and/or law enforcement for the purpose of identifying the responsible party. Until these requirements are defined in full, it is not possible to predict with certainty whether the costs of compliance will be proportionate between small and large providers. The Commission seeks to minimize the burden associated with reporting, recordkeeping, and other compliance requirements for the proposed rules, such as modifying software, developing procedures, and training staff.

32. Under the proposed rules, carriers will need to make the CPN of a calling party available to a threatened recipient of the call. They may need to work with law enforcement and the entity called to ensure there is a genuine threat in order to protect the privacy of the caller.

Steps Taken To Minimize Significant Economic Impact on Small Entities, and Significant Alternatives Considered

33. The RFA requires an agency to describe any significant alternatives that it has considered in reaching its proposed approach, which may include the following four alternatives (among others): (1) The establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities; (2) the clarification, consolidation, or simplification of compliance or reporting requirements under the rule for small entities; (3) the use of performance, rather than design, standards; and (4) an exemption from coverage of the rule, or any part thereof, for small entities.

34. The Commission has proposed rules for carriers, upon report of a threatening call from the called party, to provide any CPN of the calling party to the called party and/or law enforcement for the purpose of identifying the responsible party. The Commission requested feedback from small businesses in document FCC 17–76, and seeks comment on ways to make the proposed rules less costly. The Commission asks how to facilitate the provision of CPN to threatened entities in a manner that minimizes the administrative burdens on carriers while ensuring that such information is provided to the threatened party and law enforcement in a timely manner. The Commission seeks the input of carriers on how to best facilitate the process of providing CPN information in a timely manner to parties that report a threatening call. To help carriers protect privacy interests, the Commission seeks comment on whether it should require anyone reporting a threatening call for purposes of obtaining otherwise restricted CPN to do so in conjunction with a law enforcement agency to provide some assurance that the called party is not attempting to circumvent the privacy obligations of the rule by reporting a false threat. The Commission also asks whether excluding private individuals would limit the potential for abuse. The Commission seeks comment on how to minimize the economic impact of its proposals, particularly to small businesses.

35. The Commission expects to consider the economic impact on small entities, as identified in comments filed in response to document FCC 17–76 and the IRFA, in reaching its final conclusions and taking action in this proceeding.

Federal Rules That May Duplicate, Overlap, or Conflict With the Proposed Rule

36. None.

List of Subjects in 47 CFR Part 64

Claims, Communications common carriers, Computer technology, Credit, Foreign relations, Individuals with disabilities, Political candidates, Radio, Reporting and recordkeeping requirements, Telecommunications, Telegraph, Telephone.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

For the reasons discussed in the preamble, the Federal Communications Commission proposes to amend 47 CFR part 64 as follows:

PART 64—MISCELLANEOUS RULES RELATING TO COMMON CARRIERS

■ 1. The authority citation for part 64 continues to read as follows:

Authority: 47 U.S.C. 154, 225, 254(k), 403(b)(2)(B), (c), 715, Pub. L. 104–104, 110 Stat. 56. Interpret or apply 47 U.S.C. 201, 218, 222, 225, 226, 227, 228, 254(k), 616, 620, and the Middle Class Tax Relief and Job Creation Act of 2012, Pub. L. 112–96, unless otherwise noted.

■ 2. Amend § 64.1600 by adding paragraph (l) to read as follows:

§ 64.1600 Definitions.

* * * * *

(l) *Threatening Call.* The term ''threatening call'' means any call that includes a threat of serious and imminent unlawful action posing a substantial risk to property, life, safety, or health.

■ 3. Amend § 64.1601 by revising paragraph (d)(4) (ii) through (iv) to read as follows:

§ 64.1601 Delivery requirements and privacy restrictions.

* * * * *

(d) * * *

(4) * * *

(ii) Is used on a public agency's emergency telephone line or in conjunction with 911 emergency services, or on any entity's emergency assistance poison control telephone line;

(iii) Is provided in connection with legally authorized call tracing or trapping procedures specifically

requested by a law enforcement agency; or

(iv) Is made in connection with a threatening call. Upon report of such a threatening call, the carrier will provide any CPN of the calling party to the called party and/or law enforcement for the purpose of identifying the responsible party.

* * * * *

[FR Doc. 2017–15303 Filed 7–20–17; 8:45 am]

BILLING CODE 6712–01–P

Notices

Federal Register

Vol. 82, No. 139

Friday, July 21, 2017

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

AFRICAN DEVELOPMENT FOUNDATION

Public Quarterly Meeting of the Board of Directors

AGENCY: United States African Development Foundation.

ACTION: Notice of meeting.

SUMMARY: The US African Development Foundation (USADF) will hold its quarterly meeting of the Board of Directors to discuss the agency's programs and administration.

DATES: The meeting date is Monday, July 31, 10:00 a.m. to 1:00 p.m.

ADDRESSES: The meeting will take place via teleconference, with staff congregating at USADF, 1400 I St. Northwest, Suite # 1000 (Main Conference Room), Washington, DC 20005–2246.

FOR FURTHER INFORMATION CONTACT: Marie-Cecile Groelsema, 202–233–8883.

Authority: Public Law 96–533 (22 U.S.C. 290h).

Dated: July 18, 2017.

June B. Brown,

Interim General Counsel.

[FR Doc. 2017–15369 Filed 7–20–17; 8:45 am]

BILLING CODE P

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

[Document Number AMS–NOP–17–0038; NOP–17–06]

Notice of Meeting of the National Organic Standards Board

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Notice of public meeting, via teleconference, of the National Organic Standards Board (NOSB).

SUMMARY: In accordance with the Federal Advisory Committee Act, as amended, the Agricultural Marketing Service (AMS), U.S. Department of Agriculture (USDA), is announcing a meeting of the National Organic Standards Board (NOSB) to discuss the development of a proposal on aeroponics/bioponics/hydroponics.

DATES: August 14, 2017. 1:00 p.m. ET–3:00 p.m. ET.

Conference Call: Instructions for accessing the teleconference are available on the AMS/NOP Web site.

FOR FURTHER INFORMATION CONTACT: Ms. Michelle Arsenault, Advisory Committee Specialist, National Organic Standards Board, USDA–AMS–NOP, 1400 Independence Ave. SW., Room 2642–S, Mail Stop 0268, Washington, DC 20250–0268; Phone: (202) 720–3252; Email: *nosb@ams.usda.gov.*

SUPPLEMENTARY INFORMATION: The NOSB members will discuss the development of proposals on aeroponics/bioponics/hydroponics for a future NOSB meeting. The NOSB will not be voting on a recommendation during this conference call. The NOSB makes recommendations to the Department of Agriculture about whether substances should be allowed or prohibited in organic production and/or handling, assists in the development of standards for organic production, and advises the Secretary on other aspects of the implementation of the Organic Foods Production Act (7 U.S.C. 6501–6522).

Public Comments: The NOSB will be meeting in October 2017 and may consider a proposal on aeroponics/bioponics/hydroponics at that time. The NOSB is accepting comments, both written and oral, through October 11, 2017. *Written comments:* Written public comments will be accepted on or before 11:59 p.m. ET October 11, 2017 via *http://www.regulations.gov.* Comments submitted after this date will be provided to the NOSB, but Board members may not have adequate time to consider those comments prior to making recommendations. The NOP strongly prefers comments to be submitted electronically, however, written comments may also be submitted (*i.e.,* postmarked) by the deadline, via mail to the person listed under **FOR FURTHER INFORMATION**. *Oral Comments:* Persons or organizations wishing to make oral comments must pre-register by 11:59 p.m. ET, October 11, 2017, and can only register for one speaking slot: Either during the webinar(s) scheduled for October 24 (and October 26 if needed) or at the in-person meeting, October 31, 2017. Due to the limited time allotted for in-person public comments, commenters are strongly encouraged to comment during the webinar(s). Instructions for registering and participating in the webinar can be found at *www.ams.usda.gov/NOSBMeetings.*

Meeting Accommodations: USDA provides reasonable accommodation to individuals with disabilities where appropriate. If you need a reasonable accommodation to participate in this public meeting, please notify the person listed under **FOR FURTHER INFORMATION**. Determinations for reasonable accommodation will be made on a case-by-case basis.

Dated: July 17, 2017.

Bruce Summers,

Acting Administrator, Agricultural Marketing Service.

[FR Doc. 2017–15308 Filed 7–20–17; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

July 17, 2017.

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments are 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 August 21, 2017 will be considered. Written comments should be addressed to: Desk Officer for

Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), New Executive Office Building, 725 17th Street NW., Washington, DC 20502. Commenters are encouraged to submit their comments to OMB via email to: *OIRA_Submission@OMB.EOP.GOV* or fax (202) 395–5806 and to Departmental Clearance Office, USDA, OCIO, Mail Stop 7602, Washington, DC 20250–7602. Copies of the submission(s) may be obtained by calling (202) 720–8958.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Rural Housing Service

Title: 7 CFR 3575–A, Community Programs Guaranteed Loans.

OMB Control Number: 0575–0137.

Summary of Collection: The Rural Housing Service (RHS) is authorized by Section 306 of the Consolidated Farm and Rural Development Act (7 U.S.C. 1926) to make loans to public agencies, nonprofit corporations, and Indian tribes for the development of essential community facilities primarily serving rural residents. The Community Facilities Division of the RHS is considered Community Programs under the 7 CFR, part 3575, subpart A. Implementation of the Community Programs guaranteed loan program was affected to comply with the Appropriations Act of 1990 when Congress allocated funds for this authority. The guaranteed loan program encourages lender participation and provides specific guidance in the processing and servicing of guaranteed Community Facilities loans.

Need and Use of the Information: RHS will collect information in a written format and using several forms. RHS will use collected information to determine applicant/borrower eligibility, project feasibility, and to ensure borrowers operate on a sound basis and use loan funds for authorized purposes. Failure to collect proper information could result in improper determination of eligibility, improper use of funds, and/or unsound loans.

Description of Respondents: Not-for-profit institutions; State, Local or Tribal Government.

Number of Respondents: 680.

Frequency of Responses: Reporting: Quarterly; Annually.

Total Burden Hours: 12,401.

Charlene Parker,

Departmental Information Collection Clearance Officer.

[FR Doc. 2017–15282 Filed 7–20–17; 8:45 am]

BILLING CODE 3410–XV–P

DEPARTMENT OF AGRICULTURE

Forest Service

Medicine Bow National Forest, Wyoming, Landscape Vegetation Analysis (LaVA) Project

AGENCY: Forest Service, USDA.

ACTION: Notice of intent to prepare an environmental impact statement.

SUMMARY: The Forest Service is preparing an environmental impact statement (EIS) on its proposed treatment of 150,000 acres of insect-infested areas of the Medicine Bow National Forest (MBNF). The Forest Service believes this treatment is necessary to ensure the future health of the MBNF.

DATES: Comments concerning the scope of the analysis must be received by August 21, 2017. The Draft Environmental Impact Statement is expected in November 2017 and the Final Environmental Impact Statement is due in March 2018.

ADDRESSES: Send written comments to: LaVA Project, Medicine Bow National Forest, 2468 Jackson Street, Laramie, WY 82070, or via facsimile to 307–745–2467, c/o LaVA Project. Written comments may also be hand-delivered to the above address between 8:00 a.m. and 4:30 p.m. Mountain Time, Monday through Friday except federal holidays. Comments may also be submitted electronically at *https://cara.ecosystem-management.org/Public/CommentInput?Project=51255.*

FOR FURTHER INFORMATION CONTACT: Melissa Martin, Project Manager, at 307–745–2371. Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–811–8339 between 8:00 a.m. and 8:00 p.m., Eastern Time, Monday through Friday.

SUPPLEMENTARY INFORMATION: The Medicine Bow National Forest (MBNF) has experienced epidemic levels of mountain pine beetle and spruce bark beetle infestations since the mid to late 1990s. Although the epidemic has slowed in recent years, the infestation has left behind a changed landscape consisting primarily of regenerating forests that have an overstory of large, dead and dying trees. Action is needed to accelerate management response to this major forest health event to proactively and adaptively respond to changing forest vegetation conditions.

On March 22, 2017, Forest Service Chief Thomas L. Tidwell designated the majority of the MBNF as a landscape-scale insect and disease area under Section 602(d) of the Healthy Forests Restoration Action of 2003 (HFRA, 16 U.S.C. 6591 *et seq.*), as amended by Section 8204 of the Agricultural Act of 2014. These authorities provide for expedited environmental analysis and treatments to address areas affected by insect and disease infestations. Accordingly, the Medicine Bow Landscape Vegetation Analysis (LaVa) Project will proceed according to Section 104 of the HFRA and will be subject to subparts A and C of the U.S. Forest Service Project-Level Pre-decisional Administrative Review Process. Intended goals of the project include, but are not limited to, using tree cutting and/or prescribed burning to: make areas more resilient to future disturbance; restore, and enhance forest ecosystem components; supply forest products to local industries; provide for human safety; reduce wildfire risk to communities, infrastructure, and municipal water supplies; and improve, protect, and restore wildlife habitat.

The LaVA analysis area encompasses the Snowy Range and Sierra Madre Mountain Ranges of the MBNF and includes roughly 850,000 acres of National Forest System (NFS) lands. Of the 850,000 acres, the Forest Service has identified roughly 575,000 acres wherein treatment activities could be proposed; these areas are termed 'treatment opportunity areas' (TOAs). Actual treatments are proposed on a subset of the TOAs (150,000–350,000 acres), as described in the Proposed Action.

Purpose and Need for Action

The purpose of the project is to respond to changed forest vegetation conditions presented by the bark beetle epidemics experienced on the MBNF. The approach is to actively manage forest vegetation using tree cutting and/or prescribed burning, consistent with the goals outlined in the Governor's Task Force on Forests (Final Report, 2015), the Western Bark Beetle Strategy (July 2011), and the Wyoming Statewide Forest Resource Strategy (2010). These goals include promoting recovery from the insect infestations, improving the resiliency of green stands to future disturbances, helping to protect forested areas on adjacent private and state land, and providing for human safety. These general goals will be adapted to local

landscapes where treatments are needed based on Forest Plan direction, foreseeable conditions, and local environmental, social and economic concerns. The project is needed to:

Enhance Forest and Rangeland Resiliency to Future Insect and Disease Infestations

- Increase age class, structural, and vegetative diversity across the landscape;
- Promote forest and rangeland conditions to improve forage and wildlife habitat; and
- Actively accelerate recovery and regeneration of forest ecosystems.

Provide for Recovery of Forest Products

- Promote vegetation management to recover merchantable products; and
- Provide commercial forest products to local industries at a level commensurate with Forest Plan direction and goals.

Provide for Human Safety

- Treat hazard trees in areas not covered by the Forest-wide Hazard Tree Decision Notice (August 12, 2008);
- Treat hazard trees within and outside the wildland urban interface (WUI);
- Increase the extent of defensible space around resources at risk; and
- Create fuel breaks to slow or stop the progress of wildfires.

Provide for Protection of Infrastructure, Municipal Water Supplies, and Threatened and Endangered Species Habitat

- Treat vegetation adjacent to infrastructure and non-federally owned lands;
- Treat vegetation to protect municipal water supplies and infrastructure; and
- Treat vegetation where fire is identified as a threat to the habitat of a threatened or endangered species.

Mitigate Hazardous Fuel Loading

- Treat hazardous fuels to minimize the potential for large, high intensity/high severity wildfires; and
- Treat hazardous fuels to reduce fire behavior and the possibility of fires spreading onto adjacent, non-federal lands.

Proposed Action

The Forest Service proposes to conduct vegetation management activities on NFS lands, including inventoried roadless areas, within the Sierra Madre and Snowy Range Mountain Ranges of the MBNF. Vegetation management activities, including prescribed fire, mechanical, and hand treatment methods, could be applied to 150,000–350,000 acres to protect, restore and enhance forest ecosystem components; reduce wildfire risk to communities and municipal water supplies; supply forest products to local industries; and improve, protect, and restore wildlife habitat. Treatments would be authorized over a 10-year period beginning in 2018 and would be completed within approximately 15 years of the project decision.

Due to ever-changing conditions, the Proposed Action incorporates the principles of adaptive management in that it does not identify specific treatment units. Instead, it proposes a range of acres (150,000–350,000) that could be treated within the pre-established TOAs (575,000 acres). During project implementation, the Forest Service would cooperate with other agencies, local governments, interested stakeholders, and organizations to identify specific treatment units. Specific objectives of each treatment unit would be determined prior to any ground-disturbing activities using existing vegetation conditions and a series of project-developed field checklists. The sum of all treatments would not exceed 350,000 acres.

Specifically, the Proposed Action would allow each of the following activities to occur within the pre-established TOAs:

- Cutting trees or shrubs using a variety of treatment methods including, but not limited to, clearcutting/coppice; group and individual tree selection; salvage; mastication; sanitation; and thinning. Treatments would be designed to protect, restore, and enhance forest ecosystem components; supply forest products to local industries; provide for human safety; reduce wildfire risk to communities and municipal water supplies; and improve, protect, and restore wildlife habitat.
- Cutting trees that have encroached on grass and shrub lands to maintain desired species dominance and improve wildlife habitat.
- Prescribed burning areas using jackpot, pile burning, and broadcast burning. Maintenance burns on previously treated areas would occur to maintain desired fuels or habitat conditions.
- Prescribed burning or tree/shrub cutting on portions of inventoried roadless areas (IRAs). Treatment opportunity areas in IRAs were proposed by Cooperating Agencies and the Forest Service to protect communities at risk; threatened, endangered, and sensitive wildlife habitat; critical infrastructure; and municipal water supplies. No new permanent or temporary road construction would occur in IRAs.
- Utilizing and/or reconstructing existing open and closed NFS roads to access treatment units. Reconstruction may include road blading, culvert installation or replacement, and gravelling. Closed NFS roads would be for administrative access only (*i.e.,* they will be managed as closed to the public) and would be returned to a closed status with the method of closure being determined at implementation.
- Constructing approximately 25 miles of new, permanent NFS roads, as necessary, to access treatment areas; the final assessment of road needs has not been determined and could be more or less. All newly constructed system roads would be physically closed to public motorized vehicle use following completion of treatment activities; however, their templates would be retained for future management entries.
- Constructing approximately 1,000 miles of temporary road, as necessary, to access treatment areas; the final assessment of road needs has not been determined and could be more or less. While open, the roads would be for administrative use only (*i.e.,* they would be managed as closed to the public). Temporary roads would be decommissioned following treatment activities to preclude future motorized use and to restore ecological function; decommissioning returns a road to a natural state. Decommissioning methods may include, but are not limited to, re-contouring the road, ripping/scarifying the roadbed, removing culverts, installing drainage features, creating physical barriers to preclude motorized travel, scattering wood/rock debris onto the road, applying seed and mulch to the area, and posting signs.
- Conducting regeneration surveys, noxious weed control, native grass seeding, and road maintenance.
- Using a combination of commercial timber sales, service contracts, stewardship contracts, cooperative authorities, partner capacity, and Forest Service crews to implement the project.

Adaptive Management Process: Due to the adaptive nature of the Proposed Action (*i.e.,* a range of treatment acres v. identification of specific treatment units), the Forest Service will develop standards, protocols, and monitoring requirements to guide project implementation. Under this scenario, the Forest Service would:

- Complete all required surveys for each individual treatment area; complete required layout and marking

of each treatment area; determine appropriate design features to be applied; and document compliance with requirements of the environmental impact statement using a set of pre-established field checklists.

• Perform monitoring during and following implementation of individual treatment activities to ensure treatments are implemented as planned and that project objectives are being attained.

• Establish an annual monitoring review with interested stakeholders, partners, and collaborative groups to ensure treatments are implemented as planned and that project objectives are being attained.

Possible Alternatives

At a minimum, the environmental impact statement will disclose the effects of the Proposed Action and a No Action alternative. The No Action alternative represents no change from current conditions and serves as the baseline for the comparison among alternatives. An alternative to the Proposed Action may be developed in response to public comments.

Nature of Decision To Be Made

The Forest Supervisor of the MBNF is the deciding official for the LaVA Project. Once the NEPA analysis is completed, he will decide: Whether or not to implement, in part or full, the proposed actions or other alternatives; rationale for the decision; and design criteria, mitigation and monitoring requirements necessary for project implementation.

Scoping Process

This notice of intent initiates the scoping process, which guides the development of the environmental impact statement. It is important that reviewers provide comments at such times and in such a manner that they are useful to the agency's preparation of the environmental impact statement. Therefore, comments should be provided prior to the close of the comment period and should clearly articulate the reviewer's concerns and contentions. A more detailed scoping document may be accessed at *http://data.ecosystem-management.org/nepaweb/nepa_project_exp.php?project=51255.*

Comments received in response to this solicitation, including names and addresses of those who comment, will be part of the public record for this proposed action. Comments submitted anonymously will be accepted and considered; however, they will not become part of the public record.

Objection Process

The Forest Service is operating under Part 218—Project-level Pre-decisional Administrative Review Process (hereinafter referred to as 'objection'), 36 CFR. 218 Subparts A and C, for this analysis. Per these regulations, individuals and entities who submit timely, specific written comments regarding a proposed project or activity during any designated opportunity for public comment will have standing to file an objection. This includes requests for comments during this initial scoping period as well as comments submitted during the 45-day comment period for the draft environmental impact statement.

It is the responsibility of persons providing comments to submit them by the close of established comment periods. Only those who submit timely and specific written comments will have eligibility (36 CFR 218.5) to file an objection under 36 CFR 218.8. For objection eligibility, each individual or representative from each entity submitting timely and specific written comments must either sign the comment or verify identity upon request. Individuals and organizations wishing to be eligible to object must meet the information requirements in § 218.25(a)(3). Names and contact information submitted with comments will become part of the public record and may be released under the Freedom of Information Act.

Dated: June 23, 2017.

Jeanne M. Higgins,

Acting Associate Deputy Chief, National Forest System.

[FR Doc. 2017–15322 Filed 7–20–17; 8:45 am]

BILLING CODE 3411–15–P

DEPARTMENT OF AGRICULTURE

Rural Housing Service

Notice for Request for Revision of a Currently Approved Information Collection

AGENCY: Rural Housing Service, USDA.

ACTION: Proposed collection; comments requested.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Rural Housing Service's (RHS) intent to reinstate a previously approved information collection in support of the Single Family Housing Guaranteed Loan Program.

DATES: Comments on this notice must be received by [60 days] to be assured of consideration.

FOR FURTHER INFORMATION CONTACT: Kate Jensen, Finance and Loan Analyst, Single Family Housing Guaranteed Loan Division, Stop 0784, Room 2250, USDA Rural Development, South Agriculture Building, 1400 Independence Avenue SW., Washington, DC 20250–0784, telephone (503) 894–2382, Email *kate.jensen@wdc.usda.gov*.

SUPPLEMENTARY INFORMATION:

Title: Single Family Housing Guaranteed Loan Program.

OMB Number: 0575–0179.

Type of Request: Reinstatement of a Previously Approved Information Collection.

Abstract: Under this program, loan guarantees are provided to participating lenders who make loans to income eligible borrowers in rural areas. The purpose of this program is to promote affordable housing for low- and moderate-income borrowers in rural America.

Estimate of Burden: Public reporting burden for this collection of information is estimated to average 49 minutes per response.

Respondents: Private sector lenders participating in the Rural Development Single Family Housing Guaranteed Loan Program.

Estimated Number of Respondents: 1,476.

Estimated Number of Responses per Respondent: 737.

Estimated Number of Responses: 1,087,927.

Estimated Total Annual Burden on Respondents: 821,112.

Copies of this information collection can be obtained from Jeanne Jacobs, Regulations and Paperwork Management Branch, Support Services Division, at (202) 692–0040.

Comments: Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of USDA, including whether the information will have practical utility; (b) the accuracy of USDA's estimate of 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 may be sent to Jeanne Jacobs, Regulations and Paperwork Management Branch, Support Services Division, U.S. Department of Agriculture, Rural Development, Stop 0742–1400 Independence Avenue SW., Washington, DC 20250–0742. All

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

Dated: July 14, 2017.

Bryan Hooper,

Acting Administrator, Rural Housing Service.

[FR Doc. 2017–15297 Filed 7–20–17; 8:45 am]

BILLING CODE 3410–XY–P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Texas Advisory Committee

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act (FACA) that a meeting of the Texas Advisory Committee (Committee) to the Commission will be held at 2:00 p.m. (Central Time) August 21, 2017. The purpose of the meeting is for the Committee to discuss project topics of study.

DATES: The meeting will be held on Monday, August 21, 2017, at 2:00 p.m. CDT.

Public Call Information:
Dial: 888–471–3820.
Conference ID: 2807375.

FOR FURTHER INFORMATION CONTACT: Ana Victoria Fortes (DFO) at *afortes@usccr.gov* or (213) 894–3437.

SUPPLEMENTARY INFORMATION: This meeting is available to the public through the following toll-free call-in number: 888–471–3820, conference ID number: 2807375. Any interested member of the public may call this number and listen to the meeting. Callers can expect to incur charges for calls they initiate over wireless lines, and the Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free telephone number. Persons with hearing impairments may also follow the proceedings by first calling the Federal Relay Service at 1–800–977–8339 and providing the Service with the conference call number and conference ID number.

Members of the public are entitled to make comments during the open period at the end of the meeting. Members of the public may also submit written comments; the comments must be received in the Regional Programs Unit within 30 days following the meeting. Written comments may be mailed to the Western Regional Office, U.S. Commission on Civil Rights, 300 North Los Angeles Street, Suite 2010, Los Angeles, CA 90012. They may be faxed to the Commission at (213) 894–0508, or emailed Ana Victoria Fortes at *afortes@usccr.gov.* Persons who desire additional information may contact the Regional Programs Unit at (213) 894–3437.

Records and documents discussed during the meeting will be available for public viewing prior to and after the meeting at *http://facadatabase.gov/committee/meetings.aspx?cid=276.* Please click on the ''Meeting Details'' and ''Documents'' links. Records generated from this meeting may also be inspected and reproduced at the Regional Programs Unit, as they become available, both before and after the meeting. Persons interested in the work of this Committee are directed to the Commission's Web site, *http://www.usccr.gov,* or may contact the Regional Programs Unit at the above email or street address.

Agenda

I. Welcome
II. Approval of June 28, 2017 Minutes
III. Discussion on FY17 Civil Rights Project Ideas
IV. Public Comment
V. Next Steps
VI. Adjournment

Dated: July 18, 2017.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2017–15353 Filed 7–20–17; 8:45 am]

BILLING CODE P

COMMISSION ON CIVIL RIGHTS

Agenda and Notice of Public Meeting of the Maryland Advisory Committee

AGENCY: Commission on Civil Rights.

ACTION: Announcement of planning meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission), and the Federal Advisory Committee Act (FACA), that a planning meeting of the Maryland Advisory Committee to the Commission will convene by conference call at 12:00 p.m. (EDT) on Thursday, August 10, 2017. The purpose of the planning meeting is to review the Advisory Memorandum for its Bail Reform and Fines and Fees project and vote to submit the memorandum for Commission review.

DATES: Thursday, August 10, 2017 at 12 p.m. (EDT).

ADDRESSES: Public call-in information: Conference call-in number: 1–877–440–5787 and conference call ID: 1233406.

FOR FURTHER INFORMATION CONTACT: Ivy L. Davis, at *ero@usccr.gov* or by phone at 202–376–7533.

SUPPLEMENTARY INFORMATION: Interested members of the public may listen to the discussion by calling the following toll-free conference call-in number: 1–877–440–5787 and conference call ID: 1233406. Please be advised that before placing them into the conference call, the conference call operator will ask callers to provide their names, their organizational affiliations (if any), and email addresses (so that callers may be notified of future meetings). Callers can expect to incur charges for calls they initiate over wireless lines, and the Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free conference call-in number.

Persons with hearing impairments may also follow the discussion by first calling the Federal Relay Service at 1–800–977–8339 and providing the operator with the toll-free conference call-in number: 1–877–440–5787 and conference call ID: 1233406.

Members of the public are invited to submit written comments; the comments must be received in the regional office approximately 30 days after each scheduled meeting. Written comments may be mailed to the Eastern Regional Office, U.S. Commission on Civil Rights, 1331 Pennsylvania Avenue, Suite 1150, Washington, DC 20425, faxed to (202) 376–7548, or emailed to Evelyn Bohor at *ero@usccr.gov.* Persons who desire additional information may contact the Eastern Regional Office at (202) 376–7533.

Records and documents discussed during the meeting will be available for public viewing as they become available at *http://facadatabase.gov/committee/meetings.aspx?cid=253;* click the ''Meeting Details'' and ''Documents'' links. Records generated from this meeting may also be inspected and reproduced at the Eastern Regional Office, as they become available, both before and after the meetings. Persons interested in the work of this advisory committee are advised to go to the Commission's Web site, *www.usccr.gov,* or to contact the Eastern Regional Office at the above phone numbers, email or street address.

Agenda

I. Welcome and Introductions —Rollcall
II. Review Advisory Memorandum
III. Vote to Submit Advisory Memorandum for Commission Review
IV. Other Business
V. Adjournment

Dated: July 18, 2017.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2017–15368 Filed 7–20–17; 8:45 am]

BILLING CODE P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Alaska Advisory Committee

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act (FACA) that a meeting of the Alaska Advisory Committee (Committee) to the Commission will be held at 2:00 p.m. (Alaska Time) Thursday, July 20, 2017. The purpose of the meeting is for the Committee to discuss potential panelists to speak at the Alaska Native voting rights briefing.

DATES: The meeting will be held on Thursday, July 20, 2017, at 2:00 p.m. AKDT.

Public Call Information:
Dial: 877–719–9788.
Conference ID: 2981918.

FOR FURTHER INFORMATION CONTACT: Ana Victoria Fortes (DFO) at *afortes@usccr.gov* or (213) 894–3437.

SUPPLEMENTARY INFORMATION: This meeting is available to the public through the following toll-free call-in number: 877–719–9788, conference ID number: 2981918. Any interested member of the public may call this number and listen to the meeting. Callers can expect to incur charges for calls they initiate over wireless lines, and the Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free telephone number. Persons with hearing impairments may also follow the proceedings by first calling the Federal Relay Service at 1–800–977–8339 and providing the Service with the conference call number and conference ID number.

Members of the public are entitled to make comments during the open period at the end of the meeting. Members of the public may also submit written comments; the comments must be received in the Regional Programs Unit within 30 days following the meeting. Written comments may be mailed to the Western Regional Office, U.S. Commission on Civil Rights, 300 North Los Angeles Street, Suite 2010, Los Angeles, CA 90012. They may be faxed to the Commission at (213) 894–0508, or emailed Ana Victoria Fortes at *afortes@usccr.gov.* Persons who desire additional information may contact the Regional Programs Unit at (213) 894–3437.

Records and documents discussed during the meeting will be available for public viewing prior to and after the meeting at *http://facadatabase.gov/committee/meetings.aspx?cid=234.* Please click on the ''Meeting Details'' and ''Documents'' links. Records generated from this meeting may also be inspected and reproduced at the Regional Programs Unit, as they become available, both before and after the meeting. Persons interested in the work of this Committee are directed to the Commission's Web site, *http://www.usccr.gov,* or may contact the Regional Programs Unit at the above email or street address.

Agenda

I. Welcome
II. Approval of July 6, 2017 Minutes
III. Discussion on In-Person Briefing
- Identifying Categories of Panels
- Identifying Speakers

IV. Public Comment
V. Next Steps
VI. Adjournment

Exceptional Circumstance: Pursuant to 41 CFR 102–3.150, the notice for this meeting is given less than 15 calendar days prior to the meeting because of the exceptional circumstance of the committee needing to get preparations started for its August 2017 Alaska Native voting rights briefing.

Dated: July 18, 2017.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2017–15351 Filed 7–20–17; 8:45 am]

BILLING CODE P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the California Advisory Committee

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act (FACA) that a meeting of the California State Advisory Committee (Committee) to the Commission will be held at 12:00 p.m. (Pacific Time) Wednesday, August 16, 2017. The purpose of the meeting is for the Committee to discuss project topics of study.

DATES: The meeting will be held on Wednesday, August 16, 2017, at 12:00 p.m. PDT.

Public Call Information:
Dial: 888–516–2447.
Conference ID: 9545369.

FOR FURTHER INFORMATION CONTACT: Ana Victoria Fortes at *afortes@usccr.gov* or (213) 894–3437.

SUPPLEMENTARY INFORMATION: This meeting is available to the public through the following toll-free call-in number: 888–516–2447, conference ID number: 9545369. Any interested member of the public may call this number and listen to the meeting. Callers can expect to incur charges for calls they initiate over wireless lines, and the Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free telephone number. Persons with hearing impairments may also follow the proceedings by first calling the Federal Relay Service at 1–800–977–8339 and providing the Service with the conference call number and conference ID number.

Members of the public are entitled to make comments during the open period at the end of the meeting. Members of the public may also submit written comments; the comments must be received in the Regional Programs Unit within 30 days following the meeting. Written comments may be mailed to the Western Regional Office, U.S. Commission on Civil Rights, 300 North Los Angeles Street, Suite 2010, Los Angeles, CA 90012. They may be faxed to the Commission at (213) 894–0508, or emailed Ana Victoria Fortes at *afortes@usccr.gov.* Persons who desire additional information may contact the Regional Programs Unit at (213) 894–3437.

Records and documents discussed during the meeting will be available for public viewing prior to and after the meeting at *http://facadatabase.gov/committee/meetings.aspx?cid=237.* Please click on the ''Meeting Details'' and ''Documents'' links. Records generated from this meeting may also be inspected and reproduced at the Regional Programs Unit, as they become available, both before and after the

meeting. Persons interested in the work of this Committee are directed to the Commission's Web site, *http://www.usccr.gov,* or may contact the Regional Programs Unit at the above email or street address.

Agenda

I. Welcome
II. Approval of June 12, 2017 Minutes
III. Discussion on FY17 Civil Rights Project Ideas
IV. Public Comment
V. Adjournment

Dated: July 18, 2017.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2017–15352 Filed 7–20–17; 8:45 am]

BILLING CODE 6335–01–P

DEPARTMENT OF COMMERCE

National Telecommunications and Information Administration

First Responder Network Authority

[Docket Number 160830796–6796–02]

RIN 0660–XC030

Notice of Availability of a Final Programmatic Environmental Impact Statement for the West Region of the Nationwide Public Safety Broadband Network

AGENCY: First Responder Network Authority, National Telecommunications and Information Administration, U.S. Department of Commerce.

ACTION: Notice of availability of a final programmatic environmental impact statement.

SUMMARY: The First Responder Network Authority (''FirstNet'') announces the availability of the Final Programmatic Environmental Impact Statement for the West Region (''Final PEIS''). The Final PEIS evaluates the potential environmental impacts of the proposed nationwide public safety broadband network in the West Region (Arizona, California, Idaho, Nevada, Oregon, and Washington).

ADDRESSES: The Final PEIS is available for download from *www.regulations.gov* FIRSTNET–2017–0004. A CD of this document is also available for viewing at public libraries (see Chapter 14 of the Final PEIS for the complete distribution list).

FOR FURTHER INFORMATION CONTACT: For more information on the Final PEIS, contact Amanda Goebel Pereira, NEPA Coordinator, First Responder Network Authority, National Telecommunications and Information Administration, U.S. Department of Commerce, 12201 Sunrise Valley Drive, M/S 243, Reston, VA 20192.

SUPPLEMENTARY INFORMATION: The Middle Class Tax Relief and Job Creation Act of 2012 (Pub. L. 112–96, Title VI, 126 Stat. 256 (codified at 47 U.S.C. 1401 *et seq.*)) (the ''Act'') created and authorized FirstNet to take all actions necessary to ensure the building, deployment, and operation of an interoperable, nationwide public safety broadband network (''NPSBN'') based on a single, national network architecture. The Act meets a longstanding and critical national infrastructure need, to create a single, nationwide network that will, for the first time, allow police officers, fire fighters, emergency medical service professionals, and other public safety entities to effectively communicate with each other across agencies and jurisdictions. The NPSBN is intended to enhance the ability of the public safety community to perform more reliably, effectively, and safely; increase situational awareness during an emergency; and improve the ability of the public safety community to effectively engage in those critical activities.

The National Environmental Policy Act of 1969 (42 U.S.C. 4321–4347) (''NEPA'') requires federal agencies to undertake an assessment of environmental effects of their proposed actions prior to making a final decision and implementing the action. NEPA requirements apply to any federal project, decision, or action that may have a significant impact on the quality of the human environment. NEPA also establishes the Council on Environmental Quality (''CEQ''), which issued regulations implementing the procedural provisions of NEPA (see 40 CFR parts 1500–1508). Among other considerations, CEQ regulations at 40 CFR 1508.28 recommend the use of *tiering* from a ''broader environmental impact statement (such as a national program or policy statements) with subsequent narrower statements or environmental analysis (such as regional or basin wide statements or ultimately site-specific statements) incorporating by reference the general discussions and concentrating solely on the issues specific to the statement subsequently prepared.''

Due to the geographic scope of FirstNet (all 50 states, the District of Columbia, and five territories) and the diversity of ecosystems potentially traversed by the project, FirstNet has elected to prepare five regional PEISs. The five PEISs are divided into the East, Central, West, South, and Non-Contiguous Regions. The West Region consists of Arizona, California, Idaho, Nevada, Oregon, and Washington. The Final PEIS analyzes potential impacts of the deployment and operation of the NPSBN on the natural and human environment in the West Region, in accordance with FirstNet's responsibilities under NEPA.

Now that this PEIS has been completed and once a Record of Decision (ROD) has been signed, the proposed FirstNet projects can begin to submit the site-specific environmental documentation to determine if the proposed project has been adequately evaluated in the PEIS or whether it instead warrants a Categorical Exclusion, an Environmental Assessment, or an Environmental Impact Statement.

Dated: July 17, 2017.

Amanda Goebel Pereira,

NEPA Coordinator, First Responder Network Authority.

[FR Doc. 2017–15312 Filed 7–20–17; 8:45 am]

BILLING CODE 3510–60–P

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

Manufacturing Extension Partnership Advisory Board

AGENCY: National Institute of Standards and Technology, Commerce.

ACTION: Notice of open meeting.

SUMMARY: The National Institute of Standards and Technology (NIST) announces that the Manufacturing Extension Partnership (MEP) Advisory Board will hold an open meeting on September 27, 2017.

DATES: The meeting will be held Wednesday, September 27, 2017, from 8:00 a.m. to 12:00 p.m. Eastern Time.

ADDRESSES: The meeting will be held in Building 215, Room C103, at NIST, 100 Bureau Drive, Gaithersburg, MD 20899. Please note admittance instructions in the **SUPPLEMENTARY INFORMATION** section below.

FOR FURTHER INFORMATION CONTACT: Cheryl L. Gendron, Manufacturing Extension Partnership, National Institute of Standards and Technology, 100 Bureau Drive, Mail Stop 4800, Gaithersburg, Maryland 20899–4800, telephone number (301) 975–2785, email: *cheryl.gendron@nist.gov.*

SUPPLEMENTARY INFORMATION: The MEP Advisory Board is authorized under

Section 3003(d) of the America COMPETES Act (Pub. L. 110–69), as amended by the American Innovation and Competitiveness Act, Public Law 114–329 (2017), and codified at 15 U.S.C. 278k(m), in accordance with the provisions of the Federal Advisory Committee Act, as amended, 5 U.S.C. App. The Hollings MEP Program (Program) is a unique program, consisting of centers in all 50 states and Puerto Rico with partnerships at the state, federal, and local levels. By statute, the MEP Advisory Board provides the NIST Director with: (1) Advice on the activities, plans, and policies of the Program; (2) assessments of the soundness of the plans and strategies of the Program; and (3) assessments of current performance against the plans of the Program.

Background information on the MEP Advisory Board is available at *http://www.nist.gov/mep/about/advisory-board.cfm.*

Pursuant to the Federal Advisory Committee Act, as amended, 5 U.S.C. App., notice is hereby given that the MEP Advisory Board will hold an open meeting on Wednesday, September 27, 2017, from 8:00 a.m. to 12:00 p.m. Eastern Time. The meeting agenda will include an update on Hollings MEP programmatic operations, as well as provide guidance and advice to NIST on the development of the 2017–2022 Hollings MEP Strategic Plan. The MEP Advisory Board will also provide input to NIST on developing protocols that will connect user facilities, research, and technologies at NIST and other federal laboratories with the help of the Hollings MEP national network to support small and mid-size manufacturers, and make recommendations on how the Hollings MEP operates as a Learning Organization. This encompasses an effort to strengthen connections by sharing best practices and building Working Groups and Communities of Practice in furtherance of the Hollings MEP Program's mission. The final agenda will be posted on the MEP Advisory Board Web site at *http://www.nist.gov/mep/about/advisory-board.cfm.*

Individuals and representatives of organizations who would like to offer comments and suggestions related to the MEP Advisory Board's business are invited to request a place on the agenda. Approximately 15 minutes will be reserved for public comments at the end of the meeting. Speaking times will be assigned on a first-come, first-served basis. The amount of time per speaker will be determined by the number of requests received but is likely to be no more than three to five minutes each. Requests must be received in writing before September 15, 2017, to be considered. The exact time for public comments will be included in the final agenda that will be posted on the MEP Advisory Board Web site at *http://www.nist.gov/mep/about/advisory-board.cfm.* Questions from the public will not be considered during this period. Speakers who wish to expand upon their oral statements, those who wished to speak but could not be accommodated on the agenda, or those who are/were unable to attend in person are invited to submit written statements to the MEP Advisory Board, National Institute of Standards and Technology, 100 Bureau Drive, Mail Stop 4800, Gaithersburg, Maryland 20899–4800, via fax at (301) 963–6556, or electronically by email to *cheryl.gendron@nist.gov.*

Admittance Instructions: All visitors to the NIST site are required to pre-register to be admitted. Please submit your name, company name, time of arrival, email address and telephone number to Ms. Gendron by 5:00 p.m. Eastern Time, Friday, September 15, 2017. Non-U.S. citizens must submit additional information; please contact Ms. Gendron via email at *cheryl.gendron@nist.gov* or phone (301) 975–2785. For participants planning to attend in person, please note that federal agencies, including NIST, can only accept a state-issued driver's license or identification card for access to federal facilities if such license or identification card is issued by a state that is compliant with the REAL ID Act of 2005 (Pub. L. 109–13), or by a state that Start Printed Page 22648 has an extension for REAL ID compliance. NIST currently accepts other forms of federally-issued identification in lieu of a state-issued driver's license. For detailed information please contact Ms. Gendron at 301–975–2785 or visit: *http://nist.gov/public_affairs/visitor/.*

Phillip A. Singerman,

Associate Director for Innovations and Industry Services.

[FR Doc. 2017–15325 Filed 7–20–17; 8:45 am]

BILLING CODE 3510–13–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XF549

Pacific Islands Pelagic Fisheries; American Samoa Longline Limited Entry Program

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

ACTION: Notice; availability of permits.

SUMMARY: NMFS announces that 12 American Samoa pelagic longline limited entry permits in three vessel size classes are available for 2017. NMFS is accepting applications for these available permits.

DATES: NMFS must receive completed permit applications and payment by November 20, 2017.

ADDRESSES: Request a blank application from the NMFS Pacific Islands Regional Office (PIR), 1845 Wasp Blvd., Bldg. 176, Honolulu, HI 96818, or the PIR Web site *www.fpir.noaa.gov/Library/SFD/Samoa_LE_App_Fillable_03Jun16.pdf.* Mail your completed application and payment to: ASLE Permits, NOAA NMFS PIR, 1845 Wasp Blvd., Bldg. 176, Honolulu, HI 96818.

FOR FURTHER INFORMATION CONTACT: Walter Ikehara, Sustainable Fisheries, NMFS PIR, tel 808–725–5175, fax 808–725–5215, or email *PIRO-permits@noaa.gov.*

SUPPLEMENTARY INFORMATION: Federal regulations at 50 CFR 665.816 allow NMFS to issue new permits for the American Samoa pelagic longline limited entry program if the number of permits in a size class falls below the maximum allowed. At least 12 permits are available for issuance, as follows:

- Ten in Class A (vessels less than or equal to 40 ft in overall length);
- One in Class B (over 40 ft to 50 ft); and
- One in Class C (over 50 to 70 ft).

Please note that the number of available permits may change before the application period closes.

NMFS will only consider complete applications, which must include the completed and signed application form, evidence of documented participation in the fishery, and non-refundable payment for the application-processing fee.

If NMFS receives more completed applications than the number of available permits for a given permit class, NMFS will prioritize applicants using the information in the

applications and documentation provided by the applicants. If an applicant requests NMFS, in writing, to use NMFS longline logbook data as evidence of documented participation, the applicant must specify the qualifying vessel, official number, and month and year of the logbook records (NMFS will not conduct an unlimited search for records).

Applicants with the earliest documented participation in the fishery on a Class A sized vessel will receive the highest priorities for obtaining permits in any size class, followed by applicants with the earliest documented participation in Classes B, C, and D, in that order. In the event of a tie in the priority ranking between two or more applicants, NMFS will rank higher the applicant whose second documented participation is earlier. Detailed criteria for prioritization of eligible applicants are in the regulations at 50 CFR 665.816(g).

NMFS must receive applications by November 20, 2017 to be considered for a permit (see **ADDRESSES**). NMFS will not accept applications received after that date.

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

Dated: July 18, 2017.

Emily H. Menashes,

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

[FR Doc. 2017–15387 Filed 7–20–17; 8:45 am]

BILLING CODE 3510–22–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List: Proposed deletions

AGENCY: Committee for Purchase from People Who are Blind or Severely Disabled.

ACTION: Proposed deletions from the Procurement List.

SUMMARY: The Committee is proposing to delete products and services from the Procurement List that were previously by nonprofit agencies employing persons who are blind or have other severe disabilities.

DATES: Comments must be received on or before: August 20, 2017.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, 1401 S. Clark Street, Suite 715, Arlington, Virginia, 22202–4149.

FOR FURTHER INFORMATION OR TO SUBMIT COMMENTS CONTACT: Amy B. Jensen, Telephone: (703) 603–7740, Fax: (703) 603–0655, or email *CMTEFedReg@AbilityOne.gov.*

SUPPLEMENTARY INFORMATION: This notice is published pursuant to 41 U.S.C. 8503 (a)(2) and 41 CFR 51–2.3. Its purpose is to provide interested persons an opportunity to submit comments on the proposed actions.

Deletions

The following products and services are proposed for deletion from the Procurement List:

Products

NSN(s)—Product Name(s):
8925–01–E62–1749—Walnuts, English, Shelled, Halves and Pieces, 2.75 lb.
8925–01–E62–1745—Almonds, Shelled, Sliced, Natural
8925–01–E62–1746—Almonds, Shelled, Sliced, Blanched
8925–01–E62–1747—Almonds, Shelled, Slivered, Blanched
8925–01–E62–1748—Walnuts, English, Shelled, Halves and Pieces, 2 lb.
Mandatory Source(s) of Supply: Transylvania Vocational Services, Inc., Brevard, NC
Contracting Activity: Defense Logistics Agency Troop Support

NSN(s)—Product Name(s):
7210–01–076–1087—Mattress, Bed, Innerspring, Type III, Firm, White with Blue Stripes, 36″ x 75″
7210–01–076–1082—Mattress, Bed, Innerspring, Type III, Firm, White with Blue Stripes, 36″ x 80″
7210–01–076–1083—Mattress, Bed, Innerspring, Type III, Firm, White with Blue Stripes, 39″ x 78″
7210–01–076–8359—Mattress, Bed, Innerspring, Type III, Extra Firm, White with Blue Stripes, 38″ x 80″
7210–01–076–9031—Mattress, Bed, Innerspring, Type III, Firm, White with Blue Stripes, 29″ x 76″
7210–01–078–2593—Mattress, Bed, Innerspring, Type III, Firm, White with Blue Stripes, 36″ x 78″
7210–01–177–1492—Mattress, Bed, Innerspring, Type II, Firm, White with Blue Stripes, 36″ x 80″
7210–01–177–1494—Mattress, Bed, Innerspring, Type II, Firm, White with Blue Stripes, 38″ x 75″
7210–01–177–1495—Mattress, Bed, Innerspring, Type II, Firm, White with Blue Stripes, 38″ x 80″
7210–01–177–1497—Mattress, Bed, Innerspring, Type II, Firm, White with Blue Stripes, 53″ x 75″
7210–01–177–1498—Mattress, Bed, Innerspring, Type II, Extra Firm, White with Blue Stripes, 29″ x 76″
7210–01–177–1499—Mattress, Bed, Innerspring, Type II, Extra Firm, White with Blue Stripes, 36″ x 75″
7210–01–177–1500—Mattress, Bed, Innerspring, Type II, Extra Firm, White with Blue Stripes, 36″ x 78″
7210–01–177–1501—Mattress, Bed, Innerspring, Type II, Extra Firm, White with Blue Stripes, 36″ x 80″
7210–01–177–1503—Mattress, Bed, Innerspring, Type II, Extra Firm, White with Blue Stripes, 38″ x 75″
7210–01–177–1504—Mattress, Bed, Innerspring, Type II, Extra Firm, White with Blue Stripes, 38″ x 80″
7210–01–177–1505—Mattress, Bed, Innerspring, Type II, Extra Firm, White with Blue Stripes, 39″ x 78″
7210–01–177–1506—Mattress, Bed, Innerspring, Type II, Extra Firm, White with Blue Stripes, 53″ x 75″
7210–01–177–1507—Mattress, Bed, Innerspring, Type III, Regular, White with Blue Stripes, 29″ x 76″
7210–01–177–1508—Mattress, Bed, Innerspring, Type III, Regular, White with Blue Stripes, 36″ x 75″
7210–01–177–1509—Mattress, Bed, Innerspring, Type III, Regular, White with Blue Stripes, 36″ x 78″
7210–01–177–1510—Mattress, Bed, Innerspring, Type III, Regular, White with Blue Stripes, 36″ x 80″
7210–01–177–1512—Mattress, Bed, Innerspring, Type III, Regular, White with Blue Stripes, 38″ x 75″
7210–01–177–1513—Mattress, Bed, Innerspring, Type III, Regular, White with Blue Stripes, 38″ x 80″
7210–01–177–1514—Mattress, Bed, Innerspring, Type III, Regular, White with Blue Stripes, 39″ x 78″
7210–01–177–1515—Mattress, Bed, Innerspring, Type III, Regular, White with Blue Stripes, 53″ x 75″
7210–01–177–3628—Mattress, Bed, Innerspring, Type II, Firm, White with Blue Stripes, 36″ x 75″
Mandatory Source(s) of Supply:
Mississippi Industries for the Blind, Jackson, MS
LC Industries, Inc., Durham, NC
Winston-Salem Industries for the Blind, Inc., Winston-Salem, NC
Lions Volunteer Blind Industries, Inc., Morristown, TN
Virginia Industries for the Blind, Charlottesville, VA
Contracting Activity: General Services Administration, Fort Worth, TX

NSN(s)—Product Name(s): 6545–01–584–1582—Kit, Improved First Aid, Army, OCP
Mandatory Source(s) of Supply: Southeastern Kentucky Rehabilitation Industries, Inc., Corbin, KY
Contracting Activity: Defense Logistics Agency Troop Support

NSN(s)—Product Name(s):
8415–00–NSH–1699—Shirt, Underwear, Lightweight Cold Weather Mock Turtle, Marine Corps, Coyote, X Small
Mandatory Source(s) of Supply: Peckham Vocational Industries, Inc., Lansing, MI
Contracting Activity: W40M NORTHEREGION CONTRACT OFC

NSN(s)—Product Name(s):
8415–01–543–7018—Trousers, ECWCS. Level 2, PCU, Army, Brown, M–L
8415–01–542–7642—Trousers, ECWCS. Level 2, PCU, Army, Brown, XS
8415–01–542–8534—Trousers, Lightweight Insulating, Level 2, ECWCS, PCU, Army, Brown, XXL
8415–01–542–8538—Trousers, Lightweight Insulating, Level 2, ECWCS, PCU, Army, Brown, XXXLL

8415–01–542–8540—Trousers, Lightweight Insulating, Level 2, ECWCS, PCU, Army, Brown, XXXL
8415–01–542–8542—Trousers, ECWCS, Insulating Level 2, PCU, Army, Brown, S
8415–01–542–8546—Trousers, Lightweight Insulating, Level 2, ECWCS, PCU, Army, Brown, L
8415–01–542–8549—Trousers, Lightweight Insulating, Level 2, ECWCS, PCU, Army, Brown, L–L
8415–01–542–8552—Trousers, Lightweight Insulating, Level 2, ECWCS, PCU, Army, Brown, XL
8415–01–542–8553—Trousers, Lightweight Insulating, Level 2, ECWCS, PCU, Army, Brown, XL–L
8415–01–542–8555—Trousers, Lightweight Insulating, Level 2, ECWCS, PCU, Army, Brown, XXLL
8415–01–542–9612—Trousers, Lightweight Combat, Level 2, ECWCS, PCU, Army, Brown, MR
8415–01–542–8545—Shirt, Lightweight, Level 2, ECWCS, PCU, Army, Long Sleeved, Brown, XXLL
8415–01–542–9576—Shirt, Lightweight, Level 2, ECWCS, PCU, Army, Long Sleeved, Brown, S
8415–01–542–9598—Shirt, Lightweight, Level 2, ECWCS, PCU, Army, Long Sleeved, Brown, M
8415–01–542–9609—Shirt, Lightweight, Level 2, ECWCS, PCU, Army, Long Sleeved, Brown, XL–L
8415–01–542–9613—Shirt, Lightweight, Level 2, ECWCS, PCU, Army, Long Sleeved, Brown, XXXL
8415–01–542–9615—Shirt, Lightweight, Level 2, ECWCS, PCU, Army, Long Sleeved, Brown, XXXLL
8415–01–542–9617—Shirt, Lightweight, Level 2, ECWCS, PCU, Army, Long Sleeved, Brown, XXL
8415–01–543–7047—Shirt, Level 2, ECWCS, PCU, Army, Long Sleeved, Brown, M–L

Mandatory Source(s) of Supply: Southeastern Kentucky Rehabilitation Industries, Inc., Corbin, KY
Contracting Activity: Army Contracting Command—Aberdeen Proving Ground, Natick Contracting Division

NSN(s)—Product Name(s):
8105–01–352–1390—Bag, Contamination
8105–01–352–1391—Bag, Contamination, 12″ x 24″
8105–01–352–1392—Bag, Contamination, 24″ x 24″
8105–01–352–1394—Bag, Contamination, 36″ x 60″

Mandatory Source(s) of Supply: Relay Resources, Portland, OR
Contracting Activity: Naval Supply Systems Command

NSN(s)—Product Name(s): 6135–01–275–1363—Battery, Non-Rechargeable, 6.0V, Alkaline, NEDA 1412A
Mandatory Source(s) of Supply: Eastern Carolina Vocational Center, Inc., Greenville, NC
Contracting Activity: Defense Logistics Agency Land and Maritime

NSN(s)—Product Name(s):
6545–00–NIB–0058—Kit, Collection, Specimen, Bag, Transparent
6545–00–NIB–0059—Kit, Collection, Specimen, Bottle, White

Mandatory Source(s) of Supply: Alphapointe, Kansas City, MO
Contracting Activity: U.S. Fleet Forces Command

NSN(s)—Product Name(s):
7510–01–584–0893—Business Card Holder, Rosewood
7520–01–554–5467—Rosewood Deluxe Office Start-Up Kit

Mandatory Source(s) of Supply: Tarrant County Association for the Blind, Fort Worth, TX
Contracting Activity: General Services Administration, New York, NY

NSN(s)—Product Name(s):
7520–01–451–9188—Pen Set, Ballpoint and Fountain, Executive, Metallic Burgundy, Medium Point
7520–01–451–9192—Pen Set, Ballpoint and Fountain, Executive, Metallic Blue, Medium Point
7510–01–451–9186—Refill, Executive Fountain Pen, Blue Ink
7510–01–451–9191—Refill, Executive Fountain Pen, Black Ink
7520–01–451–2278—Pen, Executive Fountain, Refillable, Blue Barrel, Fine Tip
7520–01–451–2274—Pen, Executive, Twist Retractable, Refillable, Navy Blue, Blue Ink, Fine Point
7520–01–451–2275—Pen, Executive, Twist Retractable, Refillable, Burgundy, Black Ink, Fine Point
7520–01–451–2276—Pen, Executive, Twist Retractable, Refillable, Gun Metal, Blue Ink, Medium Point
7520–01–451–2279—Pen, Executive, Twist Retractable, Refillable, Black, Black Ink, Medium Point

Mandatory Source(s) of Supply: Industries for the Blind, Inc., West Allis, WI
Contracting Activity: General Services Administration, New York, NY

Services

Service Type: Assembly of Backpack Pump Outfit Service
Mandatory for: GSA, Southwest Supply Center: 819 Taylor Street, Fort Worth, TX
Mandatory Source(s) of Supply: Expanco, Inc., Fort Worth, TX
Contracting Activity: General Services Administration, Fort Worth, TX
Service Type: Janitorial/Custodial Service
Mandatory for: Naval & Marine Corps Reserve Center: 1620 East Saginaw Street, Lansing, MI
Mandatory Source(s) of Supply: Peckham Vocational Industries, Inc., Lansing, MI
Contracting Activity: Dept of the Navy, Naval FAC Engineeering CMD Midwest
Service Type: Janitorial/Custodial Service
Mandatory for: Atlanta Naval Air Station: 1000 Halsey Avenue, Marietta, GA
Mandatory Source(s) of Supply: Nobis Enterprises, Inc., Marietta, GA
Contracting Activity: Dept of the Navy, Naval FAC Engineeering CMD

Amy B. Jensen,

Director, Business Operations.

[FR Doc. 2017–15385 Filed 7–20–17; 8:45 am]

BILLING CODE 6353–01–P

CONSUMER PRODUCT SAFETY COMMISSION

[Docket No. CPSC–2010–0046]

Submission for OMB Review; Comment Request—Consumer Focus Groups

AGENCY: Consumer Product Safety Commission.

ACTION: Notice.

SUMMARY: As required by the Paperwork Reduction Act of 1995, the Consumer Product Safety Commission (CPSC or Commission) announces that the CPSC has submitted to the Office of Management and Budget (OMB), a request for extension of approval of a collection of information from persons who may voluntarily participate in consumer focus groups. In the **Federal Register** of May 3, 2017 (82 FR 20589), the CPSC published a notice announcing the agency's intent to seek an extension of approval of this collection of information. CPSC received no comments in response to that notice. Therefore, by publication of this notice, the Commission announces that CPSC has submitted to the OMB a request for extension of approval of that collection of information without change.

DATES: Written comments on this request for extension of approval of information collection requirements should be submitted by August 21, 2017.

ADDRESSES: Submit comments about this request by email: *OIRA_submission@omb.eop.gov* or fax: 202–395–6881. Comments by mail should be sent to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for the CPSC, Office of Management and Budget, Room 10235, 725 17th Street NW., Washington, DC 20503. In addition, written comments that are sent to OMB also should be submitted electronically at *http://www.regulations.gov,* under Docket No. CPSC–2010–0046.

FOR FURTHER INFORMATION CONTACT: Charu S. Krishnan, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; (301) 504–7221, or by email to: *ckrishnan@cpsc.gov.*

SUPPLEMENTARY INFORMATION: CPSC seeks to renew the following currently approved collection of information:

Title: Consumer Focus Groups.
OMB Number: 3041–0136.
Type of Review: Renewal of collection.
Frequency of Response: On occasion.

Affected Public: Consumers.

Estimated Number of Respondents: 650 participants.

Estimated Time per Response: 3 hours.

Total Estimated Annual Burden: 1,950 hours (650 participants × 3 hours).

General Description of Collection: Section 5(a) of the Consumer Product Safety Act (CPSA), 15 U.S.C. 2054(a), authorizes the Commission to conduct studies and investigations relating to the causes and prevention of deaths, accidents, injuries, illnesses, other health impairments, and economic losses associated with consumer products. Section 5(b) of the CPSA, 15 U.S.C. 2054(b), further provides that the Commission may conduct research, studies and investigations on the safety of consumer products or test consumer products and develop product safety test methods and testing devices.

To help identify and evaluate product-related incidents, Commission staff invites and obtains direct feedback from consumers on issues related to product safety, such as recall effectiveness, product use, and perceptions regarding safety issues. The information that the CPSC collects from future focus groups will help inform the Commission's identification and evaluation of consumer products and product use, by providing insight and information into consumer perceptions and usage patterns. In some cases, one-on-one interviews may be conducted as a more in-depth extension of a focus group or in place of a traditional focus group. This information may also assist the Commission in its efforts to support voluntary standards activities and help CPSC identify consumer safety issues requiring additional research. In addition, based on the information obtained, CPSC may be able to provide safety information to the public that is easier to read and understood by a wider range of consumers.

Dated: July 17, 2017.

Todd A. Stevenson,

Secretary, Consumer Product Safety Commission.

[FR Doc. 2017–15278 Filed 7–20–17; 8:45 am]

BILLING CODE 6355–01–P

CONSUMER PRODUCT SAFETY COMMISSION

[Docket No. CPSC–2010–0054]

Submission for OMB Review; Comment Request—Procedures for Export of Noncomplying Products

AGENCY: Consumer Product Safety Commission.

ACTION: Notice.

SUMMARY: As required by the Paperwork Reduction Act of 1995, the Consumer Product Safety Commission (CPSC or Commission) announces that the CPSC has submitted to the Office of Management and Budget (OMB) a request for extension of approval of a collection of information relating to the procedures for the export of noncomplying products (OMB No. 3041–0003). In the **Federal Register** of May 3, 2017 (84 FR 20590), the CPSC published a notice announcing the agency's intent to seek an extension of approval of this collection of information. CPSC received no comments in response to that notice. Therefore, by publication of this notice, the Commission announces that CPSC has submitted to the OMB a request for extension of approval of that collection of information without change.

DATES: Written comments on this request for extension of approval of information collection requirements should be submitted by August 21, 2017.

ADDRESSES: Submit comments about this request by email: *OIRA_submission@omb.eop.gov* or fax: 202–395–6881. Comments by mail should be sent to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for the CPSC, Office of Management and Budget, Room 10235, 725 17th Street NW., Washington, DC 20503. In addition, written comments that are sent to OMB also should be submitted electronically at *http://www.regulations.gov,* under Docket No. CPSC–2010–0054.

FOR FURTHER INFORMATION CONTACT: Charu S. Krishnan, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; (301) 504–7221, or by email to: *ckrishnan@cpsc.gov.*

SUPPLEMENTARY INFORMATION: CPSC seeks to renew the following currently approved collection of information:

Title: Procedures for the Export of Noncomplying Products.

OMB Number: 3041–0003.

Type of Review: Renewal of collection.

Frequency of Response: On occasion.

Affected Public: Exporters of products that do not comply with Commission requirements.

Estimated Number of Respondents: 5 exporters will file approximately 9 notifications.

Estimated Time per Response: 1 hour per notification.

Total Estimated Annual Burden: 45 hours (5 exporters × 9 notifications × 1 hour).

General Description of Collection: The Commission has procedures that exporters must follow to notify the Commission of the exporter's intent to export products that are banned or fail to comply with an applicable CPSC safety standard, regulation, or statute. Respondents must comply with the requirements in 16 CFR part 1019 and file a statement with the Commission in accordance with these requirements.

Dated: July 17, 2017.

Todd A. Stevenson,

Secretary, Consumer Product Safety Commission.

[FR Doc. 2017–15280 Filed 7–20–17; 8:45 am]

BILLING CODE 6355–01–P

CONSUMER PRODUCT SAFETY COMMISSION

[Docket No. CPSC–2011–0014]

Submission for OMB Review; Comment Request—Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery

AGENCY: Consumer Product Safety Commission.

ACTION: Notice.

SUMMARY: As required by the Paperwork Reduction Act of 1995, the Consumer Product Safety Commission (CPSC or Commission) announces that the CPSC has submitted to the Office of Management and Budget (OMB) a request for extension of approval of a collection of information relating to the generic clearance for the collection of qualitative feedback on agency service delivery (OMB No. 3041–0148). In the **Federal Register** of May 3, 2017 (82 FR 20591), the CPSC published a notice announcing the agency's intent to seek an extension of approval of this collection of information. CPSC received no comments in response to that notice. Therefore, by publication of this notice, the Commission announces that CPSC has submitted to the OMB a request for extension of approval of that collection of information without change.

DATES: Written comments on this request for extension of approval of information collection requirements should be submitted by August 21, 2017.

ADDRESSES: Submit comments about this request by email: *OIRA_submission@omb.eop.gov* or fax: 202–395–6881. Comments by mail should be sent to the Office of Information and

Regulatory Affairs, Attn: OMB Desk Officer for the CPSC, Office of Management and Budget, Room 10235, 725 17th Street NW., Washington, DC 20503. In addition, written comments that are sent to OMB also should be submitted electronically at *http://www.regulations.gov,* under Docket No. CPSC–2011–0014.

FOR FURTHER INFORMATION CONTACT: Charu S. Krishnan, Consumer Product Safety Commission, 4330 East-West Highway, Bethesda, MD 20814; (301) 504–7221, or by email to: *ckrishnan@cpsc.gov.*

SUPPLEMENTARY INFORMATION:

Burden Hours

Title: Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery.

OMB Number: 3041–0148.

Type of Review: Renewal of collection.

Frequency of Response: On occasion.

Affected Public: Individuals and households, businesses and organizations, state, local, or tribal government.

Average Expected Annual Number of Activities: Eight activities, including qualitative surveys, focus groups, customer satisfaction surveys, and usability tests.

Annual Number of Respondents: 1,600.

Annual responses: 1,600.

Frequency of Response: Once per request.

Average Minutes per Response: 45 minutes per response.

Annual Burden Hours: 1,200.

General Description of Collection: The CPSC will collect, analyze, and interpret information gathered through this generic clearance to identify strengths and weaknesses of current services and make improvements in service delivery based on feedback obtained through these activities. The solicitation of feedback will target areas such as: Timeliness, appropriateness, and accuracy of information; courtesy; efficiency of service delivery; and resolution of issues with service delivery. We will use the responses to plan and inform efforts to improve or maintain the quality of service CPSC offers to the public.

Dated: July 17, 2017.

Todd A. Stevenson,

Secretary, Consumer Product Safety Commission.

[FR Doc. 2017–15279 Filed 7–20–17; 8:45 am]

BILLING CODE 6355–01–P

CONSUMER PRODUCT SAFETY COMMISSION

[Docket No. CPSC–2010–0056]

Agency Information Collection Activities; Proposed Extension of Approval of Information Collection; Comment Request—Safety Standard for Bicycle Helmets

AGENCY: Consumer Product Safety Commission.

ACTION: Notice.

SUMMARY: In accordance with the requirements of the Paperwork Reduction Act (PRA) of 1995, the Consumer Product Safety Commission (Commission or CPSC) invites comments on a proposed request for extension of approval of a collection of information relating to the Safety Standard for Bicycle Helmets (OMB No. 3041–0127). The Commission will consider all comments received in response to this notice before requesting an extension of approval of this collection of information from the Office of Management and Budget (OMB).

DATES: The Office of the Secretary must receive comments not later than September 19, 2017.

ADDRESSES: You may submit comments, identified by Docket No. CPSC–2010–0056, by any of the following methods:

Electronic Submissions: Submit electronic comments to the Federal eRulemaking Portal at: *http://www.regulations.gov.* Follow the instructions for submitting comments. The Commission does not accept comments submitted by electronic mail (email), except through *www.regulations.gov.* The Commission encourages you to submit electronic comments by using the Federal eRulemaking Portal, as described above.

Written Submissions: Submit written submissions by mail/hand delivery/courier to: Office of the Secretary, Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814; telephone (301) 504–7923.

Instructions: All submissions received must include the agency name and docket number for this notice. All comments received may be posted without change, including any personal identifiers, contact information, or other personal information provided, to: *http://www.regulations.gov.* Do not submit confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public. If furnished at all, such information should be submitted in writing.

Docket: For access to the docket to read background documents or comments received, go to: *http://www.regulations.gov,* and insert the docket number CPSC–2010–0056, into the ''Search'' box, and follow the prompts.

FOR FURTHER INFORMATION CONTACT: For further information contact: Charu Krishnan, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; (301) 504–7221, or by email to: *ckrishnan@cpsc.gov.*

SUPPLEMENTARY INFORMATION: CPSC seeks to renew the following collection of information:

Title: Safety Standard for Bicycle Helmets.

OMB Number: 3041–0127.

Type of Review: Renewal of collection.

Frequency of Response: On occasion.

Affected Public: Manufacturers and importers of bicycle helmets.

Estimated Number of Respondents: 38 manufacturers and importers will maintain test records of an estimated 200 models total annually, including older models and new models. Testing on bicycle helmets must be conducted for each new production lot and the test records must be maintained for 3 years.

Estimated Time per Response: 200 hours/model to test 40 new models (including new prototypes) and an estimated 100 hours/model to test new production lots of 160 older models. Additionally, manufacturers and importers may require 4 hours annually per model for recordkeeping for approximately 200 models.

Total Estimated Annual Burden: 24,800 hours (24,000 hours for testing and 800 hours for recordkeeping).

General Description of Collection: In 1998, the Commission issued a safety standard for bicycle helmets (16 CFR part 1203). The standard includes requirements for labeling and instructions. The standard also requires that manufacturers and importers of bicycle helmets subject to the standard issue certificates of compliance based on a reasonable testing program. Every person issuing certificates of compliance must maintain certain records. Respondents must comply with the requirements in 16 CFR part 1203 for labeling and instructions, testing, certification, and recordkeeping.

Request for Comments

The Commission solicits written comments from all interested persons about the proposed collection of information. The Commission specifically solicits information relevant to the following topics:

- Whether the collection of information described above is necessary for the proper performance of the Commission's functions, including whether the information would have practical utility;
- Whether the estimated burden of the proposed collection of information is accurate;
- Whether the quality, utility, and clarity of the information to be collected could be enhanced; and
- Whether the burden imposed by the collection of information could be minimized by use of automated, electronic or other technological collection techniques, or other forms of information technology.

Dated: July 17, 2017.

Todd A. Stevenson,

Secretary, Consumer Product Safety Commission.

[FR Doc. 2017–15277 Filed 7–20–17; 8:45 am]

BILLING CODE 6355–01–P

CONSUMER PRODUCT SAFETY COMMISSION

[Docket No. CPSC–2010–0053]

Submission for OMB Review; Comment Request—Safety Standard for Multi-Purpose Lighters

AGENCY: Consumer Product Safety Commission.

ACTION: Notice.

SUMMARY: As required by the Paperwork Reduction Act of 1995, the Consumer Product Safety Commission (CPSC or Commission) announces that the CPSC has submitted to the Office of Management and Budget (OMB) a request for extension of approval of a collection of information associated with the Safety Standard for Multi-Purpose Lighters (OMB No. 3041–0130). In the **Federal Register** of May 3, 2017 (82 FR 20591), the CPSC published a notice to announce the agency's intent to seek an extension of approval of this collection of information. CPSC received no comments in response to that notice. Therefore, by publication of this notice, the Commission announces that CPSC has submitted to the OMB a request for extension of approval of that collection of information without change.

DATES: Written comments on this request for extension of approval of information collection requirements should be submitted by August 21, 2017.

ADDRESSES: Submit comments about this request by email: *OIRA_submission@omb.eop.gov* or fax: 202–395–6881. Comments by mail should be sent to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for the CPSC, Office of Management and Budget, Room 10235, 725 17th Street NW., Washington, DC 20503. In addition, written comments that are sent to OMB also should be submitted electronically at *http://www.regulations.gov,* under Docket No. CPSC–2010–0053.

FOR FURTHER INFORMATION CONTACT: Charu S. Krishnan, Consumer Product Safety Commission, 4330 East-West Highway, Bethesda, MD 20814; (301) 504–7221, or by email to: *ckrishnan@cpsc.gov.*

SUPPLEMENTARY INFORMATION: CPSC seeks to renew the following currently approved collection of information:

Title: Safety Standard for Multi-Purpose Lighters.

OMB Number: 3041–0130.

Type of Review: Renewal of collection.

Frequency of Response: On occasion.

Affected Public: Manufacturers and importers of multi-purpose lighters.

Estimated Number of Respondents: 61 firms will test on average 2 models per firm.

Estimated Time per Response: 50 hours/model.

Total Estimated Annual Burden: 6,100 hours (61 firms × 2 models × 50 hours).

General Description of Collection: The Commission issued a safety standard for multi-purpose lighters (16 CFR part 1212) in 1999. The standard includes requirements that manufacturers (including importers) of multi-purpose lighters issue certificates of compliance based on a reasonable testing program. The standard also requires that manufacturers and importers maintain certain records. Respondents must comply with these testing, certification, and recordkeeping requirements for multi-purpose lighters.

Dated: July 17, 2017.

Todd A. Stevenson,

Secretary, Consumer Product Safety Commission.

[FR Doc. 2017–15281 Filed 7–20–17; 8:45 am]

BILLING CODE 6355–01–P

DEPARTMENT OF DEFENSE

Department of the Army

[Docket ID USA–2015–0028]

Submission for OMB Review; Comment Request

ACTION: Notice.

SUMMARY: The Department of Defense has submitted to OMB for clearance, the following proposal for collection of information under the provisions of the Paperwork Reduction Act.

DATES: Consideration will be given to all comments received by August 21, 2017.

FOR FURTHER INFORMATION CONTACT: Fred Licari, 571–372–0493.

SUPPLEMENTARY INFORMATION:

Title, Associated Form and OMB Number: U.S. Army Corps of Engineers Customer Service Survey, ENG Form 5065, OMB Control Number 0710–0012.

Type of Request: Reinstatement with change.

Number of Respondents: 2,000.

Responses per Respondent: 1.

Annual Responses: 2,000.

Average Burden per Response: 10 minutes.

Annual Burden Hours: 333 hours.

Needs and Uses: The information collection requirement is necessary for the Corps to conduct surveys of customers served by our district offices, currently a total of 38 offices. Only voluntary opinions will be solicited and no information requested on the survey instrument will be mandatory. The survey form will be provided to the applicants when they receive a regulatory product, primarily a permit decision or wetland determination. The information collected will be used to assess whether Regulatory business practices or policies warrant revision to better serve the public. Without this survey the Corps would have to rely on less structured, informal methods of obtaining public input. The data collection instrument was minimized for respondent burden, while maximizing data quality. The following strategies were used to achieve these goals: 1. Questions are clearly written, 2. The questionnaire is of reasonable length, 3. The questionnaire includes only items that have been shown to be successful in previous analyses and ease in navigation.

Affected Public: Individuals or households; Business or other for-profit; Not-for-profit institutions; Farms; State, local, or tribal government.

Frequency: On occasion.

Respondent's Obligation: Voluntary.

OMB Desk Officer: Mr. Vlad Dorjets.

Comments and recommendations on the proposed information collection should be emailed to Mr. Vlad Dorjets, DoD Desk Officer, at *Oira_submission@omb.eop.gov.* Please identify the proposed information collection by DoD Desk Officer and the Docket ID number and title of the information collection.

You may also submit comments and recommendations, identified by Docket

ID number and title, by the following method:

• *Federal eRulemaking Portal*: *http://www.regulations.gov.* Follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name, Docket ID number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

DOD Clearance officer: Mr. Frederick Licari.

Written requests for copies of the information collection proposal should be sent to Mr. Licari at WHS/ESD Directives Division, 4800 Mark Center Drive, East Tower, Suite 03F09, Alexandria, VA 22350–3100.

Dated: July 18, 2017.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2017–15341 Filed 7–20–17; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal No. 16–77]

Arms Sales Notification

AGENCY: Defense Security Cooperation Agency, Department of Defense.

ACTION: Notice.

SUMMARY: The Department of Defense is publishing the unclassified text of an arms sales notification.

FOR FURTHER INFORMATION CONTACT: Pamela Young, (703) 697–9107 or Kathy Valadez, (703) 697–9217; DSCA/DSA–RAN.

SUPPLEMENTARY INFORMATION: This 36(b)(1) arms sales notification is published to fulfill the requirements of section 155 of Public Law 104–164 dated July 21, 1996. The following is a copy of a letter to the Speaker of the House of Representatives, Transmittal 16–77 with attached Policy Justification.

Dated: July 17, 2017.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

DEFENSE SECURITY COOPERATION AGENCY
201 12TH STREET SOUTH, STE 203
ARLINGTON, VA 22202-5408

JUN 02 2017

The Honorable Paul D. Ryan
Speaker of the House
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, as amended, we are forwarding herewith Transmittal No. 16-77, concerning the Air Force's proposed Letter(s) of Offer and Acceptance to the Kingdom of Saudi Arabia for defense articles and services estimated to cost $750 million. After this letter is delivered to your office, we plan to issue a news release to notify the public of this proposed sale.

Sincerely,

J. W. Rixey
Vice Admiral, USN
Director

Enclosures:
1. Transmittal
2. Policy Justification
3. Regional Balance (Classified document provided under separate cover)

Transmittal No. 16–77

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act, as amended

(i) *Prospective Purchaser:* Kingdom of Saudi Arabia

(ii) *Total Estimated Value:*

Major Defense Equipment *	$ 0 million
Other	$750 million
Total	$750 million

(iii) *Description and Quantity or Quantities of Articles or Services under Consideration for Purchase:*

Major Defense Equipment (MDE): None

Non-MDE includes:

Continuation of a blanket order training program inside and outside of the Kingdom of Saudi Arabia that includes, but is not limited to, flight training, technical training, professional military education, specialized training, mobile training teams (MTTs), and English language training. These blanket order training cases will cover all relevant types of training offered by or contracted through the U.S. Air Force or Department of Defense Agencies (DOD), to include participation in CONUS DOD-sponsored education, as well as MTTs that will travel to Saudi Arabia. This training for the Royal Saudi Air Force (RSAF) and other Saudi forces will include such subjects as civilian

casualty avoidance, the law of armed conflict, human rights command and control, and targeting via MTTs and/or broader Programs of Instruction (POIs). Program management, trainers, simulators, travel, billeting, and medical support may also be included.

(iv) *Military Department:* Air Force

(v) *Prior Related Cases, if any:*

FMS Case NFS—$44M
FMS Case NFU—$82M
FMS Case THB—$93M
FMS Case THE—$69M
FMS Case THG—$93M
FMS Case NFT—$48M
FMS Case TGP—$53M
FMS Case THD—$73M
FMS Case THF—$39M

(vi) *Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid:* None

(vii) *Sensitivity of Technology Contained in the Defense Article or Defense Services Proposed to be Sold:* None

(viii) *Date Report Delivered to Congress:* June 2, 2017

*As defined in Section 47(6) of the Arms Export Control Act.

Policy Justification

Saudi Arabia—Blanket Order Training

The Government of Saudi Arabia requested a possible sale of continued blanket order training program inside and outside of the Kingdom of Saudi Arabia that includes, but is not limited to, flight training, technical training, professional military education, specialized training, mobile training teams (MTTs), and English language training. These blanket order training cases cover all relevant types of training offered by or contracted through the U.S. Air Force or Department of Defense (DoD) Agencies, to include participation in CONUS DOD-sponsored education, as well as MTTs that will travel to Saudi Arabia. This training for the Royal Saudi Air Force (RSAF) and other Saudi forces will include such subjects as civilian casualty avoidance, the law of armed conflict, human rights command and control, and targeting via MTTs and/or broader Programs of Instruction (POIs). Program management, trainers, simulators, travel, billeting, and medical support may also be included. The estimated program cost is $750 million.

This proposed sale will contribute to the foreign policy and national security of the United States by helping to improve the security of an important partner which has been and continues to be a leading contributor of political stability and economic progress in the Middle East.

This training would support the United States' continued commitment to Saudi Arabia's security and strengthen the U.S.-Saudi Arabia strategic partnership. Assisting the RSAF supports Saudi Arabia in deterring hostile actions and increases U.S.-Saudi Arabia military interoperability. It also helps their ability to work with coalition partners during training, exercises, and operations. Saudi Arabia will have no difficulty absorbing this training and support.

The proposed sale of this equipment and support will not alter the basic military balance in the region.

Implementation of this proposed sale will not require the assignment of any additional U.S. Government or contractor representatives to Saudi Arabia.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale. All defense articles/services have been approved for release.

[FR Doc. 2017–15319 Filed 7–20–17; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF EDUCATION

[Docket No. ED–2017–ICCD–0064]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Annual Report of Children in State Agency and Locally Operated Institutions for Neglected or Delinquent Children

AGENCY: Office of Elementary and Secondary Education (OESE), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is proposing an extension of an existing information collection.

DATES: Interested persons are invited to submit comments on or before August 21, 2017.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use *http://www.regulations.gov* by searching the Docket ID number ED–2017–ICCD–0064. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. *Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Information Collection Clearance Division, U.S. Department of Education, 400 Maryland Avenue SW., LBJ, Room 216–42, Washington, DC 20202–4537.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Todd Stephenson, 202–205–1645.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Annual Report of Children in State Agency and Locally Operated Institutions for Neglected or Delinquent Children.

OMB Control Number: 1810–0060.

Type of Review: An extension of an existing information collection.

Respondents/Affected Public: State, Local, and Tribal Governments.

Total Estimated Number of Annual Responses: 2,812.

Total Estimated Number of Annual Burden Hours: 4,061.

Abstract: An annual survey is conducted to collect data on (1) the number of children enrolled in educational programs of State-operated institutions for neglected or delinquent (N or D) children, community day programs for N or D children, and adult correctional institutions and (2) the October caseload of N or D children in

local institutions. The U.S. Department of Education is required to use these data to calculate allocations under parts A and D of Title I of the Elementary and Secondary Education Act, as amended by the Every Student Succeeds Act.

Dated: July 18, 2017.

Tomakie Washington,

Acting Director, Information Collection Clearance Division, Office of the Chief Privacy Officer, Office of Management.

[FR Doc. 2017–15362 Filed 7–20–17; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket No. ED–2017–ICCD–0107]

Agency Information Collection Activities; Comment Request; Annual Protection and Advocacy of Individual Rights (PAIR) Program Assurances

AGENCY: Office of Special Education and Rehabilitative Services (OSERS), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is proposing an extension of an existing information collection.

DATES: Interested persons are invited to submit comments on or before September 19, 2017.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use *http://www.regulations.gov* by searching the Docket ID number ED–2017–ICCD–0107. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. *Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Information Collection Clearance Division, U.S. Department of Education, 400 Maryland Avenue SW., LBJ, Room 216–42, Washington, DC 20202–4537.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Samuel Pierre, 202–245–6488.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Annual Protection and Advocacy of Individual Rights (PAIR) Program Assurances.

OMB Control Number: 1820–0625.

Type of Review: An extension of an existing information collection.

Respondents/Affected Public: Private Sector.

Total Estimated Number of Annual Responses: 57.

Total Estimated Number of Annual Burden Hours: 9.

Abstract: Section 509 of the Rehabilitation Act of 1973, as amended (act), and its implementing Federal Regulations at 34 CFR part 381, require the Protection and Advocacy of Individual Rights (PAIR) grantees to submit an application to the Rehabilitation Services Administration (RSA) Commissioner in order to receive assistance under Section 509 of the act. The act requires that the application contain Assurances to which the grantee must comply. Section 509(f) of the act specifies the Assurances. There are 57 PAIR grantees. All 57 grantees are required to be part of the protection and advocacy system in each State established under the Developmental Disabilities Assistance and Bill of Rights Act of 2000 (42 U.S.C. 6041 *et seq.*).

Dated: July 18, 2017.

Tomakie Washington,

Acting Director, Information Collection Clearance Division, Office of the Chief Privacy Officer, Office of Management.

[FR Doc. 2017–15363 Filed 7–20–17; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2016–ICCD–0147]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Mandatory Civil Rights Data Collection

AGENCY: Office for Civil Rights (OCR), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is proposing a revision of an existing information collection.

DATES: Interested persons are invited to submit comments on or before August 21, 2017.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use *http://www.regulations.gov* by searching the Docket ID number ED–2016–ICCD–0147. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. *Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Information Collection Clearance Division, U.S. Department of Education, 400 Maryland Avenue SW., LBJ, Room 216–34, Washington, DC 20202–4537.

FOR FURTHER INFORMATION CONTACT: For specific questions related to the collection activities, please contact Rosa Olmeda, 202–453–5968.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also

helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Mandatory Civil Rights Data Collection.

OMB Control Number: 1870–0504.

Type of Review: A revision of an existing information collection.

Respondents/Affected Public: State, Local, or Tribal Governments.

Total Estimated Number of Annual Responses: 17,621.

Total Estimated Number of Annual Burden Hours: 1,521,827.

Abstract: The collection, use, and reporting of education data is an integral component of the mission of the U.S. Department of Education (ED). EDFacts, an ED initiative to put performance data at the center of ED's policy, management, and budget decision-making processes for all K–12 education programs, has transformed the way in which ED collects and uses data. For school years 2009–10 and 2011–12, the Civil Rights Data Collection (CRDC) was approved by OMB as part of the EDFacts information collection (1875–0240). For school years 2013–14 and 2015–16, the Office for Civil Rights (OCR) cleared the CRDC as a separate collection from EDFacts. OCR used the most current EDFacts information collection approved by OMB (1875–0240) as a model for the 2013–14 and 2015–16 CRDC information collections that were approved by OMB (1870–0504). Similarly, the currently proposed revised CRDC information collection for school year 2017–18 is modeled after the most recent OMB-approved EDFacts information collection (1850–0925). For the 2017–18 CRDC, OCR is proposing few changes, and those changes will have the net effect of reducing burden on school districts. As with previous CRDC collections, the purpose of the 2017–18 CRDC is to obtain vital data related to the civil rights laws' requirement that public local educational agencies (LEAs) and elementary and secondary schools provide equal educational opportunity. ED has analyzed the uses of many data elements collected in the 2013–14 and 2015–16 CRDCs and sought advice from experts across ED to refine, improve, and where appropriate, add or remove data elements from the collection. ED also made the CRDC data definitions and metrics consistent with other mandatory collections across ED wherever possible. ED seeks OMB approval under the Paperwork Reduction Act to collect from LEAs, the elementary and secondary education data described in the sections of Attachment A. In addition, ED requests that LEAs and other stakeholders respond to the directed questions found in Attachment A–5.

Dated: July 17, 2017.

Stephanie Valentine,

Acting Director, Information Collection Clearance Division, Office of the Chief Privacy Officer, Office of Management.

[FR Doc. 2017–15293 Filed 7–20–17; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Applications for New Awards; Promise Neighborhoods Program

AGENCY: Office of Innovation and Improvement, Department of Education.

ACTION: Notice.

SUMMARY: The Department of Education is issuing a notice inviting applications for new awards for fiscal year (FY) 2017 for the Promise Neighborhoods Program—Grant Competition, Catalog of Federal Domestic Assistance (CFDA) number 84.215N.

DATES: Applications Available: July 21, 2017.

Deadline for Notice of Intent to Apply: August 21, 2017.

Date of Pre-Application Webinars: The Promise Neighborhoods team intends to hold pre-application webinars to provide technical assistance to interested applicants. Detailed information regarding these webinar times will be provided on the Promise Neighborhoods' Web site at *https://innovation.ed.gov/what-we-do/parental-options/promise-neighborhoods-pn/.*

Deadline for Transmittal of Applications: September 5, 2017.

Deadline for Intergovernmental Review: November 3, 2017.

FOR FURTHER INFORMATION CONTACT: Adrienne Hawkins, U.S. Department of Education, 400 Maryland Avenue SW., Room 4W256, Washington, DC 20202. Telephone: (202) 453–5638 or by email: *PromiseNeighborhoods@ed.gov.*

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call the Federal Relay Service (FRS), toll free, at 1–800–877–8339.

SUPPLEMENTARY INFORMATION:

Full Text of Announcement

I. Funding Opportunity Description

Purpose of Program

The Promise Neighborhoods program is newly authorized under the Elementary and Secondary Education Act of 1965 (ESEA), as amended by the Every Student Succeeds Act (ESSA). The purpose of the Promise Neighborhoods program is to significantly improve the academic and developmental outcomes of children living in the most distressed communities of the United States, including ensuring school readiness, high school graduation, and access to a community-based continuum of high-quality services. The program serves neighborhoods with high concentrations of low-income individuals; multiple signs of distress, which may include high rates of poverty, childhood obesity, academic failure, and juvenile delinquency, adjudication, or incarceration; and schools implementing comprehensive support and improvement activities or targeted support and improvement activities under section 1111(d) of the ESEA. All strategies in the continuum of solutions must be accessible to children with disabilities and English learners.

Background

The vision of the Promise Neighborhoods program is that all children and youth living in our most distressed communities have access to great schools and strong systems of family and community support that will prepare them to attain an excellent education and successfully transition to postsecondary education and a career.

A Promise Neighborhood is both a place and a strategy. A place eligible to become a Promise Neighborhood is a geographic area [1] that is distressed, often facing inadequate access to high-quality early learning programs and services, with struggling schools, low high school and college graduation rates, high rates of unemployment, high rates of crime, and indicators of poor health. These conditions contribute to and intensify

[1] For the purpose of this notice, the Department uses the terms ''geographic area'' and ''neighborhood'' interchangeably.

the negative outcomes associated with children and youth living in poverty.

A Promise Neighborhood strategy addresses the complex, interconnected issues in the distressed community it serves. Promise Neighborhoods are led by organizations, such as nonprofit organizations, institutions of higher education, offices of chief elected officials of local governments, or Indian Tribes or Tribal organizations, that work to ensure that all children and youth in the target geographic area have access to services that lead to improved educational and developmental outcomes from cradle-to-career. The organizations ensure that services are based on the best available evidence and employ robust data collection and management systems to learn about the impact of approaches for which there is less evidence; that services are linked and integrated seamlessly; and that services include education programs as well as programs that provide family and community supports. Promise Neighborhoods enable children and youth within targeted distressed communities to participate in the full range of cradle-to-career supports that are necessary for them to realize their potential. The Department of Education's expectation is that over time, a greater proportion of the neighborhood residents receive these supports and that neighborhood indicators (see Table 1) show significant progress. For this reason, each Promise Neighborhood applicant must demonstrate several core features: (1) Significant need in the neighborhood; (2) a strategy to build pipeline services (as defined in this notice) with strong schools at the center; and (3) the organizational and relational capacity to achieve results.

This year's Promise Neighborhoods competition is different from previous years' competitions in several ways. The Promise Neighborhoods program, under the ESEA as amended by ESSA, requires applicants to propose the use of not less than 50 percent of grant funds in year one, and not less than 25 percent in year two, to support planning activities for the development and implementation of pipeline services. Because applicants must now propose to use grant funds for limited planning activities, the Department will no longer award separate Promise Neighborhoods planning and implementation grants. The priorities and some program requirements for this year's competition have also changed from previous competitions. In this year's competition, we introduce new data and performance management requirements while continuing to prioritize evidence-based (see section 8101(21) of the ESEA) activities and programs. Previously funded Promise Neighborhoods grantees have struggled to conduct meaningful data collection and evaluation activities, which include collecting the full range of data necessary to effectively employ comprehensive case and longitudinal data management systems. Such data systems are critical to effectively coordinate a range of services for high-need students and their families within a Promise Neighborhood. In response to this challenge, we now require applicants to address specific data collection and performance management requirements.

In addressing these requirements, we strongly encourage applicants to review a publication released by the Department in 2013 entitled, ''Measuring Performance: A Guidance Document for Promise Neighborhoods on Collecting Data and Reporting Results.'' [2] This publication provides guidance on Promise Neighborhoods case management and longitudinal data systems; data collection strategies, sources, and methods; and data tracking and reporting procedures.

Priorities: This competition includes three absolute priorities and four competitive preference priorities. The three absolute priorities focus on the types of neighborhoods or geographic areas that the proposed project will serve. Absolute Priority 1 is focused on non-rural and non-Tribal applicants; Absolute Priority 2 is focused on rural communities; and Absolute Priority 3 is focused on Tribal communities.

Absolute Priorities: We are establishing Absolute Priorities 1, 2, and 3 for the FY 2017 grant competition and any subsequent year in which we make awards from the list of unfunded applications from this competition in accordance with section 437(d)(1) of the General Education Provisions Act (GEPA). Applicants should indicate in their application whether they are applying under Absolute Priority 1, Absolute Priority 2, or Absolute Priority 3. If an applicant applies under Absolute Priority 2 or Absolute Priority 3 and is deemed ineligible, the application still may be considered for funding under Absolute Priority 1. The Secretary prepares a rank order of applications for each absolute priority based solely on the evaluation of their quality according to the selection criteria.

Each of the three absolute priorities constitutes its own funding category. Assuming that applications in each funding category are of sufficient quality, the Secretary intends to award grants under each absolute priority.

Under 34 CFR 75.105(c)(3) we consider only applications that meet one or more of these priorities.

These priorities are:

Absolute Priority 1—Promise Neighborhoods in Non-Rural and Non-Tribal Communities.[3]

To meet this priority, an applicant must propose to implement a Promise Neighborhood strategy that serves one or more non-rural or non-Tribal communities.

Absolute Priority 2—Promise Neighborhoods in Rural Communities.

To meet this priority, an applicant must propose to implement a Promise Neighborhood strategy that serves one or more rural communities (as defined in this notice) only.

Under section 4623 of the ESEA, the Department will use at least 15 percent of the funds available for the Promise Neighborhoods program to award grants to eligible entities (as defined in this notice) that propose to carry out the Promise Neighborhoods activities in rural areas. The Department will reduce the funds reserved for rural areas if we do not receive enough applications of sufficient quality.

Absolute Priority 3—Promise Neighborhoods in Tribal Communities.

To meet this priority, an applicant must propose to implement a Promise Neighborhood strategy that serves one or more Indian Tribes (as defined in this notice).

Competitive Preference Priorities: We are establishing Competitive Preference Priorities 1 and 2 for the FY 2017 grant competition and any subsequent year in which we make awards from the list of unfunded applications from this competition in accordance with section 437(d)(1) of the GEPA, 20 U.S.C. 1232(d)(1). Competitive Preference Priority 3 is from section 4624 of the ESEA, as amended by the ESSA, 20 U.S.C. 7231e. Competitive Preference Priority 4 is from the Promise Zones notice of final priority published in the **Federal Register** on March 27, 2014 (79 FR 17035) (Promise Zones NFP).

For FY 2017 and any subsequent year in which we make awards from the list of unfunded applications from this competition, these priorities are competitive preference priorities. Under 34 CFR 75.105(c)(2)(i), we award an additional three points to an application that meets Competitive Preference

[2] *https://www2.ed.gov/programs/promiseneighborhoods/pndataguidance.pdf.*

[3] An applicant that serves one or more non-rural or non-Tribal communities will not be disqualified because it also proposes to serve rural or Tribal communities.

Priority 1; we award three additional points to an application that meets Competitive Preference Priority 2; we award one additional point to an application that meets Competitive Preference Priority 3; and we award one additional point to an application that meets Competitive Preference Priority 4.

Applicants may address all of the competitive preference priorities. Also, applicants should identify on the abstract form and in the project narrative section of their application which competitive preference priority or priorities the applicants address. We will not award competitive preference priority points to an application that fails to clearly identify the competitive preference priority or priorities it wishes the Department to consider for purposes of earning the competitive preference priority points.

These priorities are:

Competitive Preference Priority 1—Byrne Criminal Justice Innovation (BCJI) Program (0 or 3 points).

To meet this priority, an applicant must propose to serve geographic areas that were the subject of a targeted strategy addressing crime in a specific community pursuant to a BCJI grant awarded by the U.S. Department of Justice during FY 2012 or later years. To be eligible under this priority, the applicant must either: (1) Be able to demonstrate that it has received a BCJI grant; or (2) provide, in its application, a memorandum of understanding between it and a partner that is a recipient of a BCJI grant. The memorandum of understanding must indicate a commitment on the part of the applicant and partner to coordinate implementation and align resources to the greatest extent practicable.

Competitive Preference Priority 2—Drug Free Communities (DFC) Support Program (0 or 3 points).

To receive points under this priority, the applicant must either: (1) Demonstrate that it has received a DFC grant to prevent opioid abuse (as one of its areas of focus); or (2) provide, in its application, a memorandum of understanding between it and a partner that is a recipient of a DFC grant to address opioid abuse prevention as one of its areas of focus.

Competitive Preference Priority 3—Evidence-Based Activities, Strategies, or Interventions (0 or 1 point).

To meet this priority, an applicant must propose to carry out evidence-based activities, strategies, or interventions that, based on information included in their application, are supported by promising evidence (as defined in this notice).

Competitive Preference Priority 4—Promise Zones (0 or 1 point).

This priority is for projects that are designed to serve and coordinate with a federally designated Promise Zone.

To meet this priority, an applicant must include a Certification of Consistency with Promise Zone Goals and Implementation (HUD Form 50153) signed by an authorized representative of the lead organization of a Promise Zone designated by the Department of Housing and Urban Development (HUD) or the United States Department of Agriculture. An application for Promise Neighborhoods grant funds that is not accompanied by a signed certification (HUD Form 50153) will receive zero points for this priority. The certification form is available at *//portal.hud.gov/hudportal/documents/huddoc?id=HUD_Form_50153.pdf.* To view the list of designated Promise Zones and lead organizations please go to *www.hud.gov/promisezones.*

Definitions

The definition of ''strong theory'' is from 34 CFR 77.1. The remaining definitions are established in accordance with section 437(d)(1) of GEPA, 20 U.S.C. 1232(d)(1).

The following definitions apply to this program:

Eligible entity means an organization that:

(1) Is representative of the geographic area (as defined in this notice) proposed to be served;

(2) Operates or proposes to work with and involve in carrying out its proposed project, in coordination with the school's local educational agency (LEA), at least one public elementary or secondary school that is located within the identified geographic area that the grant will serve;

(3) Is one of the following:

(a) An institution of higher education, as defined in section 102 of the Higher Education Act of 1965, as amended (HEA) (20 U.S.C. 1002);

(b) An Indian Tribe or Tribal organization, as defined in section 4 of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 5304); or

(c) One or more nonprofit entities working in formal partnership with not less than one of the following entities:

i. A high-need LEA.

ii. An institution of higher education, as defined in section 102 of the HEA (20 U.S.C. 1002).

iii. The office of a chief elected official of a unit of local government.

iv. An Indian Tribe or Tribal organization, as defined under section 4 of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 5304); and

(4) Currently provides at least one of the solutions from the applicant's proposed pipeline services in the geographic area proposed to be served.

Experimental study means a study, such as a randomized controlled trial (RCT) (as defined in this notice), that is designed to compare outcomes between two groups of individuals that are otherwise equivalent except for their assignment to either a treatment group receiving a project component (as defined in this notice) or a control group that does not. In some circumstances, a finding from a regression discontinuity design study (RDD) (as defined in this notice) or findings from a collection of single-case design studies (SCDs) (as defined in this notice) may be considered equivalent to a finding from an RCT. RCTs, RDDs, and collections of SCDs, depending on design and implementation, can Meet What Works Clearinghouse Evidence Standards without reservations.

Graduation rate means the four-year or extended-year adjusted cohort graduation rate as defined by 34 CFR 200.19(b)(1).

Note: This definition is not meant to prevent a grantee from also collecting information about the reasons why students do not graduate from the target high school, *e.g.,* dropping out or moving outside of the school district for non-academic or academic reasons.

Indian Tribe means an Indian Tribe or Tribal organization, as defined in section 4 of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 5304)

Indicators of need means currently available data that describe—

(1) Education need, which means—

(a) All or a portion of the neighborhood includes or is within the attendance zone of a low-performing school that is a high school, especially one in which the graduation rate (as defined in this notice) is less than 60 percent or a school that can be characterized as low-performing based on another proxy indicator, such as students' on-time progression from grade to grade; and

(b) Other indicators, such as significant achievement gaps between subgroups of students (as identified in section 1111(b)(2)(B)(xi) of the ESEA) within a school or LEA, high teacher and principal turnover, or high student absenteeism; and

(2) Family and community support need, which means—

(a) Percentages of children with preventable chronic health conditions (*e.g.,* asthma, poor nutrition, dental

problems, obesity) or avoidable developmental delays;

(b) Immunization rates;

(c) Rates of crime, including violent crime;

(d) Student mobility rates;

(e) Teenage birth rates;

(f) Percentage of children in single-parent or no-parent families;

(g) Rates of vacant or substandard homes, including distressed public and assisted housing; or

(h) Percentage of the residents living at or below the Federal poverty threshold.

Logic model (also known as a theory of action) means a reasonable conceptual framework that identifies key components of the proposed project (*i.e.,* the active ''ingredients'' that are hypothesized to be critical to achieving the relevant outcomes) and describes the theoretical and operational relationships among the key components and outcomes.

Meets What Works Clearinghouse Evidence Standards without reservations is the highest possible rating for a study finding reviewed by the What Works Clearinghouse (WWC). Studies receiving this rating provide the highest degree of confidence that an observed effect was caused by the project component studied. Experimental studies (as defined in this notice) may receive this highest rating. These standards are described in the WWC Procedures and Standards Handbooks, Version 3.0, which can be accessed at *http://ies.ed.gov/ncee/wwc/Handbooks.*

Meets What Works Clearinghouse Evidence Standards with reservations is the second-highest rating for a group design study reviewed by the WWC. Studies receiving this rating provide a reasonable degree of confidence that an observed effect was caused by the project component studied. Both experimental studies (such as randomized controlled trials with high rates of sample attrition) and quasi-experimental design studies (as defined in this notice) may receive this rating if they establish the equivalence of the treatment and comparison groups in key baseline characteristics. These standards are described in the WWC Procedures and Standards Handbooks, Version 3.0, which can be accessed at *http://ies.ed.gov/ncee/wwc/Handbooks.*

Pipeline services means a continuum of coordinated supports, services, and opportunities for children from birth through entry into and success in postsecondary education, and career attainment. Such services shall include, at a minimum, strategies to address through services or programs (including integrated student supports) the following:

(a) High-quality early childhood education programs.

(b) High-quality school and out-of-school-time programs and strategies.

(c) Support for a child's transition to elementary school, from elementary school to middle school, from middle school to high school, and from high school into and through postsecondary education and into the workforce, including any comprehensive readiness assessment determined necessary.

(d) Family and community engagement and supports, which may include engaging or supporting families at school or at home.

(e) Activities that support postsecondary and work-force readiness, which may include job training, internship opportunities, and career counseling.

(f) Community-based support for students who have attended the schools in the area served by the pipeline, or students who are members of the community, facilitating their continued connection to the community and success in postsecondary education and the workforce.

(g) Social, health, nutrition, and mental health services and supports.

(h) Juvenile crime prevention and rehabilitation programs.

Project component means an activity, strategy, or intervention included in a project. Evidence (as this term is used in this notice) may pertain to an individual project component, or to a combination of project components (*e.g.,* training teachers on instructional practices for English learners and follow-on coaching for these teachers).

Promising evidence means the following conditions are met:

(a) There is at least one study that is a correlational study with statistical controls for selection bias with a relevant finding (quasi-experimental design studies or experimental studies may also qualify); and

(b) The relevant finding in the study described in paragraph (a) is of a statistically significant and positive (*i.e.,* favorable) effect of the project component on a student outcome or other relevant outcome with no statistically significant and overriding negative (*i.e.,* unfavorable) evidence on that project component from other findings on the intervention reviewed by and reported in the What Works Clearinghouse that Meet What Works Clearinghouse Evidence Standards with or without reservations.

Public officials means elected officials (*e.g.,* council members, aldermen and alderwomen, commissioners, State legislators, Congressional representatives, members of the school board), appointed officials (*e.g.,* members of a planning or zoning commission, or of any other regulatory or advisory board or commission), or individuals who are not necessarily public officials (as defined in this notice), but who have been appointed by a public official to serve on the Promise Neighborhoods governing board or advisory board.

Quasi-experimental design study means a study using a design that attempts to approximate an experimental design by identifying a comparison group that is similar to the treatment group in important respects. This type of study, depending on design and implementation, can Meet What Works Clearinghouse Evidence Standards with reservations (but not without reservations).

Randomized controlled trial (RCT) means a study that employs random assignment of, for example, students, teachers, classrooms, or schools to receive the project component being evaluated (the treatment group) or not to receive the project component (the control group). The estimated effectiveness of the project component is the difference between the average outcomes for the treatment group and for the control group. These studies, depending on design and implementation, can Meet What Works Clearinghouse Evidence Standards without reservations.

Regression discontinuity design study (RDD) means a study that assigns the project component being evaluated using a measured variable (*e.g.,* assigning students reading below a cutoff score to tutoring or developmental education classes) and controls for that variable in the analysis of outcomes. The effectiveness of the project component is estimated for individuals who barely qualify to receive that component. These studies, depending on design and implementation, can Meet What Works Clearinghouse Evidence Standards without reservations.

Relevant finding means a finding from a study regarding the relationship between (A) an activity, strategy, or intervention included as a component of the logic model (as defined in this notice) for the proposed project, and (B) a student outcome or other relevant outcome included in the logic model for the proposed project.

Relevant outcome means the student outcome(s) (or the ultimate outcome if not related to students) the proposed project component is designed to

improve, consistent with the specific goals of a program.

Representative of the geographic area proposed to be served means that residents of the geographic area proposed to be served have an active role in decision-making and that at least one-third of the eligible entity's (as defined in this notice) governing board or advisory board is made up of—

(1) Residents who live in the geographic area proposed to be served, which may include residents who are representative of the ethnic and racial composition of the neighborhood's residents and the languages they speak;

(2) Residents of the city or county in which the neighborhood is located but who live outside the geographic area proposed to be served, and who are low-income (which means earning less than 80 percent of the area's median income as published by HUD);

(3) Public officials (as defined in this notice) who serve the geographic area proposed to be served (although not more than one-half of the governing board or advisory board may be made up of public officials); or

(4) Some combination of individuals from the three groups listed in paragraphs (1), (2), and (3) of this definition.

Rural community means a neighborhood that—

(1) Is served by an LEA that is currently eligible under the Small Rural School Achievement (SRSA) program or the Rural and Low-Income School (RLIS) program authorized under Title VI, Part B of the ESEA. Applicants may determine whether a particular LEA is eligible for these programs by referring to information on the following Department Web sites. For the SRSA program: *https://www2.ed.gov/programs/reapsrsa/eligible16/index.htmlFor* the RLIS program: *https://www2.ed.gov/programs/reaprlisp/eligibility.html;* or

(2) Includes only schools designated with a school locale code of 41, 42, or 43. Applicants may determine school locale codes by referring to the following Department Web site: *http://nces.ed.gov/ccd/schoolsearch/.*

Segmentation analysis means the process of grouping and analyzing data from children and families in the geographic area proposed to be served according to indicators of need (as defined in this notice) or other relevant indicators. The analysis is intended to allow grantees to differentiate and more effectively target interventions based on what they learn about the needs of different populations in the geographic area.

Single-case design study (SCD) means a study that uses observations of a single case (*e.g.,* a student eligible for a behavioral intervention) over time in the absence and presence of a controlled treatment manipulation to determine whether the outcome is systematically related to the treatment. According to the WWC Single Case Design Pilot Standards, a collection of these studies, depending on design and implementation (*e.g.,* including a sufficient number of cases and of data points per condition), can Meet What Works Clearinghouse Evidence Standards without reservations.

Strong theory means a rationale for the proposed process, product, strategy, or practice that includes a logic model.

Student achievement means—

(1) For tested grades and subjects:

(a) A student's score on the State's assessments under the ESEA; and, as appropriate,

(b) Other measures of student learning, such as those described in paragraph (2) of this definition, provided they are rigorous and comparable across classrooms and programs.

(2) For non-tested grades and subjects: Alternative measures of student learning and performance, such as student scores on pre-tests and end-of-course tests; student performance on English language proficiency assessments; and other measures of student achievement that are rigorous and comparable across classrooms.

Student mobility rate is calculated by dividing the total number of new student entries and withdrawals at a school, from the day after the first official enrollment number is collected through the end of the academic year, by the first official enrollment number of the academic year.

Note: This definition is not meant to limit a grantee from also collecting information about why students enter or withdraw from the school, *e.g.,* transferring to charter schools, moving outside of the school district for non-academic or academic reasons.

Waiver of Proposed Rulemaking: Under the Administrative Procedure Act (5 U.S.C. 553) the Department generally offers interested parties the opportunity to comment on proposed priorities, selection criteria, definitions, and other requirements. Section 437(d)(1) of GEPA, however, allows the Secretary to exempt from rulemaking requirements, regulations governing the first grant competition under a new or substantially revised program authority. This is the first grant competition for this program under section 4623–4624 of the ESEA, 20 U.S.C. 7273–7274, and therefore qualifies for this exemption. In order to ensure timely grant awards, the Secretary has decided to forgo public comment on the priorities, requirements, definitions, and selection criteria under section 437(d)(1) of GEPA. These priorities, requirements, definitions, and selection criteria will apply to the FY 2017 grant competition and any subsequent year in which we make awards from the list of unfunded applications from this competition.

Program Authority: 20 U.S.C. 7273–7274.

Applicable Regulations: (a) The Education Department General Administrative Regulations (EDGAR) in 34 CFR parts 75, 77, 79 81, 82, 84, 86, 97, 98, and 99. (b) The OMB Guidelines to Agencies on Governmentwide Debarment and Suspension (Nonprocurement) in 2 CFR part 180, as adopted and amended as regulations of the Department in 2 CFR part 3485. (c) The Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards in 2 CFR part 200, as adopted and amended as regulations of the Department in 2 CFR part 3474. (d) Promise Zones NFP.

Note: The regulations in 34 CFR part 79 apply to all applicants except federally recognized Indian Tribes.

Note: The regulations in 34 CFR part 86 apply to institutions of higher education only.

II. Award Information

Type of Award: Discretionary grants.

Estimated Available Funds: $30,000,000.

Contingent upon the availability of funds and the quality of applications, we may make additional awards in subsequent years from the list of unfunded applications from this competition.

Estimated Range of Awards: $4,000,000 to $6,000,000.

Estimated Average Size of Awards: $5,000,000.

Maximum Award: $6,000,000.

The maximum award amount is $6,000,000 per 12-month budget period. We will not fund an annual budget exceeding $6,000,000 per 12-month budget period.

Estimated Number of Awards: 5–7.

Note: The Department is not bound by any estimates in this notice.

Project Period: Up to 60 months.

Under section 4623 of the ESEA, a grant awarded under this competition will be for a period of not more than five years, and may be extended for an additional period of not more than two

years. In addition, continued funding of a grant under this competition, including an extended grant, after the third year of the initial grant period will be contingent on the eligible entity's progress toward meeting the performance metrics and annual performance objectives and outcomes under section 4625(a)(4)(C) of the ESEA.

III. Eligibility Information

1. *Eligible Applicants:* Under section 4623 of the ESEA, an eligible organization must:

(1) Be representative of the geographic area proposed to be served;

(2) Operate or propose to work with and involve in carrying out its proposed project, in coordination with the school's LEA, at least one public elementary or secondary school that is located within the identified geographic area that the grant will serve;

(3) Be one of the following:

(a) An institution of higher education, as defined in section 102 of the HEA (20 U.S.C. 1002);

(b) An Indian Tribe or Tribal organization, as defined in section 4 of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 5304); or

(c) One or more nonprofit entities working in formal partnership with not less than one of the following entities:

i. A high-need LEA.

ii. An institution of higher education, as defined in section 102 of the HEA (20 U.S.C. 1002).

iii. The office of a chief elected official of a unit of local government.

iv. An Indian Tribe or Tribal organization, as defined under section 4 of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 5304); and

(4) Currently provide at least one of the solutions from the applicant's proposed pipeline services in the geographic area proposed to be served.

2. *Cost-Sharing or Matching:* To be eligible for a grant under this competition, an applicant must demonstrate a commitment from one or more entities in the public or private sector, which may include Federal, State, and local public agencies, philanthropic organizations, private businesses, or individuals, to provide matching funds. An applicant proposing a project that meets Absolute Priority 1—Promise Neighborhoods in Non-rural and Non-Tribal Communities must obtain matching funds or in-kind donations equal to at least 100 percent of its grant award. An applicant proposing a project that meets Absolute Priority 2—Promise Neighborhoods in Rural Communities or Absolute Priority 3—Promise Neighborhoods in Tribal Communities must obtain matching funds or in-kind donations equal to at least 50 percent of its grant award.

Eligible sources of matching funds include sources of funds used to pay for solutions within the pipeline services, initiatives supported by the LEA, or public health services for children in the neighborhood. At least 10 percent of an applicant's total match must be cash or in-kind contributions from the private sector, which may include philanthropic organizations, private businesses, or individuals.

Applicants must demonstrate a commitment of matching funds in the application. Applicants must specify the source of the funds or contributions and in the case of a third-party in-kind contribution, a description of how the value was determined for the donated or contributed goods or service. Applicants must demonstrate the match commitment by including letters in their applications explaining the type and quantity of the match commitment with original signatures from the executives of organizations or agencies providing the match.

The Secretary may consider decreasing the matching requirement in the most exceptional circumstances, on a case-by-case basis. An applicant that is unable to meet the matching requirement must include in its application a request to the Secretary to reduce the matching requirement, including the amount of the requested reduction, the total remaining match contribution, and a statement of the basis for the request. The Secretary will grant this request only if an applicant demonstrates a significant financial hardship. An applicant should review the Department's cost-sharing and cost-matching regulations, which include specific limitations, in 2 CFR 200.306 and the cost principles regarding donations, capital assets, depreciations and allowable costs, set out in subpart E of 2 CFR part 200.

3. *Application Requirements:* Each applicant that receives a grant award for the Promise Neighborhoods competition must use the grant funds to implement the pipeline services and continuously evaluate the success of the program and improve the program based on data and outcomes. Applicants may use not less than 50 percent of grant funds in year one, and not less than 25 percent of grant funds in year two for planning activities to develop and implement pipeline services.

Under section 4624 of the ESEA, as amended by the ESSA, applicants must submit and address the following:

(1) A plan to significantly improve the academic outcomes of children living in the geographically defined area (neighborhood) that is served by the eligible entity by providing pipeline services that address the needs of children in the neighborhood, as identified by the needs analysis; and that is supported by effective practices.

(2) A description of the neighborhood the eligible entity will serve. Applicants may propose to serve multiple, non-contiguous geographically defined areas. In cases where target areas are non-contiguous, the applicant must explain its rationale for including non-contiguous areas.

(3) An analysis of the needs and assets of the neighborhood, including:

(a) The size and scope of the population affected;

(b) A description of the process through which the needs analysis was produced, including a description of how parents, families, and community members were engaged in such analysis;

(c) An analysis of community assets and collaborative efforts (including programs already provided from Federal and non-Federal sources) within, or accessible to, the neighborhood, including, at a minimum, early learning opportunities, family and student supports, local businesses, local educational agencies, and institutions of higher education;

(d) The steps that the eligible entity is taking at the time of the application to address the needs identified in the needs analysis; and

(e) Any barriers the eligible entity, public agencies, and other community-based organizations have faced in meeting such needs.

(4) A description of all information the entity used to identify the pipeline services to be provided, which shall not include information that is more than 3 years old. This description should address how the eligible entity plans to collect data on children served by each pipeline service; and increase the percentage of children served over time.

(5) A description of the process used to develop the Promise Neighborhoods application, including the involvement of family and community members.

(6) A description of how the pipeline services will facilitate the coordination of the following activities:

(a) Providing early learning opportunities for children, including by:

(i) Providing opportunities for families to acquire the skills to promote early learning and child development; and

(ii) Ensuring appropriate diagnostic assessments and referrals for children with disabilities and children aged 3

through 9 experiencing developmental delays, consistent with the Individuals with Disabilities Education Act (20 U.S.C. 1400 *et seq.*), where applicable.

(b) Supporting, enhancing, operating, or expanding rigorous, comprehensive, effective educational improvements, which may include high-quality academic programs, expanded learning time, and programs and activities to prepare students for postsecondary education admissions and success.

(c) Supporting partnerships between schools and other community resources with an integrated focus on academics and other social, health, and familial supports.

(d) Providing social, health, nutrition, and mental health services and supports, for children, family members, and community members, which may include services provided within the school building.

(e) Supporting evidence-based programs (see section 8101(21) of the ESEA) that assist students through school transitions, which may include expanding access to postsecondary education courses and postsecondary education enrollment aid or guidance, and other supports for at-risk youth.

(7) A description of the strategies that will be used to provide pipeline services (including a description of which programs and services will be provided to children, family members, community members, and children within the neighborhood) to support the purpose of the Promise Neighborhoods program.

(8) An explanation of the process the eligible entity will use to establish and maintain family and community engagement, including:

(a) Involving representative participation by the members of such neighborhood in the planning and implementation of the activities of each grant awarded;

(b) The provision of strategies and practices to assist family and community members in actively supporting student achievement and child development;

(c) Providing services for students, families, and communities within the school building; and

(d) Collaboration with institutions of higher education, workforce development centers, and employers to align expectations and programming with postsecondary education and workforce readiness.

(9) An explanation of how the eligible entity will continuously evaluate and improve the continuum of high-quality pipeline services to provide for continuous program improvement and potential expansion.

(10) A commitment to collecting the required Promise Neighborhoods performance indicators' data; establishing the conditions for effective case and data management; and using data to improve program outcomes. In understanding the conditions necessary to collect, manage, and utilize data for Promise Neighborhoods, an applicant is required to:

(a) Hire dedicated staff to ensure its project has sufficient personnel and/or contractors to effectively manage its data collection activities, case management, and data systems;

(b) Submit a detailed data collection and reporting plan that includes a description of how it will conduct a bi-annual neighborhood survey of children and adults in the Promise Neighborhood; collect, at least annually, data on the performance indicators in Table 1; establish clear, annual targets and goals for growth on the performance indicators; and report those data to the Department annually;

TABLE 1—PROMISE NEIGHBORHOODS PERFORMANCE INDICATORS

Result	Indicator	Source
1. Children enter kindergarten ready to succeed in school.	1. Number and percentage of children in kindergarten who demonstrate at the beginning of the program or school year age-appropriate functioning across multiple domains of early learning as determined using developmentally-appropriate early learning measures.	Administrative data from LEA.
2. Students are proficient in core academic subjects.	2.1 Number and percentage of students at or above grade level according to State mathematics assessments in at least the grades required by the ESEA (3rd through 8th grades and once in high school).	
	2.2 Number and percentage of students at or above grade level according to State English language arts assessments in at least the grades required by the ESEA.	
3. Students successfully transition from middle school grades to high school.	3.1 Attendance rate of students in 6th, 7th, 8th, and 9th grade as defined by average daily attendance.	
	3.2 Chronic absenteeism rate of students in 6th, 7th, 8th, and 9th grades.	
4. Youth graduate from high school	4. Four-year adjusted cohort graduation rate.	
5. High school graduates obtain a postsecondary degree, certification or credential.	5.1 Number and percentage of Promise Neighborhood students who enroll in a two-year or four-year college or university after graduation.	Third party data such as the National Student Clearinghouse.
	5.2 Number and percent of Promise Neighborhood students who graduate from a two-year or four-year college or university or vocational certification completion.	
6. Students are healthy	Number and percentage of children who consume five or more servings of fruits and vegetables daily.	Neighborhood survey, school climate survey or other reliable data source for population level data collection.
7. Students feel safe at school and in their community.	7. Number and percentage of children who feel safe at school and traveling to and from school as measured by a school climate survey.	
8. Students live in stable communities.	8. Student mobility rate (as defined in the notice).	

TABLE 1—PROMISE NEIGHBORHOODS PERFORMANCE INDICATORS—Continued

Result	Indicator	Source
9. Families and community members support learning in promise Neighborhood Schools.	9.1 Number and percentage of parents or family members that read to or encourage their children to read three or more times a week or reported their child read to themselves three or more times a week (birth–8th grade). 9.2 Number and percentage of parents/family members who report talking about the importance of college and career (9th–12th grade).	
10. Students have access to 21st century learning tools.	10. Number and percentage of students who have school and home access to broadband internet and a connected computing device.	

Note: The indicators in Table 1 are not intended to limit an applicant from collecting and using data from additional Family and Community Support indicators proposed to the Department. Applicants are strongly encouraged, but not required, to propose additional performance indicators aligned to the specific pipeline services proposed in their application.

(c) Describe how it will develop a case management system to track key information and progress toward outcomes for individual children and adults participating in its Promise Neighborhoods programs and to facilitate communication and the coordination of services on behalf of these individuals; and

(d) Describe how it will develop and maintain a longitudinal data system to track outcome measures and other performance indicators over time (*e.g.,* snapshots and extracts from the case management system at different points in time).

The established performance indicators for the Promise Neighborhoods program serve as indicators of improved academic and developmental outcomes for children, including indicators of school readiness, high school graduation, postsecondary education and career readiness, and other academic and developmental outcomes. Each grantee is required to collect and report data on the performance indicators annually. Subsequently, the Department will make a determination for continuation funding and grant extensions based on performance indicator outcomes and available funding.

(11) A commitment to work with the Department, and with a national evaluator for Promise Neighborhoods or another entity designated by the Department, to ensure that data collection and program design are consistent with plans to conduct a rigorous national evaluation of the Promise Neighborhoods program and of specific solutions and strategies pursued by individual grantees. This commitment must include, but need not be limited to—

(a) Ensuring that, through memoranda of understanding with appropriate entities, the national evaluator and the Department have—consistent with applicable privacy requirements—access to relevant program and project data sources (*e.g.,* administrative data and program and project indicator data), including on a quarterly basis if requested by the Department;

(b) Developing, in consultation with the national evaluator, an evaluation strategy, including identifying a credible comparison group; and

(c) Developing, in consultation with the national evaluator, a plan for identifying and collecting reliable and valid baseline data for both program participants and a designated comparison group of non-participants.

(12) Each applicant must submit, as part of its application, a preliminary memorandum of understanding, signed by each organization or agency with which it would partner in implementing the proposed Promise Neighborhood. Within the preliminary memorandum of understanding, all applicants must detail each partner's financial, programmatic, and long-term commitment with respect to the strategies described in the application.

Under section 4624(c) of the ESEA, applicants that are non-profit entities must submit a preliminary memorandum of understanding signed by each partner entity or agency, which must include at least one of the following: A high-need LEA; an institution of higher education, as defined in section 102 of the HEA (20 U.S.C. 1002); the office of a chief elected official of a unit of local government; or an Indian Tribe or Tribal organization as defined in section 4 of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 5304).

Each eligible entity that receives a grant under this program is required to prepare and submit an annual report to the Secretary that must include the following: (1) Information about the number and percentage of children in the neighborhood who are served by the grant program, including a description of the number and percentage of children accessing each support service offered as part of the pipeline of services; and (2) information relating to the metrics established under the Promise Neighborhood Performance Indicators.

In addition, grantees are required to make these data publicly available, including through electronic means. To the extent practicable, and as required by law, such information must be provided in a form and language accessible to parents and families in the neighborhood served under the Promise Neighborhoods grant. In addition, data on academic indicators pertinent to the Promise Neighborhoods program will, in most cases, already be part of statewide longitudinal data systems.

IV. Application and Submission Information

1. *Address to Request Application Package:* You can obtain an application package via the internet or from the Education Publications Center (ED Pubs). To obtain a copy via the internet, use the following address: *www.ed.gov/fund/grant/apply/grantapps/.* To obtain a copy from ED Pubs, write, fax, or call: ED Pubs, U.S. Department of Education, P.O. Box 22207, Alexandria, VA 22304. Telephone, toll free: 1–877–433–7827. FAX: (703) 605–6794. If you use a TDD or a TTY, call FRS, toll free: 1–877–576–7734.

You can contact ED Pubs at its Web site, also: *www.EDPubs.gov* or at its email address: *edpubs@inet.ed.gov.*

If you request an application package from ED Pubs, be sure to identify this program or competition as follows: CFDA number 84.215N.

Individuals with disabilities can obtain a copy of the application package in an accessible format (*e.g.,* braille, large print, audiotape, or compact disc) by contacting the person or team listed under *Accessible Format* in section VII of this notice.

2. a. *Content and Form of Application Submission:* Requirements concerning the content of an application, together

with the forms you must submit, are in the application package for this competition.

The Department will be able to develop a more efficient process for reviewing grant applications if it has a better understanding of the number of entities that intend to apply for funding under this competition. Therefore, the Secretary strongly encourages each potential applicant to notify the Department of the applicant's intent to submit an application for funding by completing a web-based form. When completing this form, applicants will provide (1) the applicant organization's name and address, and (2) information on the competitive preference priority or priorities under which the applicant intends to apply. Applicants may access this form online at *https://innovation.ed.gov/what-we-do/parental-options/promise-neighborhoods-pn/.* Applicants that do not complete this form may still apply for funding.

Page Limit: The application narrative (Part III of the application) is where you, the applicant, address the selection criteria that reviewers use to evaluate your application. We recommend that you (1) limit the application narrative to 75 pages, and (2) use the following standards:

- A ''page'' is 8.5″ x 11″, on one side only, with 1″ margins at the top, bottom, and both sides.
- Double space (no more than three lines per vertical inch) all text in the application narrative, including titles, headings, footnotes, quotations, references, and captions, as well as all text in charts, tables, figures, and graphs.
- Use a font that is either 12 point or larger or no smaller than 10 pitch (characters per inch).
- Use one of the following fonts: Times New Roman, Courier, Courier New, or Arial.

The recommended page limit does not apply to Part I, the cover sheet; Part II, the budget section, including the narrative budget justification; Part IV, the assurances and certifications; or the one-page abstract, the resumes, the bibliography, or the letters of support. However, the recommended page limit does apply to all of the application narrative.

2. b. *Submission of Proprietary Information:* Given the types of projects that may be proposed in applications for the Promise Neighborhoods program, your application may include business information that you consider proprietary. In 34 CFR 5.11 we define ''business information'' and describe the process we use in determining whether any of that information is proprietary and, thus, protected from disclosure under Exemption 4 of the Freedom of Information Act (5 U.S.C. 552, as amended).

Because we plan to make successful applications available to the public, you may wish to request confidentiality of business information.

Consistent with Executive Order 12600, please designate in your application any information that you feel is exempt from disclosure under Exemption 4. In the appropriate Appendix section of your application, under ''Other Attachments Form,'' please list the page number or numbers on which we can find this information. For additional information please see 34 CFR 5.11(c).

3. *Submission Dates and Times:*

Applications Available: July 21, 2017.

Deadline for Notice of Intent to Apply: August 21, 2017.

Date of Pre-Application Webinar: Promise Neighborhoods intends to hold pre-application webinars to provide technical assistance to interested applicants. Detailed information regarding pre-application webinar times will be provided on the Web site at *https://innovation.ed.gov/what-we-do/parental-options/promise-neighborhoods-pn/.*

Deadline for Transmittal of Applications: September 5, 2017.

Applications for grants under this competition must be submitted electronically using the *Grants.gov* Apply site (*Grants.gov*). For information (including dates and times) about how to submit your application electronically, or in paper format by mail or hand delivery if you qualify for an exception to the electronic submission requirement, please refer to *Other Submission Requirements* in section IV of this notice. We do not consider an application that does not comply with the deadline requirements.

Individuals with disabilities who need an accommodation or auxiliary aid in connection with the application process should contact the person listed under **FOR FURTHER INFORMATION CONTACT**. If the Department provides an accommodation or auxiliary aid to an individual with a disability in connection with the application process, the individual's application remains subject to all other requirements and limitations in this notice.

Deadline for Intergovernmental Review: November 3, 2017.

4. *Intergovernmental Review:* This program is subject to Executive Order 12372 and the regulations in 34 CFR part 79. Information about Intergovernmental Review of Federal Programs under Executive Order 12372 is in the application package for this competition.

Applicants that operate a school in a neighborhood served by a grant program must provide such school with the operational flexibility, including autonomy over staff, time, and budget, needed to effectively carry out the activities described in this Notice.

Grantees cannot, in carrying out activities to improve early childhood education programs, use Promise Neighborhoods funds to carry out the following activities:

(1) Assessments that provide rewards or sanctions for individual children or teachers.

(2) A single assessment that is used as the primary or sole method for assessing program effectiveness.

(3) Evaluation of children, other than for the purposes of improving instruction, classroom environment, professional development, or parent and family engagement, or program improvement.

6. *Data Universal Numbering System Number, Taxpayer Identification Number, and System for Award Management:* To do business with the Department of Education, you must—

a. Have a Data Universal Numbering System (DUNS) number and a Taxpayer Identification Number (TIN);

b. Register both your DUNS number and TIN with the System for Award Management (SAM), the Government's primary registrant database;

c. Provide your DUNS number and TIN on your application; and

d. Maintain an active SAM registration with current information while your application is under review by the Department and, if you are awarded a grant, during the project period.

You can obtain a DUNS number from Dun and Bradstreet at the following Web site: *http://fedgov.dnb.com/webform.* A DUNS number can be created within one to two business days.

If you are a corporate entity, agency, institution, or organization, you can obtain a TIN from the Internal Revenue Service. If you are an individual, you can obtain a TIN from the Internal Revenue Service or the Social Security Administration. If you need a new TIN, please allow two to five weeks for your TIN to become active.

The SAM registration process can take approximately seven business days, but may take upwards of several weeks, depending on the completeness and accuracy of the data you enter into the SAM database. Thus, if you think you might want to apply for Federal financial assistance under a program

administered by the Department, please allow sufficient time to obtain and register your DUNS number and TIN. We strongly recommend that you register early.

Note: Once your SAM registration is active, it may be 24 to 48 hours before you can access the information in, and submit an application through, *Grants.gov.*

If you are currently registered with SAM, you may not need to make any changes. However, please make certain that the TIN associated with your DUNS number is correct. Also note that you will need to update your registration annually. This may take three or more business days.

Information about SAM is available at *www.SAM.gov.* To further assist you with obtaining and registering your DUNS number and TIN in SAM or updating your existing SAM account, we have prepared a SAM.gov Tip Sheet, which you can find at: *www2.ed.gov/fund/grant/apply/sam-faqs.html.*

In addition, if you are submitting your application via *Grants.gov*, you must (1) be designated by your organization as an Authorized Organization Representative (AOR); and (2) register yourself with *Grants.gov* as an AOR. Details on these steps are outlined at the following *Grants.gov* Web page: *www.grants.gov/web/grants/register.html.*

7. *Other Submission Requirements:* Applications for grants under this competition must be submitted electronically unless you qualify for an exception to this requirement in accordance with the instructions in this section.

a. *Electronic Submission of Applications.*

Applications for grants under Promise Neighborhoods, CFDA number 84.215N, must be submitted electronically using the Governmentwide *Grants.gov* Apply site at *www.Grants.gov.* Through this site, you will be able to download a copy of the application package, complete it offline, and then upload and submit your application. You may not email an electronic copy of a grant application to us.

We will reject your application if you submit it in paper format unless, as described elsewhere in this section, you qualify for one of the exceptions to the electronic submission requirement *and* submit, no later than two weeks before the application deadline date, a written statement to the Department that you qualify for one of these exceptions. Further information regarding calculation of the date that is two weeks before the application deadline date is provided later in this section under *Exception to Electronic Submission Requirement.*

You may access the electronic grant application for the Promise Neighborhoods program at *www.Grants.gov.* You must search for the downloadable application package for this competition by the CFDA number. Do not include the CFDA number's alpha suffix in your search (*e.g.,* search for 84.215, not 84.215N).

Please note the following:

- When you enter the *Grants.gov* site, you will find information about submitting an application electronically through the site, as well as the hours of operation.
- Applications received by *Grants.gov* are date and time stamped. Your application must be fully uploaded and submitted and must be date and time stamped by the *Grants.gov* system no later than 4:30:00 p.m., Washington, DC time, on the application deadline date. Except as otherwise noted in this section, we will not accept your application if it is received—that is, date and time stamped by the *Grants.gov* system—after 4:30:00 p.m., Washington, DC time, on the application deadline date. We do not consider an application that does not comply with the deadline requirements. When we retrieve your application from *Grants.gov*, we will notify you if we are rejecting your application because it was date and time stamped by the *Grants.gov* system after 4:30:00 p.m., Washington, DC time, on the application deadline date.
- The amount of time it can take to upload an application will vary depending on a variety of factors, including the size of the application and the speed of your internet connection. Therefore, we strongly recommend that you do not wait until the application deadline date to begin the submission process through *Grants.gov.*
- You should review and follow the Education Submission Procedures for submitting an application through *Grants.gov* that are included in the application package for this competition to ensure that you submit your application in a timely manner to the *Grants.gov* system. You can also find the Education Submission Procedures pertaining to *Grants.gov* under News and Events on the Department's G5 system home page at *www.G5.gov.* In addition, for specific guidance and procedures for submitting an application through *Grants.gov*, please refer to the *Grants.gov* Web site at: *www.grants.gov/web/grants/applicants/apply-for-grants.html.*
- You will not receive additional point value because you submit your application in electronic format, nor will we penalize you if you qualify for an exception to the electronic submission requirement, as described elsewhere in this section, and submit your application in paper format.
- You must submit all documents electronically, including all information you typically provide on the following forms: The Application for Federal Assistance (SF 424), the Department of Education Supplemental Information for SF 424, Budget Information—Non-Construction Programs (ED 524), and all necessary assurances and certifications.
- You must upload any narrative sections and all other attachments to your application as files in a read-only, flattened Portable Document Format (PDF), meaning any fillable PDF documents must be saved as flattened non-fillable files. Therefore, do not upload an interactive or fillable PDF file. If you upload a file type other than a read-only, flattened PDF (*e.g.,* Word, Excel, WordPerfect, etc.) or submit a password-protected file, we will not review that material. Please note that this could result in your application not being considered for funding because the material in question—for example, the application narrative—is critical to a meaningful review of your proposal. For that reason it is important to allow yourself adequate time to upload all material as PDF files. The Department will not convert material from other formats to PDF. There is no need to password protect a file in order to meet the requirement to submit a read-only flattened PDF. And, as noted above, the Department will not review password protected files.
- Your electronic application must comply with any page limit requirements described in this notice.
- After you electronically submit your application, you will receive from *Grants.gov* an automatic notification of receipt that contains a *Grants.gov* tracking number. This notification indicates receipt by *Grants.gov* only, not receipt by the Department. *Grants.gov* will also notify you automatically by email if your application met all the *Grants.gov* validation requirements or if there were any errors (such as submission of your application by someone other than a registered Authorized Organization Representative, or inclusion of an attachment with a file name that contains special characters). You will be given an opportunity to correct any errors and resubmit, but you must still meet the deadline for submission of applications.

Once your application is successfully validated by *Grants.gov*, the Department will retrieve your application from *Grants.gov* and send you an email with

a unique PR/Award number for your application.

These emails do not mean that your application is without any disqualifying errors. While your application may have been successfully validated by *Grants.gov*, it must also meet the Department's application requirements as specified in this notice and in the application instructions. Disqualifying errors could include, for instance, failure to upload attachments in a read-only, flattened PDF; failure to submit a required part of the application; or failure to meet applicant eligibility requirements. It is your responsibility to ensure that your submitted application has met all of the Department's requirements.

- We may request that you provide us original signatures on forms at a later date.

Application Deadline Date Extension in Case of Technical Issues with the Grants.gov System: If you are experiencing problems submitting your application through *Grants.gov*, please contact the *Grants.gov* Support Desk, toll free, at 1–800–518–4726. You must obtain a *Grants.gov* Support Desk Case Number and must keep a record of it.

If you are prevented from electronically submitting your application on the application deadline date because of technical problems with the *Grants.gov* system, we will grant you an extension until 4:30:00 p.m., Washington, DC time, the following business day to enable you to transmit your application electronically or by hand delivery. You also may mail your application by following the mailing instructions described elsewhere in this notice.

If you submit an application after 4:30:00 p.m., Washington, DC time, on the application deadline date, please contact the person listed under **FOR FURTHER INFORMATION CONTACT** and provide an explanation of the technical problem you experienced with *Grants.gov*, along with the *Grants.gov* Support Desk Case Number. We will accept your application if we can confirm that a technical problem occurred with the *Grants.gov* system and that the problem affected your ability to submit your application by 4:30:00 p.m., Washington, DC time, on the application deadline date. We will contact you after we determine whether your application will be accepted.

Note: The extensions to which we refer in this section apply only to the unavailability of, or technical problems with, the *Grants.gov* system. We will not grant you an extension if you failed to fully register to submit your application to *Grants.gov* before the application deadline date and time or if the technical problem you experienced is unrelated to the *Grants.gov* system.

Exception to Electronic Submission Requirement: You qualify for an exception to the electronic submission requirement, and may submit your application in paper format, if you are unable to submit an application through the *Grants.gov* system because—

- You do not have access to the Internet; or
- You do not have the capacity to upload large documents to the *Grants.gov* system; *and*
- No later than two weeks before the application deadline date (14 calendar days or, if the fourteenth calendar day before the application deadline date falls on a Federal holiday, the next business day following the Federal holiday), you mail or fax a written statement to the Department, explaining which of the two grounds for an exception prevents you from using the internet to submit your application.

If you mail your written statement to the Department, it must be postmarked no later than two weeks before the application deadline date. If you fax your written statement to the Department, we must receive the faxed statement no later than two weeks before the application deadline date.

Address and mail or fax your statement to: Adrienne Hawkins, U.S. Department of Education, 400 Maryland Avenue SW., Room 4W256, Washington, DC 20202–5970. FAX: (202) 205–5630.

Your paper application must be submitted in accordance with the mail or hand delivery instructions described in this notice.

b. *Submission of Paper Applications by Mail.*

If you qualify for an exception to the electronic submission requirement, you may mail (through the U.S. Postal Service or a commercial carrier) your application to the Department. You must mail the original and two copies of your application, on or before the application deadline date, to the Department at the following address: U.S. Department of Education, Application Control Center, Attention: (CFDA Number 84.215N), LBJ Basement Level 1, 400 Maryland Avenue SW., Washington, DC 20202–4260.

You must show proof of mailing consisting of one of the following:

(1) A legibly dated U.S. Postal Service postmark.

(2) A legible mail receipt with the date of mailing stamped by the U.S. Postal Service.

(3) A dated shipping label, invoice, or receipt from a commercial carrier.

(4) Any other proof of mailing acceptable to the Secretary of the U.S. Department of Education.

If you mail your application through the U.S. Postal Service, we do not accept either of the following as proof of mailing:

(1) A private metered postmark.

(2) A mail receipt that is not dated by the U.S. Postal Service.

Note: The U.S. Postal Service does not uniformly provide a dated postmark. Before relying on this method, you should check with your local post office.

We will not consider applications postmarked after the application deadline date.

c. *Submission of Paper Applications by Hand Delivery.*

If you qualify for an exception to the electronic submission requirement, you (or a courier service) may deliver your paper application to the Department by hand. You must deliver the original and two copies of your application by hand, on or before the application deadline date, to the Department at the following address: U.S. Department of Education, Application Control Center, Attention: (CFDA Number 84.215N), 550 12th Street SW., Room 7039, Potomac Center Plaza, Washington, DC 20202–4260.

The Application Control Center accepts hand deliveries daily between 8:00 a.m. and 4:30:00 p.m., Washington, DC time, except Saturdays, Sundays, and Federal holidays.

Note for Mail or Hand Delivery of Paper Applications: If you mail or hand deliver your application to the Department—

(1) You must indicate on the envelope and—if not provided by the Department—in Item 11 of the SF 424 the CFDA number, including suffix letter, if any, of the competition under which you are submitting your application; and

(2) The Application Control Center will mail to you a notification of receipt of your grant application. If you do not receive this notification within 15 business days from the application deadline date, you should call the U.S. Department of Education Application Control Center at (202) 245–6288.

V. Application Review Information

1. *Selection Criteria:* The selection criteria are either from 34 CFR 75.210 or established in accordance with section 437(d)(1) of GEPA, 20 U.S.C. 1232(d)(1). All of the selection criteria are listed in this section and in the application package. The maximum score for all of the selection criteria is 100 points. The maximum score for each criterion is included in parentheses following the title of the specific selection criterion. Each criterion also includes the factors that reviewers will consider in

determining the extent to which an applicant meets the criterion.

Points awarded under these selection criteria are in addition to any points an applicant earns under the competitive preference priorities in this notice. The maximum score that an application may receive under the competitive preference priorities and the selection criteria is 108 points.

(a) *Need for the Project (15 points).*

The Secretary considers the need for the proposed project. In determining the need for the proposed project, the Secretary considers:

(1) The magnitude or severity of the problems to be addressed by the proposed project as described by indicators of need (as defined in this notice) and other relevant indicators identified in part by the needs assessment and segmentation analysis (as defined in this notice);

(2) The extent to which the geographically defined area has been described; and

(3) The extent to which specific gaps or weaknesses in services, infrastructure, or opportunities have been identified and will be addressed by the proposed project, including the nature and magnitude of those gaps or weaknesses. (34 CFR 75.210)

(b) *Quality of Project Design (30 points).*

The Secretary reviews each application to determine the quality of the project design. In determining the quality of the design of the proposed project, the Secretary considers the following factors:

(1) The extent to which the applicant describes a plan to create a complete pipeline of services, including early learning through grade 12, college- and career-readiness, and family and community supports, without time and resource gaps, that will prepare all children in the neighborhood to attain an excellent education and successfully transition to college and a career, and that will significantly increase the proportion of students in the neighborhood that are served by the complete continuum to reach scale over time;

(2) The extent to which the methods of evaluation include the use of objective performance measures that are clearly related to the intended outcomes of the project and will produce quantitative and qualitative data to the extent possible (34 CFR 75.210); and

(3) The extent to which the proposed project is supported by strong theory (as defined in this notice) (34 CFR 75.210).

(c) *Quality of Project Services (20 points).*

The Secretary considers the quality of the services to be provided by the proposed project. In determining the quality of the project services, the Secretary considers:

(1) The quality and sufficiency of strategies for ensuring equal access and treatment for eligible project participants who are members of groups that have traditionally been underrepresented based on race, color, national origin, gender, age, or disability (34 CFR 75.210);

(2) The likelihood that the services to be provided by the proposed project will lead to improvement in the achievement of students as measured against rigorous academic standards (34 CFR 75.210); and

(3) The quality of the applicant's plan to establish formal and informal partnerships, including the alignment of the visions, theories of action, and theories of change described in its memorandum of understanding, and to create a system for holding partners accountable for performance in accordance with the memorandum of understanding.

(d) *Quality of the Management Plan (20 points).*

The Secretary considers the quality of the management plan for the proposed project. In determining the quality of the management plan for the proposed project, the Secretary considers the following factors:

(1) The adequacy of the management plan to achieve the objectives of the proposed project on time and within budget, including clearly defined responsibilities, timelines, and milestones for accomplishing project tasks (34 CFR 75.210); and

(2) The adequacy of the management plan's provisions on collecting, analyzing, and using data for decision-making, learning, continuous improvement, and accountability, including whether the applicant has a plan to build, adapt, or expand a longitudinal data system that integrates student-level data from multiple sources in order to measure progress while abiding by privacy laws and requirements, and ensuring that any systems built, adapted, or expanded upon includes essential security controls.

(e) *Adequacy of Resources (15 points).*

The Secretary considers the adequacy of resources for the proposed project. In determining the adequacy of resources for the proposed project, the Secretary considers:

(1) The extent to which the costs are reasonable in relation to the number of persons to be served and to the anticipated results and benefits (34 CFR 75.210);

(2) The extent to which the applicant demonstrates that it has the resources to operate the project beyond the length of the grant, including a multi-year financial and operating model and accompanying plan; the demonstrated commitment of any partners; evidence of broad support from stakeholders (*e.g.,* State educational agencies, teachers' unions) critical to the project's long-term success; or more than one of these types of evidence (34 CFR 75.210); and

(3) The extent to which the applicant identifies existing neighborhood assets and programs supported by Federal, State, local, and private funds that will be used to implement pipeline services.

2. *Review and Selection Process:* The Department will screen applications submitted in accordance with the requirements in this notice, and will determine which applications have met eligibility and other statutory requirements.

The Department will use independent reviewers from various backgrounds and professions including: Pre-kindergarten through grade 12, teachers and principals, college and university educators, researchers and evaluators, social entrepreneurs, strategy consultants, grant makers and managers, and others with community development and education expertise. The Department will thoroughly screen all reviewers for conflicts of interest to ensure a fair and competitive review process.

Reviewers will read, prepare a written evaluation of, and score the applications assigned to their panel, using the selection criteria provided in this notice.

The Secretary prepares a rank order of applications for each absolute priority based solely on the evaluation of their quality according to the selection criteria and competitive preference priority points. The Department may use more than one tier of reviews in determining grantees, including possible site visits for applicants. Additional information about the review process will be posted on the Department's Web site.

We remind potential applicants that in reviewing applications in any discretionary grant competition, the Secretary may consider, under 34 CFR 75.217(d)(3), the past performance of the applicant in carrying out a previous award, such as the applicant's use of funds, achievement of project objectives, and compliance with grant conditions. The Secretary may also consider whether the applicant failed to submit a timely performance report or

submitted a report of unacceptable quality.

In addition, in making a competitive grant award, the Secretary also requires various assurances including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department of Education (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

3. *Risk Assessment and Special Conditions:* Consistent with 2 CFR 200.205, before awarding grants under this competition the Department conducts a review of the risks posed by applicants. Under 2 CFR 3474.10, the Secretary may impose specific conditions and, in appropriate circumstances, high-risk conditions on a grant if the applicant or grantee is not financially stable; has a history of unsatisfactory performance; has a financial or other management system that does not meet the standards in 2 CFR part 200, subpart D; has not fulfilled the conditions of a prior grant; or is otherwise not responsible.

VI. Award Administration Information

1. *Award Notices:* If your application is successful, we notify your U.S. Representative and U.S. Senators and send you a Grant Award Notification (GAN); or we may send you an email containing a link to access an electronic version of your GAN. We may notify you informally, also.

If your application is not evaluated or not selected for funding, we notify you.

2. *Administrative and National Policy Requirements:* We identify administrative and national policy requirements in the application package and reference these and other requirements in the *Applicable Regulations* section of this notice.

We reference the regulations outlining the terms and conditions of an award in the *Applicable Regulations* section of this notice and include these and other specific conditions in the GAN. The GAN also incorporates your approved application as part of your binding commitments under the grant.

3. *Reporting:* (a) If you apply for a grant under this competition, you must ensure that you have in place the necessary processes and systems to comply with the reporting requirements in 2 CFR part 170 should you receive funding under the competition. This does not apply if you have an exception under 2 CFR 170.110(b). If awarded a grant under this competition, information about the number and percentage of children in the neighborhood who are served by the grant program, including a description of the number and percentage of children accessing each support or service offered as part of the pipeline services; and information relating to the performance metrics must be stated in each annual report.

(b) At the end of your project period, you must submit a final performance report, including financial information, as directed by the Secretary. If you receive a multiyear award, you must submit an annual performance report that provides the most current performance and financial expenditure information as directed by the Secretary under 34 CFR 75.118. The Secretary may also require more frequent performance reports under 34 CFR 75.720(c). For specific requirements on reporting, please go to *www.ed.gov/fund/grant/apply/appforms/appforms.html.*

4. *Integrity and Performance System:* If you are selected under this competition to receive an award that over the course of the project period may exceed the simplified acquisition threshold (currently $150,000) under 2 CFR 200.205(a)(2) we must make a judgment about your integrity, business ethics, and record of performance under Federal awards—that is, the risk posed by you as an applicant—before we make an award. In doing so, we must consider any information about you that is in the integrity and performance system (currently referred to as the Federal Awardee Performance and Integrity Information System (FAPIIS)), accessible through SAM. You may review and comment on any information about yourself that a Federal agency previously entered and that is currently in FAPIIS.

Please note that, if the total value of your currently active grants, cooperative agreements, and procurement contracts from the Federal Government exceeds $10,000,000, the reporting requirements in 2 CFR part 200, Appendix XII, require you to report certain integrity information to FAPIIS semiannually. Please review the requirements in 2 CFR part 200, Appendix XII, if this grant plus all the other Federal funds you receive exceed $10,000,000.

5. *Performance Measures:* The Secretary has established performance indicators (*i.e.,* performance measures) for Promise Neighborhoods. Performance indicators established by the Secretary include improved academic and development outcomes for children, including indicators of school readiness, high school graduation, postsecondary education and career readiness, and other academic and developmental outcomes. These outcomes promote data-driven decision-making and access to a community-based continuum of high quality services for children living in the most distressed communities of the United States, beginning at birth. All grantees will be required to submit data annually against these performance measures as part of their annual performance report.

5. *Continuation Awards:* In making a continuation award, the Secretary considers, among other things: Whether a grantee has made substantial progress in achieving the goals and objectives of the project; whether the grantee has expended funds in a manner that is consistent with its approved application and budget; and, the performance of the grantee in meeting the targets established for each performance indicator identified in the grantee's approved data plan.

In making a continuation award, the Secretary also considers whether the grantee is operating in compliance with the assurances in its approved application, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

VII. Other Information

Accessible Format: Individuals with disabilities can obtain this document and a copy of the application package in an accessible format (*e.g.,* braille, large print, audiotape, or compact disc) on request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT**.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available via the Federal Digital System at: *www.gpo.gov/fdsys.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or PDF. To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at: *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Dated: July 18, 2017.

Margo Anderson,

Acting Assistant Deputy Secretary for Innovation and Improvement.

[FR Doc. 2017–15359 Filed 7–20–17; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Applications for New Awards; Impact Aid Discretionary Construction Grant Program

AGENCY: Office of Elementary and Secondary Education, Department of Education.

ACTION: Notice.

SUMMARY: The Department of Education is issuing a notice inviting applications for fiscal year (FY) 2017 for the Impact Aid Discretionary Construction Grant Program, Catalog of Federal Domestic Assistance (CFDA) number 84.041C.

DATES: *Applications Available:* July 21, 2017.

Deadline for Transmittal of Applications: September 15, 2017.

Deadline for Intergovernmental Review: November 14, 2017.

FOR FURTHER INFORMATION CONTACT: Amanda Ognibene, Impact Aid Program, U.S. Department of Education, 400 Maryland Avenue SW., Room 3C129, Washington, DC 20202–6244. Telephone: 202–260–3858 or by email: *Amanda.Ognibene@ed.gov.*

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call the Federal Relay Service (FRS), toll free, at 1–800–877–8339.

SUPPLEMENTARY INFORMATION:

Full Text of Announcement

I. Funding Opportunity Description

Purpose of Program: The Impact Aid Discretionary Construction Grant Program provides grants for emergency repairs and modernization of school facilities to certain local educational agencies (LEAs) that receive Impact Aid formula funds.

Priority: In accordance with 34 CFR 75.105(b)(2)(ii) and (iv), this priority is from section 7007(b)(2)(A) of the Elementary and Secondary Education Act of 1965, as amended (Act) (20 U.S.C. 7707(b)), and the regulations for this program in 34 CFR 222.177.

Absolute Priority: For FY 2017 and any subsequent year in which we make awards from the list of unfunded applications from this competition, this priority is an absolute priority. Under 34 CFR 75.105(c)(3) we consider only applications that meet this priority and otherwise follow the applicable funding provisions in 34 CFR 222.189.

This priority is:

Emergency Repair Grants.

An LEA is eligible to apply for and receive an emergency grant under this priority if it—

(a) Is eligible to receive formula construction funds for the fiscal year under section 7007(a) of the Act (20 U.S.C. 7707(a));

(b)(1) Has no practical capacity to issue bonds;

(2) Has minimal capacity to issue bonds and has used at least 75 percent of its bond limit; or

(3) Is eligible to receive funds for the fiscal year for heavily impacted districts under section 7003(b)(2) of the Act (20 U.S.C. 7707(b)(2)); and

(c) Has a school facility emergency that the Secretary has determined, consistent with 34 CFR 222.172(a) and 222.173, poses a health or safety hazard to students and school personnel.

Program Authority: 20 U.S.C. 7707(b).

Applicable Regulations: (a) The Education Department General Administrative Regulations (EDGAR) in 34 CFR parts 75 (except for 34 CFR 75.600 through 75.617), 77, 79, 82, 84, 97, 98, and 99. (b) The Office of Management and Budget Guidelines to Agencies on Governmentwide Debarment and Suspension (Nonprocurement) in 2 CFR part 180, as adopted and amended as regulations of the Department in 2 CFR part 3485. (c) The Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards in 2 CFR part 200, as adopted and amended as regulations of the Department in 2 CFR part 3474. (d) The regulations for this program in 34 CFR part 222.

II. Award Information

Type of Award: Discretionary grants.

Estimated Available Funds: $17,400,000.

Contingent upon the availability of funds and the quality of applications, we may make additional awards in FY 2018 from the list of unfunded applications from this competition.

Estimated Range of Awards: $60,000–$6,000,000.

Estimated Average Size of Awards: $2,175,000.

Estimated Number of Awards: 8.

Note: The Department is not bound by any estimates in this notice.

Project Period: Up to 60 months. We will determine each project period based on the nature of the project proposed and the time needed to complete it. We will specify this period in the grant award document.

III. Eligibility Information

1. *Eligible Applicants:* An LEA must meet the absolute priority in this notice. An LEA is eligible to receive an emergency grant under the priority if it—

(a) Is eligible to receive formula construction funds for the fiscal year under section 7007(a) of the Act (20 U.S.C. 7707(a)) because it enrolls a high percentage (at least 50 percent) of federally connected children in average daily attendance (ADA) who either reside on Indian lands or who have a parent on active duty in the U.S. uniformed services.

(b)(1) Has no practical capacity to issue bonds (as defined in 34 CFR 222.176);

(2) Has minimal capacity to issue bonds (as defined in 34 CFR 222.176) and has used at least 75 percent of its bond limit; or

(3) Is eligible to receive funds for the fiscal year for heavily impacted districts under section 7003(b)(2) of the Act (20 U.S.C. 7703(b)(2)); and

(c) Has a school facility emergency that the Secretary has determined, consistent with 34 CFR 222.172(a) and 222.173, poses a health or safety hazard to students and school personnel.

2.a. *Cost Sharing or Matching:* In reviewing proposed awards, the Secretary considers the funds available to the grantee from other sources, including local, State, and other Federal funds. See 20 U.S.C. 7707(b)(5)(A)(iii) and 34 CFR 222.174 and 222.191 through 222.193. Consistent with 34 CFR 222.192, an applicant will be required to submit the applicant's most recently available audited financial reports for three consecutive fiscal years, showing closing balances for all school funds. If significant balances (as detailed in 34 CFR 222.192) are available at the close of the applicant's FY 2016, or its most recently audited year, that are not obligated for other purposes, those funds will be considered available for the proposed emergency repair project. Available balances may reduce the amount of funds that may be awarded or eliminate the applicant's eligibility for an emergency grant award under this competition.

b. *Supplement-Not-Supplant:* This competition involves supplement-not-supplant funding requirements. As outlined in 34 CFR 222.174, grant funds under this competition may not be used to supplant or replace other available non-Federal construction money.

IV. Application and Submission Information

1. *Address to Request Application Package:* You can obtain an electronic application via the internet at: *www.G5.gov.* For assistance, please contact Amanda Ognibene, Impact Aid Program, U.S. Department of Education, 400 Maryland Avenue SW., Room 3C129, Washington, DC 20202–6244. Telephone: (202) 260–3858, FAX: (866) 799–1273, or by email: *Amanda.Ognibene@ed.gov.*

If you use a TDD or a TTY, call the FRS, toll free, at 1–800–877–8339.

Individuals with disabilities can obtain a copy of the application package in an accessible format (*e.g.,* braille, large print, audiotape, or compact disc) by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**.

2. *Content and Form of Application Submission:* Requirements concerning the content and form of an application, together with the forms you must submit, are in the application package for this competition.

3. *Submission Dates and Times:*

Applications Available: July 21, 2017.

Deadline for Transmittal of Applications: September 15, 2017.

Applications for grants under this competition must be submitted electronically using G5, the Department's grant management system, accessible through the Department's G5 site. For information (including dates and times) about how to submit your application electronically, or in paper format by mail or hand delivery if you qualify for an exception to the electronic submission requirement, please refer *Other Submission Requirements* in section IV of this notice.

We do not consider an application that does not comply with the deadline requirements.

Individuals with disabilities who need an accommodation or auxiliary aid in connection with the application process should contact the person listed under **FOR FURTHER INFORMATION CONTACT**. If the Department provides an accommodation or auxiliary aid to an individual with a disability in connection with the application process, the individual's application remains subject to all other requirements and limitations in this notice.

Deadline for Intergovernmental Review: November 15, 2017.

4. *Intergovernmental Review:* This competition is subject to Executive Order 12372 and the regulations in 34 CFR part 79. Information about Intergovernmental Review of Federal Programs under Executive Order 12372 is in the application package for this competition.

5. *Funding Restrictions:* Except for applicants with no practical capacity to issue bonds, as defined in 34 CFR 222.176, an eligible applicant's award amount may not be more than 50 percent of the total cost of an approved project and the total amount of grant funds may not exceed $4 million during any four-year period. See 34 CFR 222.193. For example, an LEA that is awarded $4 million in the first year may not receive any additional funds for the following three years. Applicants may submit only one application for one educational facility as provided by 34 CFR 222.183. If an applicant submits more than one application, the Department will consider only the first submission, as determined by the G5 e-application system. Grant recipients must, in accordance with Federal, State, and local laws, use emergency grants for permissible construction activities at public elementary and secondary school facilities. The scope of the project for a selected facility will be identified as part of the final grant award conditions. A grantee must also ensure that its construction expenditures under this program meet the requirements of 34 CFR 222.172 (allowable program activities) and 34 CFR 222.173 (prohibited activities).

We reference additional regulations outlining funding restrictions in the *Applicable Regulations* section of this notice.

6. *Data Universal Numbering System Number, Taxpayer Identification Number, and System for Award Management:* To do business with the Department of Education, you must—

a. Have a Data Universal Numbering System (DUNS) number and a Taxpayer Identification Number (TIN);

b. Register both your DUNS number and TIN with the System for Award Management (SAM), the Government's primary registrant database;

c. Provide your DUNS number and TIN on your application; and

d. Maintain an active SAM registration with current information while your application is under review by the Department and, if you are awarded a grant, during the project period.

You can obtain a DUNS number from Dun and Bradstreet at the following Web site: *http://fedgov.dnb.com/webform.* A DUNS number can be created within one to two business days.

If you are a corporate entity, agency, institution, or organization, you can obtain a TIN from the Internal Revenue Service. If you are an individual, you can obtain a TIN from the Internal Revenue Service or the Social Security Administration. If you need a new TIN, please allow two to five weeks for your TIN to become active.

The SAM registration process can take approximately seven business days, but may take upwards of several weeks, depending on the completeness and accuracy of the data you enter into the SAM database. Thus, if you think you might want to apply for Federal financial assistance under a program administered by the Department, please allow sufficient time to obtain and register your DUNS number and TIN. We strongly recommend that you register early.

Note: Once your SAM registration is active, it may be 24 to 48 hours before you can access the information in, and submit an application through, *Grants.gov.*

If you are currently registered with SAM, you may not need to make any changes. However, please make certain that the TIN associated with your DUNS number is correct. Also note that you will need to update your registration annually. This may take three or more business days.

Information about SAM is available at *www.SAM.gov.* To further assist you with obtaining and registering your DUNS number and TIN in SAM or updating your existing SAM account, we have prepared a SAM.gov Tip Sheet, which you can find at: *http://www2.ed.gov/fund/grant/apply/sam-faqs.html.*

7. *Other Submission Requirements:* Applications for grants under this competition must be submitted electronically unless you qualify for an exception to this requirement in accordance with the instructions in this section.

a. *Electronic Submission of Applications.*

Applications for grants under the Impact Aid Discretionary Construction Grant Program, CFDA number 84.041C, must be submitted electronically using the G5 system, accessible through the Department's G5 site at: *www.G5.gov.* While completing your electronic application, you will be entering data online that will be saved into a database. You may not email an electronic copy of a grant application to us.

We will reject your application if you submit it in paper format unless, as described elsewhere in this section, you qualify for one of the exceptions to the electronic submission requirement *and* submit, no later than two weeks before the application deadline date, a written statement to the Department that you qualify for one of these exceptions.

Further information regarding calculation of the date that is two weeks before the application deadline date is provided later in this section under *Exception to Electronic Submission Requirement.*

Please note the following:

- You must complete the electronic submission of your grant application by midnight, Washington, DC time, on the application deadline date. G5 will not accept an application for this competition after 11:59:59 p.m., Washington, DC time, on the application deadline date. Therefore, we strongly recommend that you do not wait until the application deadline date to begin the application process.
- The hours of operation of the G5 Web site are 6:00 a.m. Monday until 9:00 p.m. Wednesday; and 6:00 a.m. Thursday until 3:00 p.m. Sunday, Washington, DC time. Please note that, because of maintenance, the system is unavailable between 3:00 p.m. on Sundays and 6:00 a.m. on Mondays, and between 9:00 p.m. on Wednesdays and 6:00 a.m. on Thursdays, Washington, DC time. Any modifications to these hours are posted on the G5 Web site.
- You will not receive additional point value because you submit your application in electronic format, nor will we penalize you if you qualify for an exception to the electronic submission requirement, as described elsewhere in this section, and submit your application in paper format.
- You must submit all documents electronically, including all information you typically provide on the following forms: The Application for Discretionary Construction Program under Section 7007(b) and all necessary signature pages.
- You must upload any narrative sections and all other attachments to your application as files in a read-only, flattened Portable Document Format. Do not upload an interactive or fillable PDF file. If you upload a file type other than a read-only, flattened PDF (*e.g.,* Word, Excel, WordPerfect, etc.) or submit a password-protected file, we will not review that material. Please note that this could result in your application not being considered for funding because the material in question—for example, the application narrative—is critical to a meaningful review of your proposal. For that reason it is important to allow yourself adequate time to upload all material as PDF files. The Department will not convert material from other formats to PDF.
- Prior to submitting your electronic application, you may wish to print a copy of it for your records.
- After you electronically submit your application, you will receive an automatic acknowledgment that will include a unique PR/Award number for your application.
- By the application deadline date, you must fax or email to the Impact Aid Program a signed copy of the cover page and the independent emergency certification form for the Application for Discretionary Construction Program under Section 7007(b) after following these steps:

(1) Print a copy of the application from G5 for your records.

(2) The applicant's Authorizing Representative must sign and date the cover page. The local certifying official must sign the certification for an emergency application. These forms must be submitted by the application deadline in order to be considered for funding under this program.

(3) Place the PR/Award number in the upper, right-hand corner of the hard-copy signed cover page of the application.

(4) Fax or email the signed cover page and independent emergency certification to the Impact Aid Program at 1–866–799–1273 or by email to *Impact.Aid@ed.gov.* These forms must be submitted before midnight, Washington, DC time, of the application deadline in order to be considered for funding under this program.

- We may request that you provide us original signatures on other forms at a later date.

Application Deadline Date Extension in Case of G5 System Unavailability: If you are prevented from electronically submitting your application on the application deadline date because the G5 system is unavailable, we will grant you an extension until midnight, Washington, DC time, the following business day to enable you to transmit your application electronically, by mail, or by hand delivery. We will grant this extension if—

(1) You are a registered user of the G5 system and you have initiated an electronic application for this competition; and

(2) (a) G5 is unavailable for 60 minutes or more between the hours of 8:30 a.m. and 11:00 p.m., Washington, DC time, on the application deadline date; or

(b) G5 is unavailable for any period of time between 11:00 p.m. and midnight, Washington, DC time, on the application deadline date.

We must acknowledge and confirm these periods of unavailability before granting you an extension. To request this extension or to confirm our acknowledgment of any system unavailability, you may contact either (1) the person listed under **FOR FURTHER INFORMATION CONTACT** or (2) the G5 help desk at 1–888–336–8930. If G5 is unavailable due to technical problems with the system and, therefore, the application deadline is extended, an email will be sent to all registered users who have initiated a G5 application. Extensions referred to in this section apply only to the unavailability of the G5 system.

Exception to Electronic Submission Requirement: You qualify for an exception to the electronic submission requirement, and may submit your application in paper format, if you are unable to submit an application through the G5 system because—

- You do not have access to the internet; or
- You do not have the capacity to upload large documents to G5;

and

- No later than two weeks before the application deadline date (14 calendar days or, if the fourteenth calendar day before the application deadline date falls on a Federal holiday, the next business day following the Federal holiday), you mail or fax a written statement to the Department, explaining which of the two grounds for an exception prevents you from using the internet to submit your application. If you mail your written statement to the Department, it must be postmarked no later than two weeks before the application deadline date. If you fax your written statement to the Department, we must receive the faxed statement no later than two weeks before the application deadline date.

Address and mail or fax your statement to: Amanda Ognibene, Impact Aid Program, U.S. Department of Education, 400 Maryland Avenue SW., Room 3C129, Washington, DC 20202–6244. Telephone: 202–260–3858. FAX: 1–866–799–1273.

Your paper application must be submitted in accordance with the mail or hand delivery instructions described in this notice.

b. *Submission of Paper Applications by Mail.*

If you qualify for an exception to the electronic submission requirement, you may mail (through the U.S. Postal Service or a commercial carrier) your application to the Department. You must mail the original and two copies of your application, on or before the application deadline date, to the Department at the following address: U.S. Department of Education, Impact Aid Program, Attention: (CFDA Number 84.041C), Room 3C129, 400 Maryland

Avenue SW., Washington, DC 20202–6244.

You must show proof of mailing consisting of one of the following:

(1) A legibly dated U.S. Postal Service postmark.

(2) A legible mail receipt with the date of mailing stamped by the U.S. Postal Service.

(3) A dated shipping label, invoice, or receipt from a commercial carrier.

(4) Any other proof of mailing acceptable to the Secretary of the U.S. Department of Education.

If you mail your application through the U.S. Postal Service, we do not accept either of the following as proof of mailing:

(1) A private metered postmark.

(2) A mail receipt that is not dated by the U.S. Postal Service.

Note: The U.S. Postal Service does not uniformly provide a dated postmark. Before relying on this method, you should check with your local post office.

We will not consider applications postmarked after the application deadline date.

c. *Submission of Paper Applications by Hand Delivery.*

If you qualify for an exception to the electronic submission requirement, you (or a courier service) may deliver your paper application to the Department by hand. You must deliver the original and two copies of your application, by hand, on or before the application deadline date, to the Department at the following address: U.S. Department of Education, Impact Aid Program, Attention: (CFDA Number 84.041C), Room 3C129, 400 Maryland Avenue SW., Washington, DC 20202–6244.

The Impact Aid Program accepts hand deliveries daily between 8:00 a.m. and 4:30 p.m., Washington, DC time, except Saturdays, Sundays, and Federal holidays.

Note for Mail or Hand Delivery of Paper Applications: If you mail or hand deliver your application to the Department—

(1) You must indicate on the envelope—if not provided by the Department—the CFDA number, including suffix letter, if any, of the competition under which you are submitting your application; and

(2) The Impact Aid Program will mail to you a notification of receipt of your grant application. If you do not receive this grant notification within 15 business days from the application deadline date, you should call the U.S. Department of Education Impact Aid Program at (202) 260–3858.

V. Application Review Information

1. *Selection Criteria:* Consistent with 34 CFR 75.209, the selection criteria for this competition are from the applicable statutory and regulatory provisions as indicated after each criterion. The maximum score for each criterion is indicated in parentheses. Within each criterion, the Secretary evaluates each factor equally, unless otherwise specified. The maximum score that an application may receive is 100 points.

(a) Severity of the school facility problem to be addressed by the proposed project (34 CFR 222.189(a)(1)) (Maximum 30 points).

(i) Justification that the proposed emergency project will address a deficiency that poses a health or safety hazard to occupants of the facility, and consistency of the emergency description and the proposed project with the certifying local official's statement (34 CFR 222.185(a) and (c)) (15 points).

(ii) Impact of the emergency condition on the health and safety of the building occupants and how free public education program delivery in the instructional school facility is adversely affected (34 CFR 222.172, 222.173, 222.176, and 222.185(b)). Applicants should describe: The systems or areas of the facility involved (*e.g.,* HVAC, roof, floor, windows; the type of space affected, such as instructional, resource, food service, recreational, general support, or other areas); the percentage of building occupants affected by the emergency; and the importance of the facility or affected area to the instructional program (15 points).

(b) Project urgency (Maximum 28 points).

(i) Risk to occupants if the facility condition is not addressed (34 CFR 222.176, definition of ''emergency''). Applicants should describe: Projected increased future costs; the anticipated effect of the proposed project on the useful life of the facility or the need for major construction; and the age and condition of the facility and date of last renovation of affected areas.

(ii) The justification for rebuilding, if proposed (34 CFR 222.172(c)).

(c) Effects of Federal presence (section 7007(b)(4)(B) and (C) and 34 CFR 222.184(b)) (Maximum 30 points).

(i) Amount of non-taxable Federal property in the applicant LEA (percentage of Federal property divided by 10) (10 points).

(ii) The number of federally connected children identified in section 7003(a)(1)(A), (B), (C), and (D) of the Act in the LEA (percentage of identified children in LEA divided by 10) (10 points).

(iii) The number of federally connected children identified in section 7003(a)(1)(A), (B), (C), and (D) of the Act in the school facility (percentage of identified children in school facility divided by 10) (10 points).

(d) Ability to respond or pay (section 7007(b)(4)(A)) (Maximum 12 points).

(i) The percentage of its bonding capacity used by the LEA. Four points will be distributed based on this percentage such that: Four points will be given to an LEA that has used 75 percent or more of its bonding capacity; three points will be given to an LEA that has used 50 percent to 74 percent of its bonding capacity; two points will be given to an LEA that has used 25 percent to 49 percent of its bonding capacity; and one point will be given to an LEA that has used less than 25 percent of its bond limit. LEAs that do not have limits on bonded indebtedness established by their States will be evaluated by assuming that their bond limit is 10 percent of the assessed value of real property in the LEA. LEAs deemed to have no practical capacity to issue bonds will receive all four points (4 points).

(ii) Assessed value of real property per student (applicant LEA's total assessed valuation of real property per pupil as a percentile ranking of all LEAs in the State). Points will be distributed by providing all four points to LEAs in the State's poorest quartile and only one point to LEAs in the State's wealthiest quartile (4 points).

(iii) Total tax rate for capital or school purposes (applicant LEA's tax rate for capital or school purposes as a percentile ranking of all LEAs in the State). If the State authorizes a tax rate for capital expenditures, then these data must be used; otherwise, data on the total tax rate for school purposes are used. Points will be distributed by providing all four points to LEAs in the State's highest-taxing quartile and only one point to LEAs in the State's lowest-taxing quartile (4 points).

2. *Review and Selection Process:* (a) We remind potential applicants that in reviewing applications in any discretionary grant competition, the Secretary may consider, under 34 CFR 75.217(d)(3), the past performance of the applicant in carrying out a previous award, such as the applicant's use of funds, achievement of project objectives, and compliance with grant conditions. The Secretary may also consider whether the applicant failed to submit a timely performance report or submitted a report of unacceptable quality.

In addition, in making a competitive grant award, the Secretary requires various assurances including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial

assistance from the Department of Education (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

(b) Upon receipt, Impact Aid program staff will screen all applications to eliminate any applications that do not meet the eligibility standards, are incomplete, or are late. Applications that do not include a signed cover page and a signed independent emergency certification submitted by fax or email before midnight, Washington, DC time on the application deadline are considered incomplete and will not be considered for funding. Program staff will also calculate the scores for each application under criteria (c) and (d). Panel reviewers will assess the applications under criteria (a) and (b).

(c) Applications are ranked based on the total number of points received during the review process. Those with the highest scores will be at the top of the funding slate.

(d) Applicants may submit only one application for one educational facility. If an applicant submits multiple applications, the Department will only consider the first sequentially submitted application, as provided under 34 CFR 222.183.

3. *Risk Assessment and Special Conditions:* Consistent with 2 CFR 200.205, before awarding grants under this program the Department conducts a review of the risks posed by applicants. Under 2 CFR 3474.10, the Secretary may impose special conditions and, in appropriate circumstances, high-risk conditions on a grant if the applicant or grantee is not financially stable; has a history of unsatisfactory performance; has a financial or other management system that does not meet the standards in 2 CFR part 200, subpart D; has not fulfilled the conditions of a prior grant; or is otherwise not responsible.

4. *Integrity and Performance System:* If you are selected under this competition to receive an award that over the course of the project period may exceed the simplified acquisition threshold (currently $150,000), under 2 CFR 200.205(a)(2) we must make a judgment about your integrity, business ethics, and record of performance under Federal awards—that is, the risk posed by you as an applicant—before we make an award. In doing so, we must consider any information about you that is in the integrity and performance system (currently referred to as the Federal Awardee Performance and Integrity Information System (FAPIIS)), accessible through SAM. You may review and comment on any information about yourself that a Federal agency previously entered and that is currently in FAPIIS.

Please note that, if the total value of your currently active grants, cooperative agreements, and procurement contracts from the Federal Government exceeds $10,000,000, the reporting requirements in 2 CFR part 200, Appendix XII, require you to report certain integrity information to FAPIIS semiannually. Please review the requirements in 2 CFR part 200, Appendix XII, if this grant plus all the other Federal funds you receive exceed $10,000,000.

VI. Award Administration Information

1. *Award Notices:* If your application is successful, we notify your U.S. Representative and U.S. Senators and send you a Grant Award Notification (GAN); or we may send you an email containing a link to access an electronic version of your GAN. We may notify you informally, also.

If your application is not evaluated or not selected for funding, we notify you.

2. *Administrative and National Policy Requirements:* We identify administrative and national policy requirements in the application package and reference these and other requirements in the *Applicable Regulations* section of this notice.

We reference the regulations outlining the terms and conditions of an award in the *Applicable Regulations* section of this notice and include these and other specific conditions in the GAN. The GAN also incorporates your approved application as part of your binding commitments under the grant.

3. *Reporting:* (a) If you apply for a grant under this competition, you must ensure that you have in place the necessary processes and systems to comply with the reporting requirements in 2 CFR part 170 should you receive funding under the competition. This does not apply if you have an exception under 2 CFR 170.110(b).

(b) At the end of your project period, you must submit a final performance report, including financial information, as directed by the Secretary. If you receive a multiyear award, you must submit an annual performance report that provides the most current performance and financial expenditure information as directed by the Secretary under 34 CFR 75.118. The Secretary may also require more frequent performance reports under 34 CFR 75.720(c). For specific requirements on reporting, please go to *www.ed.gov/fund/grant/apply/appforms/appforms.html.*

4. *Performance Measures:* The Department has established the following performance measure for this program: An increasing percentage of LEAs receiving Impact Aid Construction funds will report that the overall condition of their school buildings is adequate. Data for this measure will be reported to the Department on Table 10 of the application for Impact Aid Section 7003 Basic Support Payments.

5. *Feasibility Study:* For applicants that request funding for new construction and that are selected for funding, the Department will require a feasibility of construction study prior to making an award determination. This independent third-party study must demonstrate that the chosen construction site is viable and the infrastructure will be able to sustain the new facility or addition.

VII. Other Information

Accessible Format: Individuals with disabilities can obtain this document and a copy of the application package in an accessible format (*e.g.,* braille, large print, audiotape, or compact disc) on request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT**.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. Free internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available via the Federal Digital System at: *www.gpo.gov/fdsys.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or PDF. To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at: *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Dated: July 18, 2017.

Jason Botel,

Acting Assistant Secretary for Elementary and Secondary Education.

[FR Doc. 2017–15389 Filed 7–20–17; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER17–2087–000]

Hog Creek Wind Project, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of Hog Creek Wind Project, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is August 3, 2017.

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.

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-referenced proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for electronic review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov.* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: July 14, 2017.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2017–15330 Filed 7–20–17; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. AC17–230–000]

AEP Texas Central Company; AEP Texas North Company; Notice of Request for Waiver

Take notice that on July 14, 2017, AEP Texas Central Company and AEP Texas North Company filed a request for waiver of requirement to file FERC Form No. 3–Q, as required by 18 CFR 141.400.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

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

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

Comments: 5:00 p.m. Eastern Time on July 24, 2017.

Dated: July 17, 2017.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2017–15333 Filed 7–20–17; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Staff Attendance at the Southwest Power Pool Regional Entity Trustee, Regional State Committee, Members' Committee and Board of Directors' Meetings

The Federal Energy Regulatory Commission (Commission) hereby gives notice that members of its staff may attend the meetings of the Southwest Power Pool, Inc. Regional State Committee (RSC), Regional Entity Trustee (RET), Members' Committee and Board of Directors as noted below. Their attendance is part of the Commission's ongoing outreach efforts.

The meetings will be held at the Hyatt Regency Denver, 650 15th Street, Denver, Colorado 80202. The phone number is (888) 421–1442. All meetings are Mountain Time.

SPP RET

July 24, 2017 (8:00 a.m.–3:00 p.m.)

SPP RSC

July 24, 2017 (1:00 p.m.–5:00 p.m.)

SPP Members/Board of Directors

July 25, 2017 (8:00 a.m.–3:00 p.m.)

The discussions may address matters at issue in the following proceedings:

Docket No. ER15–2028, *Southwest Power Pool, Inc.*
Docket No. ER15–2115, *Southwest Power Pool, Inc.*
Docket No. ER15–2324, *Southwest Power Pool, Inc.*
Docket No. EL16–91, *Southwest Power Pool, Inc.*
Docket No. EL16–110, *Southwest Power Pool, Inc.*
Docket No. ER16–204, *Southwest Power Pool, Inc.*
Docket No. ER16–1286, *Southwest Power Pool, Inc.*
Docket No. ER16–1341, *Southwest Power Pool, Inc.*
Docket No. ER16–1546, *Southwest Power Pool, Inc.*
Docket No. ER16–2522, *Southwest Power Pool, Inc.*
Docket No. ER16–2523, *Southwest Power Pool, Inc.*
Docket No. EL17–11, *Alabama Power Co.*
Docket No. EL17–21, *Kansas Electric Co.*
Docket No. EL17–69, *Buffalo Dunes Wind Project*
Docket No. ER17–264, *Southwest Power Pool, Inc.*

Docket No. ER17–426, *Southwest Power Pool, Inc.*
Docket No. ER17–428, *Southwest Power Pool, Inc.*
Docket No. ER17–772, *Southwest Power Pool, Inc.*
Docket No. ER17–889, *Southwest Power Pool, Inc.*
Docket No. ER17–1092, *Southwest Power Pool, Inc.*
Docket No. ER17–1098, *Southwest Power Pool, Inc.*
Docket No. ER17–1110, *Southwest Power Pool, Inc.*
Docket No. ER17–1319, *Southwest Power Pool, Inc.*
Docket No. ER17–1371, *Southwest Power Pool, Inc.*
Docket No. ER17–1379, *Southwest Power Pool, Inc.*
Docket No. ER17–1508, *Southwest Power Pool, Inc.*
Docket No. ER17–1482, *Southwest Power Pool, Inc.*
Docket No. ER17–1575, Southwest Power Pool, Inc.
Docket No. ER17–1610, *Southwest Power Pool, Inc.*
Docket No. ER17–1643, *Southwest Power Pool, Inc.*
Docket No. ER17–1694, *Southwest Power Pool, Inc.*
Docket No. ER17–1733, *Southwest Power Pool, Inc.*
Docket No. ER17–1759, *Southwest Power Pool, Inc.*
Docket No. ER17–1795, *Southwest Power Pool, Inc.*
Docket No. ER17–1803, *Southwest Power Pool, Inc.*
Docket No. ER17–1804, *Southwest Power Pool, Inc.*
Docket No. ER17–1806, *Southwest Power Pool, Inc.*
Docket No. ER17–1809, *Southwest Power Pool, Inc.*
Docket No. ER17–1811, *Southwest Power Pool, Inc.*
Docket No. ER17–1813, *Southwest Power Pool, Inc.*
Docket No. ER17–1814, *Southwest Power Pool, Inc.*
Docket No. ER17–1815, *Southwest Power Pool, Inc.*
Docket No. ER17–1897, *Southwest Power Pool, Inc.*
Docket No. ER17–1945, *Southwest Power Pool, Inc.*
Docket No. ER17–2027, *Southwest Power Pool, Inc.*
Docket No. ER17–2032, *Southwest Power Pool, Inc.*
Docket No. ER17–2038, *Southwest Power Pool, Inc.*

These meetings are open to the public.

For more information, contact Patrick Clarey, Office of Energy Market Regulation, Federal Energy Regulatory Commission at (317) 249–5937 or *patrick.clarey@ferc.gov.*

Dated: July 14, 2017.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2017–15335 Filed 7–20–17; 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: EG17–124–000.
Applicants: Lackawanna Energy Center LLC.
Description: Notice of Self-Certification of Exempt Wholesale Generator Status of Lackawanna Energy Center LLC.
Filed Date: 7/13/17.
Accession Number: 20170713–5127.
Comments Due: 5 p.m. ET 8/3/17.

Docket Numbers: EG17–125–000.
Applicants: SUNE Beacon Site 5, LLC.
Description: Notice of Self-Certification of EWG Status of SunE Beacon Site 5 LLC.
Filed Date: 7/13/17.
Accession Number: 20170713–5135.
Comments Due: 5 p.m. ET 8/3/17.

Docket Numbers: EG17–126–000.
Applicants: Rattlesnake Power, LLC.
Description: Self-Certification of EG of Rattlesnake Power, LLC.
Filed Date: 7/13/17.
Accession Number: 20170713–5136.
Comments Due: 5 p.m. ET 8/3/17.

Docket Numbers: EG17–127–000.
Applicants: Apple Blossom Wind, LLC.
Description: Self-Certification of EWG of Apple Blossom Wind, LLC.
Filed Date: 7/13/17.
Accession Number: 20170713–5155.
Comments Due: 5 p.m. ET 8/3/17.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10–2331–067; ER10–2319–057; ER10–2317–057; ER13–1351–039; ER10–2330–064.
Applicants: J.P. Morgan Ventures Energy Corporation, BE Alabama LLC, BE CA LLC, Utility Contract Funding, L.L.C., Florida Power Development LLC.
Description: Notice of Non-Material Change in Status of the J.P. Morgan Sellers.
Filed Date: 7/13/17.
Accession Number: 20170713–5226.
Comments Due: 5 p.m. ET 8/3/17.

Docket Numbers: ER11–4505–002.
Applicants: Backyard Farms Energy LLC.
Description: Notice of Non-Material Change in Status of Backyard Farms Energy LLC.
Filed Date: 7/13/17.
Accession Number: 20170713–5225.
Comments Due: 5 p.m. ET 8/3/17.

Docket Numbers: ER17–2086–000.
Applicants: PJM Interconnection, L.L.C.
Description: § 205(d) Rate Filing: Amendment to Service Agreement No. 1405, Queue No. O11 to Assign to BC Landfill to be effective 11/23/2005.
Filed Date: 7/13/17.
Accession Number: 20170713–5057.
Comments Due: 5 p.m. ET 8/3/17.

Docket Numbers: ER17–2087–000.
Applicants: Hog Creek Wind Project, LLC.
Description: Baseline eTariff Filing: MBR Appliciation to be effective 9/11/2017.
Filed Date: 7/13/17.
Accession Number: 20170713–5132.
Comments Due: 5 p.m. ET 8/3/17.

Docket Numbers: ER17–2088–000.
Applicants: Apple Blossom Wind, LLC.
Description: Baseline eTariff Filing: Apple Blossom Wind, LLC Petition for Order Accepting Market-Based Rate Tariff to be effective 9/1/2017.
Filed Date: 7/13/17.
Accession Number: 20170713–5169.
Comments Due: 5 p.m. ET 8/3/17.

Docket Numbers: ER17–2089–000.
Applicants: Idaho Power Company.
Description: § 205(d) Rate Filing: 2017 Update to Depreciation Rates to be effective 6/1/2017.
Filed Date: 7/14/17.
Accession Number: 20170714–5002.
Comments Due: 5 p.m. ET 8/4/17.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For

other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: July 14, 2017.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2017–15328 Filed 7–20–17; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. AC17–227–000]

Pike County Light and Power Company; Notice of Request for Waiver

Take notice that on July 6, 2017, Pike County Light and Power Company filed a request for waiver of requirement for its Certified Public Accountant (CPA) to file a statement certifying data in its FERC Form 1–F for a calendar year and in lieu thereof to file a CPA certification based on a fiscal year, which runs from September to September.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

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

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

Comments: 5:00 p.m. Eastern Time on July 27, 2017.

Dated: July 17, 2017.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2017–15332 Filed 7–20–17; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER17–2088–000]

Apple Blossom Wind, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of Apple Blossom Wind, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is August 3, 2017.

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.

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-referenced proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for electronic review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov.* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: July 14, 2017.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2017–15331 Filed 7–20–17; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC17–138–000.
Applicants: 83WI 8me, LLC.
Description: Application for Authorization under Section 203 of the Federal Power Act and Request for Expedited Consideration and Confidential Treatment of 83WI 8me, LLC.
Filed Date: 7/14/17.
Accession Number: 20170714–5229.
Comments Due: 5 p.m. ET 8/4/17.

Docket Numbers: EC17–139–000.
Applicants: Minnesota Wind Holdings, LLC, Jeffers Wind 20, LLC, Community Wind North, LLC, North Community Turbines LLC, North Wind Turbines LLC, Community Wind North 1 LLC, Community Wind North 2 LLC, Community Wind North 3 LLC, Community Wind North 5 LLC, Community Wind North 6 LLC, Community Wind North 7 LLC, Community Wind North 8 LLC, Community Wind North 9 LLC, Community Wind North 10 LLC, Community Wind North 11 LLC, Community Wind North 13 LLC, Community Wind North 15 LLC.
Description: Joint Application for Approval under Section 203 of the Federal Power Act of Minnesota Wind Holdings, LLC, et al.
Filed Date: 7/14/17.
Accession Number: 20170714–5235.
Comments Due: 5 p.m. ET 8/4/17.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER16–2186–000.
Applicants: Deseret Generation & Transmission Co-operative, Inc.
Description: Response to June 19, 2017 Request for Additional Information of Deseret Generation & Transmission Co-operative, Inc.
Filed Date: 7/14/17.
Accession Number: 20170714–5068.
Comments Due: 5 p.m. ET 8/4/17.

Docket Numbers: ER17–2093–000.
Applicants: PJM Interconnection, L.L.C.
Description: § 205(d) Rate Filing: Original Service Agreement No. 4753—NITSA among PJM and Buckeye Power to be effective 6/1/2014.
Filed Date: 7/14/17.
Accession Number: 20170714–5151.
Comments Due: 5 p.m. ET 8/4/17.

Docket Numbers: ER17–2094–000.
Applicants: PJM Interconnection, L.L.C.
Description: § 205(d) Rate Filing: Original Service Agreement No. 4754—NITSA among PJM and IMPA to be effective 10/1/2004.
Filed Date: 7/14/17.
Accession Number: 20170714–5155.
Comments Due: 5 p.m. ET 8/4/17.

Docket Numbers: ER17–2095–000.
Applicants: Black Hills Power, Inc.
Description: § 205(d) Rate Filing: Filing of Executed Transmission Interconnection Agreements to be effective 9/12/2017.
Filed Date: 7/14/17.
Accession Number: 20170714–5168.
Comments Due: 5 p.m. ET 8/4/17.

Docket Numbers: ER17–2096–000.
Applicants: New York Independent System Operator, Inc.
Description: § 205(d) Rate Filing: 205 BSM rules—forecast determinations, escalation factors & inflation rates to be effective 9/12/2017.
Filed Date: 7/14/17.
Accession Number: 20170714–5182.
Comments Due: 5 p.m. ET 8/4/17.

Docket Numbers: ER17–2097–000.
Applicants: Midcontinent Independent System Operator, Inc.
Description: § 205(d) Rate Filing: 2017–07–14_Dynamic Narrowly Constrained Area (NCA) Filing to be effective 11/11/2017.
Filed Date: 7/14/17.
Accession Number: 20170714–5186.
Comments Due: 5 p.m. ET 8/4/17.

Docket Numbers: ER17–2098–000.
Applicants: Black Hills Power, Inc.
Description: § 205(d) Rate Filing: Generation Dispatch and Energy Mgmt Agmt with Gillette, WY to be effective 9/12/2017.
Filed Date: 7/14/17.
Accession Number: 20170714–5209.
Comments Due: 5 p.m. ET 8/4/17.

Docket Numbers: ER17–2099–000.
Applicants: Black Hills Power, Inc.
Description: § 205(d) Rate Filing: Generation Dispatch & Energy Management Agmt with Montana-Dakota Utilities Co. to be effective 9/12/2017.
Filed Date: 7/14/17.
Accession Number: 20170714–5212.
Comments Due: 5 p.m. ET 8/4/17.

Docket Numbers: ER17–2100–000.
Applicants: Black Hills Power, Inc.
Description: § 205(d) Rate Filing: 2017 Amended Generation Dispatch and Energy Mgmt Agmt with Gillette, WY to be effective 9/12/2017.
Filed Date: 7/14/17.
Accession Number: 20170714–5222.
Comments Due: 5 p.m. ET 8/4/17.

Take notice that the Commission received the following electric securities filings:

Docket Numbers: ES17–41–000.
Applicants: Louisville Gas & Electric Company.
Description: Application under Section 204 of the Federal Power Act of Louisville Gas and Electric Company.
Filed Date: 7/17/17.
Accession Number: 20170717–5028.
Comments Due: 5 p.m. ET 8/7/17.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and § 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: July 17, 2017.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2017–15334 Filed 7–20–17; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #2

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER17–2090–000.
Applicants: SolUnesco, LLC.
Description: SolUnesco Request for Waiver.
Filed Date: 7/14/17.
Accession Number: 20170714–5099.
Comments Due: 5 p.m. ET 7/24/17.

Docket Numbers: ER17–2091–000.
Applicants: Northern States Power Company, a Minnesota corporation.
Description: Notice of Cancellation of Rate Schedule(s) No. 331 and No. 508 of Northern States Power Company, a Minnesota corporation.
Filed Date: 7/14/17.
Accession Number: 20170714–5122.
Comments Due: 5 p.m. ET 8/4/17.

Docket Numbers: ER17–2092–000.
Applicants: Cleco Power LLC.
Description: § 205(d) Rate Filing: Amendment 1 to Interconnection Agreement between Cleco and LAGEN to be effective 7/15/2017.
Filed Date: 7/14/17.
Accession Number: 20170714–5131.
Comments Due: 5 p.m. ET 8/4/17.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: July 14, 2017.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2017–15329 Filed 7–20–17; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OAR–2015–0341; FRL–9962–92–OAR]

Notice of Availability of Two Updated Chapters in the Environmental Protection Agency's Air Pollution Control Cost Manual

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of availability and public comment period.

SUMMARY: The Environmental Protection Agency (EPA) is providing notice that two chapters of the current EPA Air Pollution Control Cost Manual (Control Cost Manual) have been updated. The EPA is requesting comment on: Chapter 1, Section 3 and Section 3.1, ''Carbon Adsorbers,'' and Chapter 1, Section 3 and Section 3.2, ''Flares.'' These two Control Cost Manual chapters cover control measures for volatile organic compound (VOC) emissions.

DATES: Comments must be received on or before October 19, 2017. Please refer to **SUPPLEMENTARY INFORMATION** for additional information on submitting comments on the provided data.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OAR–2015–0341, to the *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or withdrawn. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the Web, Cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Larry Sorrels, Health and Environmental Impacts Division, Environmental Protection Agency, C439–02, 109 T.W. Alexander Drive, Research Triangle Park, NC 27709; telephone number: (919) 541–5041; fax number: (919) 541–0839; email address: *sorrels.larry@epa.gov.*

SUPPLEMENTARY INFORMATION: The EPA is requesting comment on the specific Control Cost Manual chapters included in this notice.

I. General Information

A. What should I consider as I prepare my comments for the EPA?

1. *Submitting CBI.* Do not submit this information to the EPA through *www.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 the EPA docket office, 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 Code of Federal Regulation (CFR) part 2.

2. *Tips for Preparing your Comments.* When submitting comments, remember to: Identify the notification by docket number and other identifying information (subject heading, **Federal Register** date and page number).

- Follow directions—The agency may ask you to respond to specific questions or organize comments by referencing a CFR part or section number.
- Explain why you agree or disagree; suggest alternatives and substitute language/data for your requested changes.
- Describe any assumptions and provide any technical information and/or data that you used.
- If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.
- Provide specific examples to illustrate your concerns, and suggest alternatives.
- Explain your views as clearly as possible, avoiding the use of profanity or personal threats.
- Make sure to submit your comments by the comment period deadline identified.

II. Information Available for Public Comment

The EPA is requesting comment on two updated chapters of the EPA Air Pollution Control Cost Manual. The Control Cost Manual contains individual chapters on control measures, including data and equations to aid users in estimating capital costs for installation and annual costs for operation and maintenance of these measures. The Control Cost Manual is used by the EPA for estimating the impacts of rulemakings, and serves as a basis for sources to estimate costs of controls that are Best Available Control Technology under the New Source Review Program, and Best Available Retrofit Technology under the Regional Haze Program and for other programs.

The two updated Control Cost Manual chapters are: Chapter 1, Section 3 and Section 3.1, Carbon Adsorbers; Chapter 1, Section 3 and Section 3.2, Flares. These two revised Control Cost Manual chapters can be found in the docket for the Control Cost Manual update (Docket ID No. EPA–HQ–OAR–2015–0341). The current Control Cost Manual version (sixth edition) is available at *http://epa.gov/ttn/catc/products.html#cccinfo,* and was last updated in 2003. The Consolidated Appropriations Act of 2014 requested that the EPA begin development of a seventh edition of the Control Cost Manual. The EPA has met with state, local, and tribal officials to discuss plans for the Control Cost Manual update as called for under the Consolidated Appropriations Act of 2014. The EPA has met with other groups as well at their request. The EPA has recently updated the selective non-catalytic reduction (SNCR) and selective catalytic reduction (SCR) chapters, the first two chapters (Chapter 1, Section 4; Chapter 2, Section 4, respectively) completed for the seventh edition of the Control Cost Manual, and made them available to the public in May 2016 (81 FR 38702, June 14, 2016). In addition, the EPA has submitted updated draft versions of the Refrigerated Condensers (Chapter 1, Section 3 and Section 3.1) and Incinerators (Chapter 2, Section 3, Section 3.2, now Incinerators/Oxidizers) chapters and the Cost Estimation: Concepts and Methodology chapter (Chapter 2, Section 1) as part of a notice released on September 22, 2016 (81 FR 65352). The Agency is currently reviewing comments submitted in response to the NODA, and will finalize these three chapters in the near future.

To help focus review of the Carbon Adsorbers (Chapter 1, Section 3, and Section 3.1) and Flares (Chapter 1, Section 3 and Section 3.2) chapters, we offer the following list of questions that the EPA is particularly interested in addressing in the updated chapters. Commenters are welcome to address any aspects of these chapters. Please

provide supporting data for responses to these questions and for other comments on the chapters.

For the Carbon Adsorbers chapter:

(1) What is a reasonable estimate of equipment life (defined as design or operational life) for this control measure?

(2) Is the description of carbon adsorbers complete, up to date, and accurate, particularly with regard to control of VOC?

(3) Are the cost correlations, factors, and equations for carbon adsorbers accurate? If not, how should they be revised? Please provide data, if possible, to address inaccuracies.

(4) Are the estimates of VOC removal or control efficiency for carbon adsorbers accurate? If not, what are more accurate estimates? Please provide data, if possible, to address inaccuracies.

For the Flares chapter:

(1) What is a reasonable estimate of equipment life (defined as design or operational life) for this control measure?

(2) Is the description of flares technology complete, up to date, and accurate?

(3) Are the cost correlations, factors, and equations for flares accurate? If not, how should they be revised? Please provide data, if possible, to address inaccuracies.

(4) Are the estimates of flares VOC destruction efficiency accurate? If not, what are more accurate estimates? Please provide data, if possible, to address inaccuracies.

Dated: May 23, 2017.

Stephen Page,

Director, Office of Air Quality Planning and Standards.

[FR Doc. 2017–15344 Filed 7–20–17; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9964–82–OAR]

EPA's Intent To Disclose Confidential Business Information (CBI) Contained in Vehicle Sales Data for Model Years 2015 to the U.S. Energy Information Administration (EIA) for Use in Modeling and Projecting Energy Demand in the Light-Duty Vehicle Sector

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: On June 23, 2017, the Environmental Protection Agency (EPA) received a written request from the U.S. Energy Information Administration (EIA) for historical model year sales data for year 2015 by manufacturer and nameplate. This requested data may contain confidential business information (CBI). The EPA may disclose business information to other Federal agencies that otherwise is not available to the public if certain requirements are met. The EPA intends to share certain information, detailed below, with EIA ten (10) days after publication of this notice. The information requested has been used to model and project energy demand in the light-duty vehicle sector and is critical to EIA's efforts to project energy demand, fuel efficiency, fuel consumption, and greenhouse gas emissions for the transportation sector. EIA has agreed to keep the data confidential and not disclose it further.

DATES: The sales data will be disclosed to EIA on or after July 31, 2017.

FOR FURTHER INFORMATION CONTACT: Sara Zaremski, Office of Transportation and Air Quality, Compliance Division, Environmental Protection Agency, 2000 Traverwood Drive, Ann Arbor, MI 48105; telephone number: 734–214–4362; fax number: 734–214– 4053; email address: *zaremski.sara@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

Entities potentially affected by this action are those involved with the production and sale of motor vehicles. Regulated categories include:

Category	NAICS [1] Codes	SIC [2] Codes	Examples of potentially regulated entities
Industry	336111, 336112	3711	Light-duty vehicle and light-duty truck manufacturers.

[1] North American Industry Classification System (NAICS).
[2] Standard Industrial Classification (SIC) system code.

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by the disclosure.

II. EIA's Request for Model Year Sales Data for Year 2015

In their June 23, 2017 request letter to EPA, EIA requested that EPA provide to EIA historical model year sales data for year 2015 by manufacturer and nameplate. As noted earlier in this document, EIA uses this information to model and project energy demand in the light-duty vehicle sector. Additionally, EIA noted that these data are critical to EIA's continued efforts to project energy demand, fuel efficiency, fuel consumption, and greenhouse gas emissions for the transportation sector. Previously, EIA had been unable to obtain official model year sales data for 2015 due to the fact that it contained CBI. The specific data they requested includes all the data fields currently available in the Excel files provided on the *fueleconomy.gov* Web site (see the Download Fuel Economy Data page at *http://www.fueleconomy.gov/feg/download.shtml*).

Additionally, EIA requested the following data fields: model year sales, tank size, track width, wheelbase, curb weight, horsepower, interior volume, fleet (DP, IP, LT), and test weight. EIA indicated that they are aware that this information is subject to claims of confidential business information. EIA's letter states ''We will take the necessary steps to ensure the data are secure and kept confidential. EIA routinely works with sensitive data and has strong data handling safeguards in place.''

Pursuant to 40 CFR 2.209(c), EPA may disclose business information to another Federal agency if: (1) EPA receives a written request for disclosure of the information from a duly authorized officer or employee of the other agency; (2) the request sets forth the official purpose for which the information is needed; (3) when the information has been claimed as confidential or has been determined to be confidential, the responsible EPA office provides notice to each affected business of the type of information to be disclosed and to whom it is to be disclosed, and such notice may be given by notice published in the **Federal Register** at least 10 days prior to disclosure; (4) EPA notifies the other agency of any unresolved business confidentiality claim covering the information and of any determination under this subpart that the information is entitled to confidential treatment, and that further disclosure of the information may be a violation of the Trade Secrets Act, 18 U.S.C. 1905; and

(5) the other agency agrees in writing that in accordance with the law, it will not disclose further any information designated as confidential.

In the case at hand, all of the required elements of 40 CFR 2.209(c) have been met upon publication of this notice.

III. Impact on Vehicle Manufacturers

Given that EIA is aware that the shared information is CBI or has been claimed as CBI, and intends to take the necessary steps to ensure that the data provided is kept secure and confidential, there is no impact on vehicle manufacturers to the release of this data.

Dated: July 5, 2017.

Byron Bunker,

Director, Compliance Division, Office of Transportation & Air Quality.

[FR Doc. 2017–15377 Filed 7–20–17; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OECA–2017–0206; FRL–9964–67–OECA]

Clean Water Act Class II: Proposed Administrative Settlement, Penalty Assessment and Opportunity To Comment Regarding JPMorgan Chase Bank, N.A.

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has entered into a Consent Agreement with JPMorgan Chase Bank, N.A. (JPMC or Respondent) to resolve violations of the Clean Water Act (CWA), the Clean Air Act (CAA), the Resource Conservation and Recovery Act (RCRA) and the Emergency Planning and Community Right-to-Know Act (EPCRA) and their implementing regulations.

The Administrator is hereby providing public notice of this Consent Agreement and proposed Final Order (CAFO), and providing an opportunity for interested persons to comment on the CAFO. Upon closure of the public comment period, the CAFO and any public comments will be forwarded to the Agency's Environmental Appeals Board (EAB).

DATES: Comments are due on or before August 21, 2017.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OECA–2017–0206, to the *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or withdrawn. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the Web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www2.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Philip Milton, Waste and Chemical Enforcement Division (2249–A), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue NW., Washington, DC 20460; telephone: (202) 564–5029; fax: (202) 564–0010; email: *milton.philip@epa.gov.*

SUPPLEMENTARY INFORMATION:

Background

This proposed settlement agreement is the result of voluntary disclosures of CWA, CAA, RCRA and EPCRA violations by JPMC to the EPA. JPMC and affiliated entities comprise one of the largest financial services firms in the United States, offering investment banking, financial services for consumers and small businesses, commercial banking, financial transaction processing and asset management, both domestically and internationally. JPMorgan Chase Bank, N.A. is a national banking association with its main office located at 1111 Polaris Parkway, Columbus, Ohio 43240.

On August 6, 2014, EPA accepted JPMC's June 19, 2014 proposal to enter into an audit agreement to audit 133 facilities owned and/or operated by JPMC or affiliated entities for compliance with the CAA, CWA, EPCRA, and RCRA under EPA's *Incentives for Self-Policing: Discovery, Disclosure, Correction and Prevention of Violations* (Audit Policy), 65 FR 19618 (April 11, 2000). On December 19, 2014, JPMC provided its final report.

In follow-up to its 2014 Audit and JPMC's commitment to prevent recurrence of noncompliance in the future, JPMC developed and implemented a compliance management system (CMS) that incudes annual auditing. JPMC approached the design of this annual audit program with the same integrity and objectivity as used in the original 2014 Audit program. With the benefit of this expertise, JPMC conducted annual internal audits in 2015 (at 42 sites) and 2016 (at 39 sites) and disclosed additional potential noncompliance discovered through its 2015 and 2016 internal audits on November 20, 2015 and December 2, 2016, respectively.

All violations discovered and disclosed by the Respondent are listed in Attachments A and B to the CAFO.

Proposed Settlement

The EPA determined that Respondent satisfactorily completed its audit and has met all conditions set forth in the Audit Policy for the violations identified in Attachment A of the CAFO. Therefore, 100 percent of the gravity-based penalty calculated for the violations identified in Attachment A of the CAFO is being waived.

Attachment B of the CAFO identifies certain violations that did not meet all the conditions of the Audit Policy. For these violations, a gravity-based penalty of $52,977 is assessed.

For all violations listed in Attachments A and B, EPA calculated an economic benefit of noncompliance of $177,415. This number was calculated using specific cost information provided by Respondent and use of the Economic Benefit (BEN) computer model.

JPMC has agreed to pay a total civil penalty of $230,392 for all the violations identified in Attachments A and B of the CAFO. Of this amount, $177,415 is the economic benefit of noncompliance and $52,977 is the gravity-based penalty for the violations listed in Attachment B of the CAFO.

Of this total amount, $16,731 is attributable to the CAA violations, $88,538 is attributable to the CWA SPCC violations, $27,649 is attributable to the RCRA violations, and $97,474 is attributable to the EPCRA violations.

The EPA and Respondent negotiated the Consent Agreement in accordance with the Consolidated Rules of Practice, 40 CFR part 22, specifically 40 CFR 22.13(b) and 22.18(b) (*In re: JPMorgan Chase Bank, N.A.*; enforcement settlement identifier numbers CAA–HQ–2017–6001, CWA–HQ–2017–6001; EPCRA–HQ–2017–6001; and RCRA–HQ–2017–6001). This Consent Agreement is subject to public notice and comment under Section

311(b)(6)(C) of the CWA, 33 U.S.C. 1321(b)(6)(C). The procedures by which the public may comment on a proposed CWA Class II penalty order, or participate in a Class II penalty proceeding, are set forth in 40 CFR 22.45. The deadline for submitting public comment on this proposed Final Order is [*INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE* **Federal Register**]. All comments will be transferred to the EAB for consideration. The EAB's powers and duties are outlined in 40 CFR 22.4(a).

Disclosed and Corrected Violations

CWA

Respondent disclosed that it failed to prepare and/or implement a Spill Prevention, Control, and Countermeasure (SPCC) Plan in violation of CWA Section 311(j), 33 U.S.C. 1321(j), and the implementing regulations found at 40 CFR part 112, at the following forty-four (44) facilities located in Arizona, California, Delaware, Florida, Indiana, Kentucky, Louisiana, Massachusetts, Michigan, New Hampshire, New Jersey, New York, Ohio, and Texas, identified in Attachments A and B of the CAFO.

Facility	Street	City	State
Sky Harbor Operations Center	1820 E Sky Harbor Circle S	Phoenix	Arizona.
560 Mission Street	560 Mission Street	San Francisco	California.
Iron Hill-Cole House Bldg.	4041 Ogletown Road	Newark	Delaware.
880 Powder Mill Rd	880 Powder Mill Rd	Wilmington	Delaware.
Four Christina Center	300 King Street	Wilmington	Delaware.
7255 Baymeadows Way	7255 Baymeadows Way	Jacksonville	Florida.
7301 Baymeadows Way	7301 Baymeadows Way	Jacksonville	Florida.
H01—H03 Highland Manor Drive	10410–30 Highland Manor Drive	Tampa	Florida.
4200 W Cypress Street	4200 W. Cypress Street, Suite 350	Tampa	Florida.
HO1–10430 Highland Manor	10430 Highland Manor Drive	Tampa	Florida.
Indianapolis West Operation Center	7610 West Washington Street	Indianapolis	Indiana.
IRS Louisville Operations	5101 Interchange Way	Louisville	Kentucky.
Vault Complex	1245 Edwards Road	Harahan	Louisiana.
Delta Drive Complex	780 Kansas Lane 780 Delta Drive. 700 Kansas Lane.	Monroe	Louisiana.
Zachary Command Center	4431–B Highway 19	Zachary	Louisiana.
451 D Street	70 Fargo Street	Boston	Massachusetts.
Belleville Technology Center	9000 Haggerty Road	Belleville	Michigan.
1 Northeastern Blvd 4 Northeastern Blvd. 5 Northeastern Blvd.	1 Northeastern Blvd 4 Northeastern Blvd 5 Northeastern Blvd	Salem	New Hampshire.
Carlstadt Data Center	600 Commerce Boulevard	Carlstadt	New Jersey.
NOC 5—575 Washington	575 Washington Boulevard	Jersey City	New Jersey.
Weehawken Data Center	300 Boulevard East	Weehawken	New Jersey.
Flatbush Ave	883 Flatbush Avenue	Brooklyn	New York.
WM5469 Dekalb	9 DeKalb Ave	Brooklyn	New York.
New Rochelle Main St	491 Main Street	New Rochelle	New York.
SoHo	525 Broadway	New York	New York.
383 Madison Avenue (BSC)	383 Madison Avenue	New York	New York.
WM5477 East Village	130 Second Ave	New York	New York.
270 Park Avenue	270 Park Avenue	New York	New York.
1000 Polaris	1000 Polaris Parkway	Columbus	Ohio.
Polaris McCoy Center	1111 Polaris Parkway	Columbus	Ohio.
3415 Vision Drive	3415 Vision Drive	Columbus	Ohio.
340 McCoy Building	340 South Cleveland Avenue	Westerville	Ohio.
370 McCoy Building	370 South Cleveland Avenue	Westerville	Ohio.
380 McCoy Building	380 South Cleveland Avenue	Westerville	Ohio.
Arlington Call Center	4501 New York Avenue	Arlington	Texas.
WM7097 Dallas EDC 1	2500 Marsh Lane	Carrolton	Texas.
Freeport IV	1111 North Point Drive	Coppell	Texas.
Freeport TX	625 Freeport Parkway	Coppell	Texas.
JPMIP One	14201 North Dallas Parkway	Farmers Branch	Texas.
1111 Fannin	1111 Fannin	Houston	Texas.
WM7266 Royal Ridge Operations Center RROC.	3929 W John Carpenter Freeway	Irving	Texas.
Lake Vista III (BSC)	2780 Lake Vista Drive	Lewisville	Texas.
Lake Vista 7—Lewisville	2777 Lake Vista Drive	Lewisville	Texas.
WM2200 Stone Oak Bldg C	20855 Stone Oak Parkway	San Antonio	Texas.

Under CWA Section 311(b)(6)(A), 33 U.S.C. 1321(b)(6)(A), any owner, operator, or person in charge of a vessel, onshore facility, or offshore facility from which oil is discharged in violation of CWA Section 311(b)(3), 33 U.S.C. 1321(b)(3), or who fails or refuses to comply with any regulations that have been issued under CWA Section 311(j), 33 U.S.C. 1321(j), may be assessed an administrative civil penalty of up to $226,338 by the EPA. Class II proceedings under CWA Section 311(b)(6), 33 U.S.C. 1321(b)(6), are conducted in accordance with 40 CFR part 22. As authorized by CWA Section 311(b)(6), 33 U.S.C. 1321(b)(6), the EPA has assessed a civil penalty for these violations.

Pursuant to CWA Section 311(b)(6)(C), 33 U.S.C. 1321(b)(6)(C), the EPA will not issue an order in this proceeding prior to the close of the public comment period.

EPCRA

Respondent disclosed that it violated EPCRA Section 311(a), 42 U.S.C. 11021(a), and the implementing regulations found at 40 CFR part 370, at seventy-four (74) facilities listed in Attachments A and B of the CAFO when it failed to submit a Material Safety Data Sheet (MSDS) for a hazardous chemical(s) and/or extremely hazardous substance(s) or, in the alternative, a list of such chemicals, to the LEPCs, SERCs, and the fire departments with jurisdiction over these facilities. These seventy-four (74) facilities are located in the following states: Arizona, California, Delaware, Florida, Georgia, Illinois, Indiana, Kentucky, Louisiana, Massachusetts, Missouri, New Hampshire, New Jersey, New York, Ohio, and Texas.

Respondent disclosed that it violated EPCRA Section 312(a), 42 U.S.C. 11022(a), and the implementing regulations found at 40 CFR part 370, at seventy-three (73) facilities listed in Attachments A and B of the CAFO when it failed to prepare and submit emergency and chemical inventory forms to the LEPCs, SERCs, and the fire departments with jurisdiction over these facilities. These seventy-one facilities are located in the following states: Arizona, California, Delaware, Florida, Illinois, Indiana, Kentucky, Louisiana, Massachusetts, Missouri, New Hampshire, New Jersey, New York, Ohio, and Texas.

Under EPCRA Section 325, 42 U.S.C. 11045, the Administrator may issue an administrative order assessing a civil penalty against any person who has violated applicable emergency planning or right-to-know requirements, or any other requirement of EPCRA. Proceedings under EPCRA Section 325, 42 U.S.C. 11045, are conducted in accordance with 40 CFR part 22. The EPA, as authorized by EPCRA Section 325, 42 U.S.C. 11045, has assessed a civil penalty for these violations.

CAA

ODS Requirements

Respondent disclosed that it violated CAA Sections 608(a)(1) and (2), 42 U.S.C. 7671g(a)(l) and (2), and the implementing regulations found 40 CFR part 82, at thirty-four (34) facilities listed in Attachments A and B of the CAFO when it failed to maintain records required by 40 CFR 82.166 for its appliances. These thirty-four (34) facilities are located in the following states: Arizona, California, Illinois, Louisiana, Michigan, Missouri, New York, Ohio, Oklahoma, Oregon, Texas, and Wisconsin.

CAA NSPS Subpart IIII

Respondent disclosed that it failed to comply with CAA Section 111, 42 U.S.C. 7411, and 40 CFR part 60, subpart IIII when it failed to maintain a 12-month rolling total log of the hours of operation for four (4) compression ignition internal combustion engines (emergency generators) at one (1) facility in Michigan.

Under CAA Section 113(d), 42 U.S.C. 7413(d), the Administrator may issue an administrative penalty order to any person who has violated or is in violation of any applicable requirement or prohibition of the CAA, including any rule, order, waiver, permit, or plan. Proceedings under CAA Section 113(d), 42 U.S.C. 7413(d), are conducted in accordance with 40 CFR part 22. The EPA, as authorized by the CAA, has assessed a civil penalty for these violations.

RCRA

Respondent disclosed that it failed to comply with RCRA Section 3002 of RCRA, 42 U.S.C. 6922, and the regulations found at 40 CFR part 273, at seventy-eight (78) facilities listed in Attachments A and B of the CAFO when it failed to maintain proper universal waste disposal and handling by failing to properly store, label, or inventory spent fluorescent lamps and tubes, used lead-acid batteries, and by failing to train employees in proper identification. These seventy-eight (78) facilities are located in the following states: Arizona, California, Colorado, Delaware, Florida, Georgia, Illinois, Indiana, Kentucky, Louisiana, Michigan, New Hampshire, New Jersey, New York, Ohio, Oklahoma, Texas, Washington, and Wisconsin.

Under RCRA Section 3008, 42 U.S.C. 6928, the Administrator may issue an order assessing a civil penalty for any past or current violation the RCRA. Proceedings under RCRA Section 3008, 42 U.S.C. 6928, are conducted in accordance with 40 CFR part 22. The EPA, as authorized by the RCRA, has assessed a civil penalty for these violations.

List of Subjects

Environmental protection.

Dated: June 29, 2017.

Susan Shinkman,

Director, Office of Civil Enforcement, Office of Enforcement and Compliance Assurance.

[FR Doc. 2017–15376 Filed 7–20–17; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9965–19-Region 1]

Proposed CERCLA Administrative Cost Recovery Settlement: Parker Street Waste Site, New Bedford, Massachusetts

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of proposed settlement; request for public comments.

SUMMARY: Notice is hereby given of a proposed administrative cost settlement for recovery of response costs concerning the Parker Street Waste Site, located in New Bedford, Bristol County, Massachusetts with the Settling Party the City of New Bedford. The proposed settlement requires the Settling Party pay EPA $1,600,000 to settle EPA's past response costs, which currently amount to $18,408,619. In exchange, EPA will provide the Settling Party with a covenant not to sue for past costs. The settlement has been approved by the Environmental and Natural Resources Division of the United States Department of Justice. For 30 days following the date of publication of this notice, the Agency will receive written comments relating to the settlement for recovery of response costs. The Agency will consider all comments received and may modify or withdraw its consent to this cost recovery settlement if comments received disclose facts or considerations which indicate that the settlement is inappropriate, improper, or inadequate. The Agency's response to any comments received will be available for public inspection at the New Bedford Free Public Library, 613 Pleasant Street, New Bedford 02740 and at the Environmental Protection Agency—Region I, 5 Post Office Square, Suite 100, Boston, MA 02109–3912.

DATES: Comments must be submitted by August 21, 2017.

ADDRESSES: Comments should be addressed to John Kilborn, Senior Enforcement Counsel, U.S. Environmental Protection Agency, 5 Post Office Square, Suite 100 (OES04–3), Boston, MA 02109–3912 (Telephone No. 617–918–1893) and should reference the Parker Street Waste Site, U.S. EPA Docket No: CERCLA 01–2012–0040.

FOR FURTHER INFORMATION CONTACT: A copy of the proposed settlement may be obtained from Stacy Greendlinger, Office of Site Remediation and Restoration, U.S. Environmental Protection Agency, Region I, 5 Post Office Square, Suite 100 (OSRR02–2),

Boston, MA 02109–3912, (617) 918–1403; *greendlinger.stacy@epa.gov.* Technical questions can also be directed to Stacy Greendlinger. For legal questions, John Kilborn, Office of Environmental Stewardship, U.S. Environmental Protection Agency, Region I, 5 Post Office Square, Suite 100 (OES04–3), Boston, MA 02109–3912, (617) 918–1893; *kilborn.john@epa.gov*.

SUPPLEMENTARY INFORMATION: This proposed administrative settlement for recovery of past response costs concerning the Parker Street Waste Site, located in New Bedford, Bristol County, Massachusetts is made in accordance with Section 122(h)(l) of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA). EPA covenants not to sue or take administrative action against the Settling Party, the City of New Bedford, pursuant to Section 107(a) of CERCLA, 42 U.S.C. 9607(a), for Past Response Costs. In exchange, the Settling Party agrees to pay EPA $1,600,000. Payment of such amount shall be due within 30 days after the Effective Date and, if timely paid, shall include no interest. If payment is not paid as stipulated, interest shall accrue beginning as of the Effective Date and shall continue to accrue on any unpaid amount until the total amount due has been received. For 30 days following the date of publication of this notice, the Agency will receive written comments relating to the settlement for recovery of response costs. The Effective Date of the Agreement is the date upon which EPA notifies the City that the public comment period has closed and that such comments, if any, do not require that EPA modify or withdraw from the Agreement.

Dated: June 22, 2017.

Bryan Olson,

Director, Office of Site Remediation and Restoration.

[FR Doc. 2017–15378 Filed 7–20–17; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9964–92–Region 6]

Underground Injection Control Program; Hazardous Waste Injection Restrictions; Petition for Exemption Reissuance—Class I Hazardous Waste Injection; Vopak Logistics Services USA Inc. Deer Park, Texas

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of a final decision on a UIC no migration petition reissuance.

SUMMARY: Notice is hereby given that a reissuance of an exemption to the Land Disposal Restrictions, under the 1984 Hazardous and Solid Waste Amendments to the Resource Conservation and Recovery Act, has been granted to Vopak for one Class I hazardous waste injection well located at their Deer Park, Texas facility. The company has adequately demonstrated to the satisfaction of the Environmental Protection Agency by the petition reissuance application and supporting documentation that, to a reasonable degree of certainty, there will be no migration of hazardous constituents from the injection zone for as long as the waste remains hazardous. This final decision allows the underground injection by Vopak of the specific restricted hazardous wastes identified in this exemption reissuance, into Class I hazardous waste injection Well WDW–157 until December 31, 2030, unless EPA moves to terminate this exemption or other petition condition limitations are reached. Additional conditions included in this final decision may be reviewed by contacting the Region 6 Ground Water/UIC Section. A public notice was issued May 3, 2017, and the public comment period closed on June 19, 2017, and no comments were received. This decision constitutes final Agency action and there is no Administrative appeal. This decision may be reviewed/appealed in compliance with the Administrative Procedure Act.

DATES: This action is effective as of June 23, 2017.

ADDRESSES: Copies of the petition reissuance and all pertinent information relating thereto are on file at the following location: Environmental Protection Agency, Region 6, Water Division, Safe Drinking Water Branch (6WQ–S), 1445 Ross Avenue, Dallas, Texas 75202–2733.

FOR FURTHER INFORMATION CONTACT: Philip Dellinger, Chief Ground Water/UIC Section, EPA—Region 6, telephone (214) 665–8324.

Dated: June 23, 2017.

William K. Honker,

Director, Water Division.

[FR Doc. 2017–15382 Filed 7–20–17; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OEI–2017–0380; FRL–9964–69–OEI]

Proposed Information Collection Request; Comment Request; Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency is planning to submit an information collection request (ICR), ''Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery'' to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. Before doing so, EPA is soliciting public comments on specific aspects of the proposed information collection as described below. This is a proposed extension of the ICR, which is currently approved through November 30, 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.

DATES: Comments must be submitted on or before September 19, 2017.

ADDRESSES: Submit your comments, referencing Docket ID No. EPA–HQ–OEI–2017–0380 online using *www.regulations.gov* (our preferred method), or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW., Washington, DC 20460.

EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

FOR FURTHER INFORMATION CONTACT: Courtney Kerwin, Office of Environmental Information, Regulatory Support Division, Environmental Protection Agency, Mail Code 2822T 1200 Pennsylvania Ave. NW., Washington, DC 20460; telephone number: 202–566–1669 and email address*: Kerwin.courtney@epa.gov.*

SUPPLEMENTARY INFORMATION: The supporting documents for this ICR (Generic Clearance for the Collection of Qualitative Feedback on Agency Service

Delivery, EPA ICR No. 2434.75, OMB Control No. 2010–0042), which explain in detail the information that the EPA will be collecting, are available in the public docket for this ICR. The docket can be viewed online at *www.regulations.gov* or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW., Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit *http://www.epa.gov/dockets.*

Pursuant to section 3506(c)(2)(A) of the PRA, EPA is soliciting comments and information to enable it to: (i) 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; (ii) 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; (iii) enhance the quality, utility, and clarity of the information to be collected; and (iv) 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. 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. At that time, EPA will issue another **Federal Register** notice to announce the submission of the ICR to OMB and the opportunity to submit additional comments to OMB.

Abstract: The information collection activity provides a means to garner qualitative customer and stakeholder feedback in an efficient, timely manner, in accordance with the Administration's commitment to improving service delivery. Qualitative feedback includes information that provides useful insights on perceptions and opinions, but are not statistical surveys that yield quantitative results that can be generalized to the population of study.

This feedback will provide insights into customer or stakeholder perceptions, experiences and expectations, provide an early warning of issues with service, or focus attention on areas where communication, training or changes in operations might improve delivery of products or services. These collections will allow for ongoing, collaborative and actionable communications between the Agency and its customers and stakeholders. It will also allow feedback to contribute directly to the improvement of program management. The solicitation of feedback will target areas such as: Timeliness, appropriateness, accuracy of information, courtesy, efficiency of service delivery, and resolution of issues with service delivery. Responses will be assessed to plan and inform efforts to improve or maintain the quality of service offered to the public. If this information is not collected, vital feedback from customers and stakeholders on the Agency's services will be unavailable.

The Agency will only submit a collection for approval under this generic clearance if: The collections are voluntary; the collections are low-burden for respondents and are low-cost for both the respondents and the Federal Government; the collections are noncontroversial and do not raise issues of concern to other Federal agencies; the collection is targeted to the solicitation of opinions from respondents who have experience with the program or may have experience with the program in the near future; personally identifiable information (PII) is collected only to the extent necessary and is not retained; information gathered will be used only internally for general service improvement and program management purposes and is not intended for release outside of the agency; information gathered will not be used for the purpose of substantially informing influential policy decisions; information gathered will yield qualitative information.

Respondents/affected entities: Individuals and Households; Businesses and Organizations; State, Local or Tribal Government.

Respondent's obligation to respond: Voluntary.

Estimated number of respondents: 120,000 (total).

Frequency of response: Once per request.

Total estimated burden: 30,000 hours. Burden is defined at 5 CFR 1320.03(b).

Total estimated cost: There are no annualized capital or operation & maintenance costs.

Changes in estimates: There is an increase of 10,000 hours annually in the total estimated respondent burden compared with the ICR currently approved by OMB. This increase in hours is due to the increase in the use of surveys by the Agency.

Courtney Kerwin,

Director, Regulatory Support Division.

[FR Doc. 2017–15345 Filed 7–20–17; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9963–99-Region 6]

Clean Air Act Operating Permit Program; Petitions for Objection to State Operating Permit for Bunge North America, Inc. Destrehan Grain Elevator, Destrehan, St. Charles Parish, Louisiana

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of final action.

SUMMARY: Pursuant to the Clean Air Act (CAA), the EPA Administrator signed an Order, dated June 7, 2017, denying a petition asking EPA to object to the operating permit issued by the Louisiana Department of Environmental Quality (LDEQ) to Bunge North America, Inc. (Bunge) for its Destrehan Grain Elevator. Title V operating permit number 2520–00048–V5 was issued on December 18, 2015 by the LDEQ to Bunge for modifications to the Destrehan Grain Elevator located in St. Charles Parish, Louisiana. EPA's June 7, 2017 Order responds to a petition submitted on January 24, 2016 by the Tulane Environmental Law Clinic on behalf of Petitioners Ms. Cynthia Portera and Ms. Toni Offerman. Sections 307(b) and 505(b)(2) of the Act provide that a petitioner may ask for judicial review of those portions of the Orders that deny objections raised in the petitions in the appropriate United States Court of Appeals. Any petition for review shall be filed within 60 days from the date this notice appears in the **Federal Register**, pursuant to section 307(b) of the Act.

ADDRESSES: You may review copies of the final Order, the petition, and other supporting information at EPA Region 6, 1445 Ross Avenue, Dallas, Texas 75202–2733.

EPA requests that if at all possible, you contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section to view copies of the final Order, petition, and other supporting information. You may view the hard copies Monday through Friday, from 9:00 a.m. to 3:00 p.m., excluding Federal holidays. If you wish to examine these documents, you should make an appointment at least 24 hours before the visiting day. Additionally, the final June 7, 2017 Order is available electronically at: *https://www.epa.gov/sites/production/files/2017-06/documents/bunge_response2016.pdf.*

FOR FURTHER INFORMATION CONTACT: Brad Toups at (214) 665–7258, email address: *toups.brad@epa.gov* or the above EPA, Region 6 address.

SUPPLEMENTARY INFORMATION: The CAA affords EPA a 45-day period to review, and object, as appropriate, to a title V operating permit proposed by a state permitting authority. Section 505(b)(2) of the CAA and 40 CFR 70.8(d) authorizes any person to petition the EPA Administrator, within 60 days after the expiration of this review period, to object to a title V operating permit if EPA has not done so. Petitions must be based only on objections to the permit that were raised with reasonable specificity during the public comment period provided by the state, unless the petitioner demonstrates that it was impracticable to raise these issues during the comment period or unless the grounds for the issue arose after this period.

EPA received the petition from the Petitioners on January 24, 2016 for the operating permit issued on December 18, 2015 to Bunge North America, Inc. Destrehan Grain Elevator, Destrehan, St. Charles Parish, Louisiana.

The Petitioner requests that the Administrator object to the proposed operating permit issued by the LDEQ to Bunge based on two claims. The claims are described in detail in Section IV of the Order. In summary, the issues raised are that: (1) The permit fails to comply with the Act's requirements for inclusion of a compliance plan and schedule in an issued permit; and, (2) the permit should have addressed the state 'Environmental Assessment' as mandated under Louisiana Revised Statute R.S. 30:2018(C) for any source undergoing a 'substantial modification.' The Order issued on June 7, 2017 responds to the Petition and explains the basis for EPA's decision.

Dated: June 29, 2017.

Samuel Coleman,

Acting Regional Administrator, Region 6.

[FR Doc. 2017–15324 Filed 7–20–17; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9965–16–OA]

Local Government Advisory Committee: Request for Nominations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of request for nominations.

SUMMARY: EPA's Local Government Advisory Committee (LGAC) is a federal advisory committee chartered in 1992 under the Federal Advisory Committee Act (FACA) to advise the EPA Administrator ''from the field'' on a broad range of environmental issues impacting local governments. Current LGAC committee members, and future qualified nominees, hold either elected or non-elected/appointed positions and possess leadership experience—whether managerial or technical/programmatic—in the following contexts: Small community or township government (under 10,000 population); moderate-size or large city government; county government; state government; and, tribal government.

This notice solicits nominations to fill 10–15 vacancies on EPA's LGAC—currently comprised of 35 individuals—beginning in July, 2017. Vacancies are anticipated to be filled by September, 2017.

DATES: Nominations are reviewed on an ongoing basis. However, to be considered for September 2017 appointments, nominations should be submitted by August 10, 2017.

ADDRESSES: Submit nominations electronically to *eargle.frances@epa.gov* with a subject heading of 'LGAC 2017 NOMINATION'. You may also submit nominations by mail to: M. Frances Eargle, LGAC Designated Federal Officer, Office of Congressional and Intergovernmental Relations (OCIR), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue NW., (MC1301A), Washington, DC 20460. Non-electronic submissions must follow the same format and contain the same information.

FOR FURTHER INFORMATION CONTACT: M. Frances Eargle, Designated Federal Officer for the LGAC, U.S. EPA; telephone (202)564–3115; email: *eargle.frances@epa.gov.*

SUPPLEMENTARY INFORMATION:

Nominations: The credentials of all applicants/nominees will be fully considered, but viable candidates must—at a minimum—fall within the vocational/experiential parameters outlined in the Summary above. In addition to experience in local and/or state government, additional criteria to be considered may include: Experience with public-private partnerships; coalition-building and grass-roots involvement; implementation of environmental regulatory programs, whether federally-delegated, state-required or locally-mandated, including permitting programs, Brownfields, Superfund clean-up, air and water quality, and solid waste management; and, rural and/or small community economic development. Diversity in vocational/career background, including private sector/industry experience, agricultural sector experience, professional affiliations, and demonstrated familiarity with local, regional and national environmental issues, also may be considered.

LGAC members are appointed for 1–2 year terms and are eligible for reappointment. The Committee meets several times a year, and the Administrator may ask members to serve on Subcommittees and Workgroups to develop reports and recommendations to address specific policy issues. The average workload for members is approximately 5 to 8 hours per month. While EPA is unable to provide compensation for services, official Committee travel and related expenses (lodging, etc.) will be fully reimbursed.

Nominations can be submitted in electronic format (preferred) or in hard copy format (see **ADDRESSES** section above). To be considered, all nominations should include:

- Current contact information for the applicant/nominee, including name, organization (and position within that organization), current business address, email address, and daytime telephone number;
- Brief statement describing the nominee's interest in serving on the LGAC;
- Resume and short biography (no more than 2 paragraphs) describing professional, educational and other pertinent qualifications of the nominee, including a list of relevant activities as well as any current or previous service on advisory committees; and,
- Letter(s) of recommendation from a third party (or parties) supporting the nomination. Letter(s) should describe how the nominee's experience and knowledge will bring value to the work of the LGAC.

Other sources, in addition to this **Federal Register** notice, may be utilized in the solicitation of nominees. EPA expressly values and welcomes diversity. In an effort to obtain nominations of diverse candidates, the agency encourages nominations of women and men of all racial and ethnic groups. Individuals may self-nominate.

Dated: June 30, 2017.

M. Arnita Hannon-Christmon,

Acting Director, State and Local Relations, Office of Congressional and Intergovernmental Relations.

[FR Doc. 2017–15383 Filed 7–20–17; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–9034–3]

Environmental Impact Statements; Notice of Availability

Responsible Agency: Office of Federal Activities, General Information (202) 564–7146 or *http://www.epa.gov/nepa.*

Weekly receipt of Environmental Impact Statements (EISs)
Filed 07/10/2017 Through 07/14/2017
Pursuant to 40 CFR 1506.9

Notice

Section 309(a) of the Clean Air Act requires that EPA make public its comments on EISs issued by other Federal agencies. EPA's comment letters on EISs are available at: *http://www.epa.gov/compliance/nepa/eisdata.html.*

EIS No. 20170130, Final, FHWA, UT, West Davis Corridor, *Review Period Ends:* 08/31/2017, *Contact:* Paul Ziman 801–955–3525.

EIS No. 20170131, Final, DOC, PROG, Nationwide Public Safety Broadband Network for the Western United States, *Review Period Ends:* 08/21/2017, *Contact:* Amanda Goebel Pereira 571–665–6072.

EIS No. 20170132, Final, TVA, TN, Multiple Reservoir Land Management Plans, *Review Period Ends:* 08/21/2017, *Contact:* Matthew Higdon 865–632–8051.

EIS No. 20170133, Final, Caltrans, CA, Northwest SR138 Corridor, *Review Period Ends:* 08/21/2017, *Contact:* Susan Tse 213–897–1621.

Amended Notices

EIS No. 20170032, Draft, USFS, OR, Ringo Project, *Comment Period Ends:* 09/05/2017, *Contact:* Lillian Cross 541–433–3200, Revision to FR Notice Published 03/17/2017; Reopening Comment to End 09/05/2017.

Dated: July 18, 2017.

Dawn Roberts,

Management Analyst, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 2017–15384 Filed 7–20–17; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The applications will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than August 16, 2017.

A. Federal Reserve Bank of St. Louis (David L. Hubbard, Senior Manager) P.O. Box 442, St. Louis, Missouri 63166–2034. Comments can also be sent electronically to *Comments.applications@stls.frb.org:*

1. *Simmons First National Corporation,* Pine Bluff, Arkansas; to acquire voting shares of First Texas BHC, Inc., Fort Worth, Texas; and thereby indirectly acquire shares of Southwest Bank, Fort Worth, Texas.

Board of Governors of the Federal Reserve System, July 18, 2017.

Yao-Chin Chao,

Assistant Secretary of the Board.

[FR Doc. 2017–15361 Filed 7–20–17; 8:45 am]

BILLING CODE 6210–01–P

GENERAL SERVICES ADMINISTRATION

[OMB Control No. 3090–0163; Docket 2017–0001; Sequence 5]

Information Collection; General Services Acquisition Regulation; Information Specific to a Contract or Contracting Action (Not Required by Regulation)

AGENCY: Office of Acquisition Policy, General Services Administration (GSA).

ACTION: Notice of request for public comments regarding an extension to an existing OMB clearance.

SUMMARY: Under the provisions of the Paperwork Reduction Act, the Regulatory Secretariat Division will be submitting to the Office of Management and Budget (OMB) a request to review and approve an extension of a previously approved information collection requirement regarding Information Specific to a Contract or Contracting Action (not required by regulation).

DATES: Submit comments on or before: September 19, 2017.

ADDRESSES: Submit comments identified by Information Collection 3090–0163, Information Specific to a Contract or Contracting Action (Not Required by Regulation), by any of the following methods:

- *Regulations.gov: http://www.regulations.gov.* Submit comments via the Federal eRulemaking portal by searching the OMB control number 3090–0163. Select the link ''Comment Now'' that corresponds with ''Information Collection 3090–0163, Information Specific to a Contract or Contracting Action (Not Required by Regulation)''. Follow the instructions provided on the screen. Please include your name, company name (if any), and ''Information Collection 3090–0163, Information Specific to a Contract or Contracting Action (Not Required by Regulation),'' on your attached document.
- *Mail:* General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW., Washington, DC 20405. ATTN: Ms. Sosa/IC 3090–0163, Information Specific to a Contract or Contracting Action (Not Required by Regulation).

Instructions: Please submit comments only and cite Information Collection 3090–0163, Information Specific to a Contract or Contracting Action (Not Required by Regulation), in all correspondence related to this collection. Comments received generally will be posted without change to *http://www.regulations.gov,* including any personal and/or business confidential information provided. To confirm receipt of your comment(s), please check *www.regulations.gov,* approximately two to three days after submission to verify posting (except allow 30 days for posting of comments submitted by mail).

FOR FURTHER INFORMATION CONTACT: Ms. Jennifer Calik, Procurement Analyst, GSA Acquisition Policy Division, at

telephone 312–353–6090 or email *jennifer.calik@gsa.gov.*

SUPPLEMENTARY INFORMATION:

A. Purpose

GSA has various mission responsibilities related to the acquisition and provision of supplies, transportation, information technology, telecommunications, real property management, and disposal of real and personal property. These mission responsibilities generate requirements that are realized through the solicitation and award of public contracts. In Fiscal Year 2016, these contracts had values ranging from under $100 to over $777,000,000, including the base and all options.

Most GSA procurement-related information collections are required by the Federal Acquisition Regulation (FAR) or General Services Administration Acquisition Regulation (GSAR); each clause requiring such a collection must be individually approved by OMB. However, some solicitations require contractors to submit information specific to that contracting action, such as information needed to evaluate offers (*e.g.,* specific instructions for technical and price proposals, references for past performance) or data used to administer resulting contracts (*e.g.,* project management plans).

This information collection is currently associated with GSA's information collection requirements contained in solicitations issued in accordance with the Uniform Contract Format under FAR Part 14, Sealed Bidding (see GSAR 514.201–1); FAR Part 15, Contracting by Negotiation (see GSAR 515.204–1); and solicitations under FAR Part 12, Acquisition of Commercial Items, when issued in accordance with the policy and procedures of FAR Part 14 and FAR Part 15 (see GSAR 512.301). This includes information collection requirements found in GSA Federal Supply Schedule (FSS) solicitations.

B. Annual Reporting Burden

Respondents: 347,239.
Responses per Respondent: 1.
Total Responses: 347,239.
Hours per Response: .40.
Total Burden Hours: 138,896.

C. Public Comments

Public comments are particularly invited on: Whether this collection of information is necessary and whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate and based on valid assumptions and methodology; and ways to enhance the quality, utility, and clarity of the information to be collected.

Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street, Washington, DC 20405, telephone 202–501–4755. Please cite OMB Control No. 3090–0163, Information Specific to a Contract or Contracting Action (Not Required by Regulation), in all correspondence.

Jeffrey A. Koses,

Senior Procurement Executive, Office of Acquisition Policy, Office of Government-wide Policy.

[FR Doc. 2017–15343 Filed 7–20–17; 8:45 am]

BILLING CODE 6820–61–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Extension of Funding to Special Olympics

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Disease Control and Prevention (CDC) within the Department of Health and Human Services announces the intent to extend the fund to Special Olympics Inc. To improve knowledge and awareness about the usefulness and effectiveness of health promotion programs and policy, systems and environmental improvements for people with intellectual disabilities.

DATES: Funding is extended from September 30, 2017 to March 31, 2018.

ADDRESSES:

Agency Contacts: CDC encourages inquiries concerning this announcement. For programmatic technical assistance, contact: Mary Helen Witten, Project Officer, Department of Health and Human Services, Centers for Disease Control and Prevention, National Center on Birth Defects and Developmental Disabilities, 1600 Clifton Road NE., Mailstop E–88, Atlanta, GA 30333, Email: *muw4@cdc.gov.*

For financial, grants management, or budget assistance, contact: Barbara Strother, Grants Management Specialist, Department of Health and Human Services, Centers for Disease Control and Prevention, Office of Financial Resources, 2920 Brandywine Road, Atlanta, GA 30341–4146, Email: *kty4@cdc.gov.*

FOR FURTHER INFORMATION CONTACT: L.C. Browning, Office of Grants Services (OGS), Technical Information Management Section (TIMS), *ogstims@cdc.gov,* 770–498–2700.

SUPPLEMENTARY INFORMATION:

Part I. Overview Information

This notice announces the Centers for Disease Control and Prevention's (CDC) intent to extend the fund to Special Olympics Inc.

Federal Agency Name: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (DHHS).

Funding Opportunity Title: National Centers on Health Promotion for People with Disabilities.

Announcement Type: Cooperative Agreement.

Agency Funding Opportunity Number: CDC–RFA–DD16–1602.

Catalog of Federal Domestic Assistance (CFDA) Number: 93.184 Disabilities Prevention.

Dates: September 30, 2017–March 31, 2018.

Part II. Full Text

Award Information:

Eligibility Information: These funds will be awarded to Special Olympics, Inc. under Funding Opportunity Announcement DD16–1602, National Centers on Health Promotion for People with Disabilities. Under the proposed supplement, the recipient has been identified as the only qualified organization to perform the required activities.

Request Application Package: The application package will be distributed via an email attachment to the recipient by the Grants Management Specialist. Applications are due August 11, 2017.

Application Package: August 11, 2017.

Submission Dates and Times: August 11, 2017, 11:59 p.m. Eastern Time.

Reports and Proposals must be submitted by August 11, 2017 for the supplemental period (9/30/2017 through 3/31/2018). Late or incomplete reports could result in an enforcement action such as a delay in the award. CDC will accept requests for a deadline extension on rare occasions and after adequate justification has been provided.

General Application Packet Tips:

- Properly label each item of the application packet
- Each section should use 1.5 spacing with one-inch margins

- Number all narrative pages only
- This report must not exceed 20 pages excluding administrative reporting; web links are allowed
- Where the instructions on the forms conflict with these instructions, follow these instructions

1. CDC requires the use of PDF format for ALL attachments.

2. Use of file formats other than PDF may result in the file being unreadable by CDC staff.

Checklist of Required Contents of Application Packet:

1. SF–424 Application for Federal Domestic Assistance—Short Organizational Form
2. SF–424A Budget Information-Non-Construction
3. Itemized Budget Jus tification
4. Certifications and Assurances

1. SF–424 Application for Federal Domestic Assistance—Short Organizational Form

Complete all sections:

A. In addition to inserting the legal name of your organization in Block #5a, insert the CDC Award Number provided in the CDC Notice of Award. Failure to provide your award number could cause delay in processing your application.

B. Please insert your organization's Business Official information in Block #8.

2. SF–424A Budget Information and Justification

A. Complete all applicable sections.

B. Analysis of Remaining Time and Funds.

1. Based on the current rate of obligation, if it appears there will be un-obligated funds at the end of the current budget period, provide detailed actions that will be taken to obligate this amount.

2. If it appears there will be insufficient funds, provide a detailed justification of the shortfall and list the actions taken to bring the obligations in line with the authorized funding level.

C. The proposed budget should be based on the federal funding level stated in the letter from CDC.

D. The budget justification must be prepared in the general form, format, and to the level of detail as described in the CDC Budget Guidance. The sample budget guidance is provided on CDC's internet at: *http://www.cdc.gov/grants/applying/application-resources.html.*

E. For any new proposed subcontracts provide the information specified in the Budget Guidance.

F. When non-federal matching is required, provide a line-item list of non-federal contributions including source, amount, and/or value of third party contributions proposed to meet a matching requirement.

G. Applicants should send their application via email attachment(s) to Barbara Strother at *kty4@cdc.gov.*

3. Indirect Cost Rate Agreement

Requirements for development and submission of indirect (F&A) cost rate proposals and cost allocation plans for all grantees are contained in 45 CFR part 75, Appendices III through VII.

4. Program Requirements

Project Narrative: Provide a summary of planned activities to be conducted during the remainder of Year 2 for the period September 30, 2017–March 31, 2018.

Section I. New Budget Period Proposed Objectives and Activities

Provide a detailed description of proposed activities, objectives, and performance measures for the new budget period as described below.

A. List the proposed objectives for the upcoming budget period. These objectives must support the intent of the original Funding Opportunity Announcement (FOA) or Program Announcement (PA).

B. Each objective and activity must contain a performance or outcome measure that assesses the effectiveness of the project.

C. Provide an updated work plan that cross walks to the objectives and associated performance measures, program strategies and activities, target dates for completion, and person(s) responsible for the activities. Awardees are strongly encouraged to use the sample Excel-based work plan provided by the Disability and Health Branch. The work plan must be uploaded as a PDF file and included in the appendix.

Any proposed changes in programmatic priorities must be within the scope of the approved funding opportunity announcement and Notice of Award. CDC will work with each awardee to refine and consolidate work plans within 30 days of award as needed.

Review and Selection Process

A merit review will be conducted by the CDC Program Office. The merit review will cover technical and cost matters. The initial application received an objective review to ensure recipient complies with all the activities required. The recipient was selected thru a competitive process during the initial FOA award.

Terrance Perry,

Director, Office of Grants Services, Centers for Disease Control and Prevention.

[FR Doc. 2017–15161 Filed 7–20–17; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–5525–N]

Medicare, Medicaid and Children's Health Insurance Program (CHIP); Meeting on Behavioral Health Payment and Care Delivery

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice of meeting.

SUMMARY: This notice announces a public meeting to discuss ideas for a potential behavioral health payment model to improve health care quality and access, while lowering the cost of care for Medicare, Medicaid, or Children's Health Insurance Program (CHIP) beneficiaries with behavioral health conditions.

DATES:

Meeting Date: This meeting will be held at 10 a.m. until 5 p.m. Eastern Standard Time (EST) on Friday, September 8, 2017. The meeting is open to the public, but attendance is limited to the space available.

Meeting Registration: Individuals must register online at *https://innovation.cms.gov/resources/behavioral-health-paymentcare-summit.html* by 12:00 a.m. EST on August 25, 2017.

Submission of Written Questions or Statements: Individuals may submit written questions or statements by email, online, fax, or mail to the address listed in the **ADDRESSES** section of this notice by 12:00 a.m. EST. on August 25, 2017.

ADDRESSES:

Meeting Location: The meeting will be held in the Grand Auditorium, at the CMS Central Office, 7500 Security Boulevard, Baltimore, MD 21244–1850.

Submission of Written Questions or Statements: Individuals may submit written questions or statements by email at *CMMIBHSummit@ketchum.com,* online at *https://innovation.cms.gov/resources/behavioral-health-paymentcare-summit.html,* by fax to 410–786–1048, or by mail to the CMS Innovation Center, Attn: CMMIBH

Summit mailstop 08–64, 2810 Lord Baltimore Drive, Suite 130, Windsor Mill, MD 21244.

FOR FURTHER INFORMATION CONTACT: *CMMIBHSummit@ketchum.com,* for questions about this meeting.

News Media: Press inquiries will be handled at *press@cms.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The Center for Medicare and Medicaid Innovation (the Innovation Center) within the Centers for Medicare & Medicaid Services (CMS) was established by section 1115A of the Social Security Act (the Act). The Congress created the Innovation Center for the purpose of testing ''innovative payment and service delivery models to reduce program expenditures . . . while preserving or enhancing the quality of care'' for those individuals who receive Medicare, Medicaid, or Children's Health Insurance Program (CHIP) benefits. New payment and service delivery model tests are designed by the Innovation Center in accordance with the requirements of section 1115A of the Act. During the design of a model test, the Innovation Center builds on the ideas received from stakeholders and consults with clinical and analytical experts with expertise in medicine and health care management, as well as with representatives of relevant Federal agencies, beneficiaries and caregivers, health care providers, advocacy groups, and other experts in the field.

The Innovation Center is interested in designing a potential payment or service delivery model to improve health care quality and access, while lowering the cost of care for Medicare, Medicaid, or CHIP beneficiaries with behavioral health conditions. The model may include participation by other payers, qualify as an Advanced Alternative Payment Model (APM), improve health care provider participation in telehealth services, and address the needs of beneficiaries with deficits in care in the following potential areas leading to poor clinical outcomes or potentially avoidable expenditures: (1) Substance use disorders; (2) mental disorders in the presence of co-occuring conditions; (3) Alzheimer's disease and related dementias; and/or (4) behavioral health workforce challenges.

The Innovation Center solicits and selects organizations to participate in voluntary model tests through open, competitive processes. The process follows established protocols to ensure that it is fair and transparent, provides opportunities for potential participants to ask questions regarding the Innovation Center's expectations, and relies on multi-stakeholder input to inform selection of the most qualified participants. Many factors are used in the design and selection of models to be tested. The Innovation Center does not test unsolicited proposals, but does use such ideas to inform model design.

II. Meeting Topic and Format

The meeting will include four panel sessions of behavioral health experts of varied backgrounds who will discuss substance use disorders, mental health in the presence of co-occuring conditions, Alzheimer's disease and related dementias, and behavioral health workforce development.

All stakeholders, including community health organizations, medical societies, health care providers, State Medicaid agencies, advocacy groups, non-profit organizations, and other interested parties are invited to participate in this meeting by: (1) Listening to panelists discuss payment for and delivery of behavioral health services and share experiences of furnishing behavioral health services; (2) asking questions to panelists; and (3) making brief individual statements. We note that the time for participants to make statements will be limited to 2 minutes per panel.

The recommendations provided during this meeting will assist us, as we explore the possibility of designing a model test to address behavioral health payment and service delivery.

III. Registration Instructions

Participants must register at *https://innovation.cms.gov/resources/behavioral-health-paymentcare-summit.html* no later than 12 a.m. EST on August 25, 2017 to attend the meeting. We will accept written questions and statements, not to exceed one single-spaced, typed page, by email, on-line, fax, or mail to the addresses specified in the **ADDRESSES** section of this notice, by the dates specified in the **DATES** section of this notice.

IV. Security, Building, and Parking Guidelines

The meeting is open to the public, but attendance will be limited based on meeting room capacity. Seating capacity is limited to approximately 400 registrants. Persons wishing to attend this meeting must register by the dates specified in the **DATES** section of this notice.

This meeting will be held in a Federal government building; therefore, Federal security measures are applicable. The on-site check-in for visitors will be held from 9:00 a.m. to 10:00 a.m. We recommend that confirmed registrants arrive reasonably early, to allow additional time to clear security. We recommend arrival no later than 9:30 a.m. to complete the security checkpoints and be escorted for the start of the meeting at 10:00 a.m. Security measures include the following:

- Presentation of government-issued photographic identification to the Federal Protective Service or Guard Service personnel. As of October 10, 2015, visitors seeking access to federal agency facilities using their state-issued driver's license or identification cards must present proper identification issued by a state that is compliant with the REAL ID Act of 2005 (Pub. L. 109–13, 119 Statute 302, enacted on May 11, 2005) or a state that has received an extension. What constitutes proper identification and whether a driver's license is acceptable identification for accessing a federal facility may vary, based on which state issued the driver's license. For detailed information, please refer to the Department of Homeland Security (DHS) Web site at: *http://www.dhs.gov.* When planning to visit a federal facility, visitors who have further questions about acceptable forms of identification are encouraged to contact the facility to determine acceptable identification.
- Inspection of vehicle's interior and exterior (this includes engine and trunk inspection) at the entrance to the grounds. Parking permits and instructions will be issued after the vehicle inspection. Participants not in possession of a valid identification or who are in possession of prohibited items will be denied access to the complex. Prohibited items on federal property include but are not limited to, alcoholic beverages, illegal narcotics, explosives, firearms or other dangerous weapons (including pocketknives), dogs or other animals except service animals.
- Inspection, via metal detector or other applicable means of all persons entering the building. We note that all items brought into CMS, whether personal or for the purpose of presentation or to support a presentation, are subject to inspection. We cannot assume responsibility for coordinating the receipt, transfer, transport, storage, set up, safety, or timely arrival of any personal belongings or items used for presentation or to support a presentation.

Note: Individuals who are not registered in advance will not be permitted to enter the building and will be unable to attend the meeting. The public may not enter the building earlier than 45 minutes prior to the start of check-in of the meeting (8:15 a.m.).

All visitors must be escorted in areas other than the lower and first floor levels in the CMS Central Office.

V. Special Accommodations

Individuals requiring special accommodations must include the request for these services when registering for the meeting.

VI. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping, or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Dated: July 17, 2017.

Patrick Conway,

Deputy Administrator for Innovation and Quality & Director, Centers for Medicare & Medicaid Services.

[FR Doc. 2017–15374 Filed 7–20–17; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–2405–N]

RIN 0938–ZB34

Medicaid Program; State Allotments for Payment of Medicare Part B Premiums for Qualifying Individuals (QIs): Federal Fiscal Year 2014 and Federal Fiscal Year 2015 through Calendar Year 2015

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This notice sets forth the states' final allotments available to pay the Medicare Part B premiums for Qualifying Individuals (QIs) for the federal fiscal year (FY) 2014 and the preliminary QI allotments for federal FY 2015 which is extended through calendar year (CY) 2015 (December 2015) by the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). The amounts of these QI allotments were determined in accordance with the methodology set forth in regulations and reflect funding for the QI program made available under recent legislation.

DATES: The final QI allotments for payment of Medicare Part B premiums for FY 2014 are effective October 1, 2013. The preliminary QI allotments for FY 2015, extended through CY 2015 are effective October 1, 2014.

FOR FURTHER INFORMATION CONTACT: Jennifer Gibson, (410) 786–5404 or Toni Cincibus at (410) 786–2997.

SUPPLEMENTARY INFORMATION:

I. Background

A. QI Allotments for FY 2014

As amended by section 621 of the American Taxpayer Relief Act of 2012 (ATRA) (Pub. L. 112–240, enacted on January 2, 2013), section 1933(g)(2) of the Social Security Act (the Act) provided $300 million in funding for the period October 1, 2013 through December 31, 2013, the first quarter of fiscal year (FY) 2014. Section 1201 of Division B of the legislation ''Pathway for SGR Reform Act of 2013'' (Pub. L. 113–67 enacted on December 26, 2013) provided an additional $200 million and authority for the Qualifying Individual (QI) program for the period January 1, 2014 through March 31, 2014 (second quarter of FY 2014). In addition, section 201 of the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. 113–93 enacted on April 1, 2014) revised the $200 to $485 million and extended the period for which such funds were available to the end of September 2014. Therefore, the total funding available for the QI program for FY 2014 is $785 million ($300 million for the first quarter of FY 2014, and $485 million for the second through fourth quarters of FY 2014).

B. QI Allotments for FY 2015/CY 2015 and Thereafter

Section 201 of PAMA extended the authority and funding for the QI program for FY 2015 as follows: $300 million for the period October 1, 2014 through December 31, 2014 (first quarter of FY 2015); and, $250 million for the period January 1, 2015 through March 31, 2015 (second quarter FY 2015). Section 211 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10, enacted on April 16, 2015) further extended the authority and funding for the QI program for FY 2015 as follows: $535 million for the period April 1, 2015 through December 31, 2015, effectively changing QI to a calendar year basis from a fiscal year basis. Therefore, a total of $1.085 billion is available for the QI program for FY/CY 2015.

Section 211 of MACRA also permanently extended the QI program while allocating $980 million for CY 2016.

C. Methodology for Calculating the Fiscal Year/Calendar Year QI Allotments.

The amounts of the states' final FY 2014 and preliminary FY/CY 2015 QI allotments, contained in this notice, were determined in accordance with the methodology set forth in existing regulations at 42 CFR 433.10(c)(5) and reflect funding for the QI program made available under the legislation discussed above.

II. Tables

The final QI allotments for FY 2014 and the preliminary QI allotments for FY/CY 2015 are shown by state in Table 1 and Table 2, respectively:

Table 1—Final Qualifying Individuals Allotments for October 1, 2013 through September 30, 2014.

Table 2—Preliminary Qualifying Individuals Allotments for October 1, 2014 through December 31, 2015.

BILLING CODE 4120–01–P

TABLE 1: Final Qualifying Individuals Allotments for October 1, 2013 through September 30, 2014

STATE	Initial QI Allotments for FY 2014			FY 2014	Need	Pct of Tot.	Reduction Pool	Pct of Tot.	Reduction Adj. For	Increase Adj. For	Final
	Number of Individuals /3 (000s)	Percentage of Total Col B/Tot. Col B	Initial QI Allotment Col C x $785,000,000	Estimated QI Expenditures /1	(Difference) If E>D, E-D	Need States F/(Tot. of F)	for Non-Need States If D >= E, D - E	Non-Need States H/(Tot. of H)	Non-Need States Col. I x $90,352,735	Need States Col. G x $90,352,735	FY 2014 QI Allotment /2
A	B	C	D	E	F	G	H	I	J	K	L
Alabama	33	2.13%	$16,756,145	$23,696,386	$6,940,241	7.6813%	Need	Need	Need	$6,940,241	$23,696,386
Alaska	2	0.13%	$1,015,524	$322,358	NA	NA	$693,166	0.4245%	$383,589	NA	$631,935
Arizona	29	1.88%	$14,725,097	$20,123,492	$5,398,394	5.9748%	Need	Need	Need	$5,398,394	$20,123,492
Arkansas	25	1.62%	$12,694,049	$14,293,779	$1,599,730	1.7705%	Need	Need	Need	$1,599,730	$14,293,779
California	130	8.41%	$66,009,056	$26,896,570	NA	NA	$39,112,486	23.9554%	$21,644,314	NA	$44,364,741
Colorado	12	0.78%	$6,093,144	$6,886,161	$793,017	0.8777%	Need	Need	Need	$793,017	$6,886,161
Connecticut	15	0.97%	$7,616,429	$4,579,305	NA	NA	$3,037,125	1.8602%	$1,680,703	NA	$5,935,726
Delaware	5	0.32%	$2,538,810	$3,191,163	$652,353	0.7220%	Need	Need	Need	$652,353	$3,191,163
District of Columbia	2	0.13%	$1,015,524	$0	NA	NA	$1,015,524	0.6220%	$561,977	NA	$453,547
Florida	133	8.60%	$67,532,342	$75,214,664	$7,682,322	8.5026%	Need	Need	Need	$7,682,322	$75,214,664
Georgia	46	2.98%	$23,357,050	$36,617,968	$13,260,917	14.6768%	Need	Need	Need	$13,260,917	$36,617,968
Hawaii	6	0.39%	$3,046,572	$1,319,852	NA	NA	$1,726,720	1.0576%	$955,543	NA	$2,091,029
Idaho	8	0.52%	$4,062,096	$3,013,777	NA	NA	$1,048,319	0.6421%	$580,125	NA	$3,481,970
Illinois	63	4.08%	$31,989,004	$25,892,362	NA	NA	$6,096,642	3.7340%	$3,373,798	NA	$28,615,206
Indiana	41	2.65%	$20,818,241	$4,642,454	NA	NA	$16,175,786	9.9072%	$8,951,459	NA	$11,866,782
Iowa	17	1.10%	$8,631,953	$4,694,170	NA	NA	$3,937,783	2.4118%	$2,179,115	NA	$6,452,838
Kansas	18	1.16%	$9,139,715	$5,469,486	NA	NA	$3,670,229	2.2479%	$2,031,055	NA	$7,108,661
Kentucky	35	2.26%	$17,771,669	$14,902,094	NA	NA	$2,869,575	1.7575%	$1,587,983	NA	$16,183,685
Louisiana	29	1.88%	$14,725,097	$21,902,176	$7,177,079	7.9434%	Need	Need	Need	$7,177,079	$21,902,176
Maine	7	0.45%	$3,554,334	$6,773,918	$3,219,584	3.5633%	Need	Need	Need	$3,219,584	$6,773,918
Maryland	22	1.42%	$11,170,763	$9,819,479	NA	NA	$1,351,284	0.8276%	$747,782	NA	$10,422,981
Massachusetts	27	1.75%	$13,709,573	$10,467,761	NA	NA	$3,241,812	1.9855%	$1,793,974	NA	$11,915,599
Michigan	37	2.39%	$18,787,193	$14,713,589	NA	NA	$4,073,604	2.4950%	$2,254,277	NA	$16,532,916
Minnesota	18	1.16%	$9,139,715	$6,304,595	NA	NA	$2,835,120	1.7364%	$1,568,917	NA	$7,570,799
Mississippi	20	1.29%	$10,155,239	$15,193,401	$5,038,162	5.5761%	Need	Need	Need	$5,038,162	$15,193,401
Missouri	44	2.85%	$22,341,527	$12,771,470	NA	NA	$9,570,056	5.8614%	$5,295,938	NA	$17,045,588
Montana	6	0.39%	$3,046,572	$1,733,158	NA	NA	$1,313,414	0.8044%	$726,825	NA	$2,319,746
Nebraska	7	0.45%	$3,554,334	$2,112,476	NA	NA	$1,441,858	0.8831%	$797,904	NA	$2,756,430
Nevada	7	0.45%	$3,554,334	$5,601,555	$2,047,221	2.2658%	Need	Need	Need	$2,047,221	$5,601,555
New Hampshire	6	0.39%	$3,046,572	$2,390,776	NA	NA	$655,796	0.4017%	$362,908	NA	$2,683,663
New Jersey	45	2.91%	$22,849,288	$8,711,840	NA	NA	$14,137,448	8.6588%	$7,823,470	NA	$15,025,818
New Mexico	9	0.58%	$4,569,858	$4,121,311	NA	NA	$448,546	0.2747%	$248,219	NA	$4,321,638
New York	102	6.60%	$51,791,721	$45,728,113	NA	NA	$6,063,608	3.7138%	$3,355,517	NA	$48,436,203
North Carolina	48	3.10%	$24,372,574	$31,178,378	$6,805,804	7.5325%	Need	Need	Need	$6,805,804	$31,178,378
North Dakota	4	0.26%	$2,031,048	$670,731	NA	NA	$1,360,317	0.8332%	$752,781	NA	$1,278,267
Ohio	59	3.82%	$29,957,956	$28,395,381	NA	NA	$1,562,575	0.9570%	$864,708	NA	$29,093,248
Oklahoma	23	1.49%	$11,678,525	$10,558,185	NA	NA	$1,120,340	0.6862%	$619,981	NA	$11,058,544
Oregon	16	1.03%	$8,124,191	$14,973,321	$6,849,130	7.5804%	Need	Need	Need	$6,849,130	$14,973,321
Pennsylvania	83	5.37%	$42,144,243	$33,422,399	NA	NA	$8,721,844	5.3419%	$4,826,549	NA	$37,317,694
Rhode Island	5	0.32%	$2,538,810	$2,472,178	NA	NA	$66,632	0.0408%	$36,873	NA	$2,501,937
South Carolina	33	2.13%	$16,756,145	$12,449,637	NA	NA	$4,306,508	2.6376%	$2,383,163	NA	$14,372,982
South Dakota	3	0.19%	$1,523,286	$1,721,514	$198,228	0.2194%	Need	Need	Need	$198,228	$1,721,514
Tennessee	43	2.78%	$21,833,765	$32,350,845	$10,517,081	11.6400%	Need	Need	Need	$10,517,081	$32,350,845

STATE	Initial QI Allotments for FY 2014			FY 2014	Need	Pct of Tot.	Reduction Pool	Pct of Tot.	Reduction Adj. For	Increase Adj. For	Final
	Number of Individuals /3 (000s)	Percentage of Total Col B/Tot. Col B	Initial QI Allotment Col C x $785,000,000	Estimated QI Expenditures /1	(Difference) If E>D, E-D	Need States F/(Tot. of F)	for Non-Need States If D >= E, D - E	Non-Need States H/(Tot. of H)	Non-Need States Col. I x $90,352,735	Need States Col. G x $90,352,735	FY 2014 QI Allotment /2
A	B	C	D	E	F	G	H	I	J	K	L
Texas	108	6.99%	$54,838,292	$64,992,473	$10,154,181	11.2384%	Need	Need	Need	$10,154,181	$64,992,473
Utah	7	0.45%	$3,554,334	$2,328,151	NA	NA	$1,226,183	0.7510%	$678,553	NA	$2,875,781
Vermont	3	0.19%	$1,523,286	$3,542,578	$2,019,292	2.2349%	Need	Need	Need	$2,019,292	$3,542,578
Virginia	33	2.13%	$16,756,145	$14,142,933	NA	NA	$2,613,212	1.6005%	$1,446,116	NA	$15,310,029
Washington	26	1.68%	$13,201,811	$6,302,602	NA	NA	$6,899,209	4.2256%	$3,817,928	NA	$9,383,883
West Virginia	20	1.29%	$10,155,239	$6,842,837	NA	NA	$3,312,403	2.0288%	$1,833,038	NA	$8,322,201
Wisconsin	22	1.42%	$11,170,763	$4,758,159	NA	NA	$6,412,604	3.9275%	$3,548,647	NA	$7,622,116
Wyoming	4	0.26%	$2,031,048	$876,335	NA	NA	$1,154,713	0.7072%	$639,003	NA	$1,392,045
Total	1,546	100.00%	$785,000,000	$712,080,292	$90,352,735	100.0000%	$163,272,443	100.0000%	$90,352,735	$90,352,735	$785,000,000

Footnotes:

/1 FY 2014 Estimates from July 2014 CMS Survey of States; Estimates Are For Months October 2013 Through September 2014

/2 For Need States, Final FY 2014 QI Allotment is equal to Initial QI Allotment in Column D increased by amount in Column K

For Non-Need States, Final FY 2014 QI Allotment is equal to Initial QI Allotment in Column D reduced by amount in Column J

/3 Three-year average (2011-2013) of number (000) of Medicare beneficiaries in State who are not enrolled in Medicaid but whose incomes are at least 120% but less than 135% of Federal poverty level

Source: Census Bureau Annual Social and Economic Supplement (ASEC) to the 2013 Current Population Survey (CPS) and American Community Survey (ACS)

TABLE 2 - Preliminary Qualifying Individuals Allotments for October 1, 2014 through December 31, 2015

STATE	Initial QI Allotments for FY/CY 2015			FY/CY 2015	Need	Pct of Tot.	Reduction Pool	Pct of Tot.	Reduction Adj. For	Increase Adj. For	PRELIMINARY
	Number of Individuals /3 (000s)	Percentage of Total Col B/Tot. Col B	Initial QI Allotment Col C x $1,085,000,000	Estimated QI Expenditures /1	(Difference) If E>D, E-D	Need States F/(Tot. of F)	for Non-Need States If D >= E, D - E	Non-Need States H/(Tot. of H)	Non-Need States Col. I x $96,858,633	Need States Col. G x $96,858,633	FY/CY 2015 QI Allotment /2
A	B	C	D	E	F	G	H	I	J	K	L
Alabama	28	1.86%	$20,186,047	$30,976,550	$10,790,504	11.1405%	Need	Need	Need	$10,790,504	$30,976,550
Alaska	1	0.07%	$720,930	$434,555	NA	NA	$286,375	0.1199%	$116,153	NA	$604,777
Arizona	35	2.33%	$25,232,558	$27,849,001	$2,616,443	2.7013%	Need	Need	Need	$2,616,443	$27,849,001
Arkansas	25	1.66%	$18,023,256	$18,805,843	$782,587	0.8080%	Need	Need	Need	$782,587	$18,805,843
California	134	8.90%	$96,604,651	$34,292,335	NA	NA	$62,312,317	26.0934%	$25,273,668	NA	$71,330,983
Colorado	13	0.86%	$9,372,093	$9,694,438	$322,345	0.3328%	Need	Need	Need	$322,345	$9,694,438
Connecticut	17	1.13%	$12,255,814	$7,212,468	NA	NA	$5,043,346	2.1119%	$2,045,564	NA	$10,210,250
Delaware	5	0.33%	$3,604,651	$4,289,518	$684,867	0.7071%	Need	Need	Need	$684,867	$4,289,518
District of Columbia	1	0.07%	$720,930	$0	NA	NA	$720,930	0.3019%	$292,407	NA	$428,520
Florida	141	9.37%	$101,651,163	$98,272,103	NA	NA	$3,379,059	1.4150%	$1,370,535	NA	$100,280,628
Georgia	46	3.06%	$33,162,791	$47,600,998	$14,438,207	14.9065%	Need	Need	Need	$14,438,207	$47,600,998
Hawaii	6	0.40%	$4,325,581	$1,942,958	NA	NA	$2,382,624	0.9977%	$966,384	NA	$3,359,197
Idaho	9	0.60%	$6,488,372	$4,367,060	NA	NA	$2,121,312	0.8883%	$860,397	NA	$5,627,975
Illinois	50	3.32%	$36,046,512	$34,240,619	NA	NA	$1,805,893	0.7562%	$732,464	NA	$35,314,048
Indiana	37	2.46%	$26,674,419	$4,958,221	NA	NA	$21,716,197	9.0937%	$8,808,017	NA	$17,866,401
Iowa	17	1.13%	$12,255,814	$5,789,147	NA	NA	$6,466,667	2.7079%	$2,622,859	NA	$9,632,955
Kansas	13	0.86%	$9,372,093	$6,513,947	NA	NA	$2,858,146	1.1969%	$1,159,255	NA	$8,212,838
Kentucky	30	1.99%	$21,627,907	$18,955,745	NA	NA	$2,672,162	1.1190%	$1,083,820	NA	$20,544,087
Louisiana	28	1.86%	$20,186,047	$28,700,745	$8,514,698	8.7909%	Need	Need	Need	$8,514,698	$28,700,745
Maine	5	0.33%	$3,604,651	$7,505,280	$3,900,629	4.0271%	Need	Need	Need	$3,900,629	$7,505,280
Maryland	19	1.26%	$13,697,674	$13,020,083	NA	NA	$677,591	0.2837%	$274,829	NA	$13,422,846
Massachusetts	22	1.46%	$15,860,465	$12,832,837	NA	NA	$3,027,629	1.2678%	$1,227,996	NA	$14,632,469
Michigan	41	2.72%	$29,558,140	$19,795,574	NA	NA	$9,762,565	4.0881%	$3,959,664	NA	$25,598,476
Minnesota	19	1.26%	$13,697,674	$8,246,189	NA	NA	$5,451,485	2.2828%	$2,211,104	NA	$11,486,570
Mississippi	18	1.20%	$12,976,744	$19,947,679	$6,970,935	7.1970%	Need	Need	Need	$6,970,935	$19,947,679
Missouri	38	2.52%	$27,395,349	$19,813,722	NA	NA	$7,581,627	3.1748%	$3,075,083	NA	$24,320,266
Montana	5	0.33%	$3,604,651	$2,260,805	NA	NA	$1,343,846	0.5627%	$545,060	NA	$3,059,592
Nebraska	6	0.40%	$4,325,581	$2,593,233	NA	NA	$1,732,348	0.7254%	$702,635	NA	$3,622,947
Nevada	8	0.53%	$5,767,442	$7,665,777	$1,898,335	1.9599%	Need	Need	Need	$1,898,335	$7,665,777
New Hampshire	6	0.40%	$4,325,581	$3,345,263	NA	NA	$980,318	0.4105%	$397,614	NA	$3,927,968
New Jersey	42	2.79%	$30,279,070	$9,663,178	NA	NA	$20,615,892	8.6329%	$8,361,737	NA	$21,917,333
New Mexico	10	0.66%	$7,209,302	$4,978,869	NA	NA	$2,230,434	0.9340%	$904,656	NA	$6,304,646
New York	100	6.64%	$72,093,023	$58,165,791	NA	NA	$13,927,232	5.8320%	$5,648,839	NA	$66,444,184
North Carolina	51	3.39%	$36,767,442	$36,691,398	NA	NA	$76,044	0.0318%	$30,843	NA	$36,736,599
North Dakota	3	0.20%	$2,162,791	$853,152	NA	NA	$1,309,639	0.5484%	$531,185	NA	$1,631,605
Ohio	62	4.12%	$44,697,674	$34,993,773	NA	NA	$9,703,901	4.0635%	$3,935,870	NA	$40,761,804
Oklahoma	23	1.53%	$16,581,395	$13,289,152	NA	NA	$3,292,244	1.3786%	$1,335,323	NA	$15,246,072
Oregon	17	1.13%	$12,255,814	$20,047,859	$7,792,045	8.0448%	Need	Need	Need	$7,792,045	$20,047,859
Pennsylvania	78	5.18%	$56,232,558	$45,312,919	NA	NA	$10,919,639	4.5726%	$4,428,969	NA	$51,803,589
Rhode Island	6	0.40%	$4,325,581	$3,257,565	NA	NA	$1,068,017	0.4472%	$433,184	NA	$3,892,397
South Carolina	31	2.06%	$22,348,837	$15,406,348	NA	NA	$6,942,489	2.9072%	$2,815,850	NA	$19,532,987
South Dakota	3	0.20%	$2,162,791	$2,150,870	NA	NA	$11,921	0.0050%	$4,835	NA	$2,157,956

STATE	Initial QI Allotments for FY/CY 2015			FY/CY 2015	Need	Pct of Tot.	Reduction Pool	Pct of Tot.	Reduction Adj. For	Increase Adj. For	PRELIMINARY
	Number of Individuals /3 (000s)	Percentage of Total Col B/Tot. Col B	Initial QI Allotment Col C x $1,085,000,000	Estimated QI Expenditures /1	(Difference) If E>D, E-D	Need States F/(Tot. of F)	for Non-Need States If D >= E, D - E	Non-Need States II/(Tot. of II)	Non-Need States Col. I x $96,858,633	Need States Col. G x $96,858,633	FY/CY 2015 QI Allotment /2
A	B	C	D	E	F	G	H	I	J	K	L
Tennessee	45	2.99%	$32,441,860	$40,251,355	$7,809,494	8.0628%	Need	Need	Need	$7,809,494	$40,251,355
Texas	100	6.64%	$72,093,023	$100,116,770	$28,023,747	28.9326%	Need	Need	Need	$28,023,747	$100,116,770
Utah	7	0.47%	$5,046,512	$2,984,195	NA	NA	$2,062,316	0.8636%	$836,469	NA	$4,210,043
Vermont	3	0.20%	$2,162,791	$4,476,588	$2,313,797	2.3888%	Need	Need	Need	$2,313,797	$4,476,588
Virginia	34	2.26%	$24,511,628	$18,207,073	NA	NA	$6,304,555	2.6400%	$2,557,106	NA	$21,954,522
Washington	23	1.53%	$16,581,395	$14,419,554	NA	NA	$2,161,841	0.9053%	$876,836	NA	$15,704,560
West Virginia	19	1.26%	$13,697,674	$8,616,906	NA	NA	$5,080,769	2.1276%	$2,060,743	NA	$11,636,932
Wisconsin	22	1.46%	$15,860,465	$6,234,417	NA	NA	$9,626,048	4.0309%	$3,904,293	NA	$11,956,172
Wyoming	3	0.20%	$2,162,791	$1,012,914	NA	NA	$1,149,876	0.4815%	$466,386	NA	$1,696,405
Total	1,505	100.00%	$1,085,000,000	$943,053,337	$96,858,633	100.0000%	$238,805,296	100.0000%	$96,858,633	$96,858,633	$1,085,000,000

Footnotes:

/1 FY/CY 2015 Estimates from July 2015 CMS Survey of States; Estimates Are For Months October 2014 Through December 2015

/2 For Need States, FY/CY 2015 QI Allotment is equal to Initial QI Allotment in Column D increased by amount in Column K

For Non-Need States, FY/CY 2015 QI Allotment is equal to Initial QI Allotment in Column D reduced by amount in Column J

/3 Three-year average (2012-2014) of number (000) of Medicare beneficiaries in State who are not enrolled in Medicaid but whose incomes are at least 120% but less than 135% of Federal poverty level

Source: Census Bureau Annual Social and Economic Supplement (ASEC) to the 2014 Current Population Survey (CPS) and American Community Survey (ACS)

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The following describes the information contained in the columns of Table 1 and Table 2:

Column A—*State.* Column A shows the name of each state. Columns B through D show the determination of an Initial QI Allotment for FY 2014 (Table 1) or FY/CY 2015 (Table 2) for each state, based only on the indicated Census Bureau data.

Column B—*Number of Individuals.* Column B contains the estimated average number of Medicare beneficiaries for each state that are not covered by Medicaid whose family income is at least 120 but less than 135 percent of the federal poverty level. With respect to the *final FY 2014 QI allotment (Table 1),* Column B contains the number of such individuals for the years 2011 through 2013, as obtained from the Census Bureau's Annual Social and Economic Supplement to the 2013 Current Population Survey. With respect to the *preliminary FY/CY 2015 QI allotment (Table 2),* Column B contains the number of such individuals for the years 2012 through 2014, as obtained from the Census Bureau's Annual Social and Economic Supplement to the 2014 Current Population Survey and the American Community Survey (ACS).

Column C—*Percentage of Total.* Column C provides the percentage of the total number of individuals for each state, that is, the Number of Individuals for the state in Column B divided by the sum total of the Number of Individuals for all states in Column B.

Column D—*Initial QI Allotment.* Column D contains each state's Initial QI Allotment for FY 2014 (Table 1) or FY/CY 2015 (Table 2), calculated as the state's Percentage of Total in Column C multiplied by the total amount available nationally for QI allotments for the fiscal year/calendar year. The total amount available nationally for QI allotments each fiscal year is $785,000,000 for FY 2014 (Table 1) and $1,085,000,000 for FY/CY 2015 (Table 2).

Columns E through L show the determination of the States' Final QI Allotments for FY 2014 (Table 1) or Preliminary QI Allotments for FY/CY 2015 (Table 2).

Column E—*FY 2014 or FY/CY 2015 Estimated QI Expenditures.* Column E contains the states' estimates of their total QI expenditures for FY 2014 (Table 1) or FY/CY 2015 (Table 2) based on information obtained from states in the summer of 2014 and as updated.

Column F—*Need (Difference).* Column F contains the additional amount of QI allotment needed for those states whose estimated expenditures in Column E exceeded their Initial QI allotments in Column D for FY 2014 (Table 1) or for FY/CY 2015 (Table 2). For such states, Column F shows the amount in Column E minus the amount in Column D. For other ''Non-Need'' States, Column F shows ''NA.''

Column G—*Percent of Total Need States.* For states whose projected QI expenditures in Column E are greater than their initial QI allotment in Column D for FY 2014 (Table 1) or FY/CY 2015 (Table 2), respectively, Column G shows the percentage of total need, determined as the amount for each Need State in Column F divided by the sum of the amounts for all states in Column F. For Non-Need States, the entry in Column G is ''NA.''

Column H—*Reduction Pool for Non-Need States.* Column H shows the amount of the pool of surplus QI allotments for FY 2014 (Table 1) or FY/CY 2015 (Table 2), respectively, for those states that project QI expenditures for the fiscal year/calendar year that are less than the Initial QI allotment for the fiscal year/calendar year (referred to as Non-Need States). For states for which the estimates in Column E of QI expenditures for FY 2014 or FY/CY 2015, respectively, are equal to or less than their Initial QI allotments in Column D for FY 2014 or FY/CY 2015, respectively, Column H shows the amount in Column D minus the amount in Column E. For the states with a need, Column H shows ''Need''. The reduction pool of excess QI allotments is equal to the sum of the amounts in Column H.

Column I—*Percent of Total Non-Need States.* For states whose projected QI expenditures in Column E are less than their Initial QI allotment in Column D for FY 2014 (Table 1) or FY/CY2015 (Table 2), Column I shows the percentage of the total reduction pool in Column H, determined as the amount for each Non-Need State in Column H divided by the sum of the amounts for all States in Column H. For Need States, the entry in Column I is ''Need.''

Column J—*Reduction Adjustment for Non-Need States.* Column J shows the amount of adjustment needed to reduce the Initial QI allotments in Column D for FY 2014 (Table 1) or FY/CY 2015 (Table 2) for Non-Need States in order to address the total need shown in Column F. The amount in Column J is determined as the percentage in Column I for Non-Need States multiplied by the lesser of the total need in Column F (equal to the sum of Needs in Column F) or the total Reduction Pool in Column H (equal to the sum of the Non-Need amounts in Column H). For Need States, the entry in Column J is ''Need.''

Column K—*Increase Adjustment for Need States.* Column K shows the amount of adjustment to increase the Initial QI Allotment in Column D for FY 2014 (Table 1) or FY/CY 2015 (Table 2) for Need States in order to address the total need shown for the fiscal year in Column F. The amount in Column K is determined as the percentage in Column G for Need States multiplied by the lesser of the total need in Column F (equal to the sum of Needs in Column F) or the total Reduction Pool in Column H (equal to the sum of the Non-Need amounts in Column H). For Non-Need States, the entry in Column K is ''NA.''

Column L—*Final FY 2014 QI Allotment (Table 1) or Preliminary FY/CY 2015 QI Allotment (Table 2).* Column L contains the Final QI Allotment for each state for FY 2014 (Table 1) or the Preliminary QI Allotment for FY/CY 2015 (Table 2). For states that need additional QI allotment amounts for the fiscal year based on Estimated QI Expenditures in Column E as compared to their Initial QI allotments in Column D for the fiscal year (states with a projected need amount are shown in Column F), Column L is equal to the Initial QI allotment in Column D for FY 2014 (Table 1) or FY/CY 2015 (Table 2) plus the amount determined in Column K for Need States. For Non-Need States (states with a projected surplus in Column H), Column L is equal to the QI Allotment in Column D reduced by the Reduction Adjustment amount in Column J.

III. Collection of Information Requirements

This notice does not impose any information collection or recordkeeping requirements. Consequently, it does not need Office of Management and Budget review under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Dated: June 7, 2017.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: July 17, 2017.

Thomas E. Price,

Secretary, Department of Health and Human Services.

[FR Doc. 2017–15372 Filed 7–20–17; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Child Support Enforcement Program Expenditure Report (Form OCSE–396) and the Child Support Enforcement Program Collection Report (Form OCSE–34).

OMB No.: 0970–0181.

Description: State and Tribal agencies administering the Child Support Enforcement Program under Title IV–D of the Social Security Act are required to provide information each fiscal quarter to the Office of Child Support Enforcement (OCSE) concerning administrative expenditures and the receipt and disposition of child support payments from non-custodial parents. State title IV–D agencies report quarterly expenditures and collections using Forms OCSE–396 and OCSE–34, respectively. Tribal title IV–D agencies report quarterly expenditures using Form SF–425, as prescribed in program regulations, and formerly reported quarterly collections using only a modified version of Form OCSE–34. The information collected on these reporting forms is used to compute quarterly grant awards to States, the annual incentive payments to States, and provides valuable information on program finances of States and Tribes. The collected information is also included in a published annual statistical and financial report, available to the general public.

In response to an earlier **Federal Register** Notice (77 FR 72352 December, 2012), this agency received comments to support the minor changes and revisions to these forms at this time. As we continued to discuss improvements to these reporting forms with State and Tribal grantees we list a few minor revisions that have been incorporated to facilitate grant award operations and grantee financial reporting. These revisions were limited to any changes that allow Tribal grantees to, at least, use the same quarterly collection report submitted by State grantees. Additionally, further clarification was provided to reduce confusion over the inclusion of the Federal share of funding in computations of claims and to standardize treatment of claims. Finally, there were minor revisions in the title of the forms by reverting to the original designation as Form OCSE–396 and Form OCSE–34 and minor changes to the existing wording to improve clarity and accuracy.

One respondent was concerned with the Tribal and State governments using the same OCSE–34 Form, which was perceived to lead to an added burden and confusion about the submission of specific data elements. Our sense is that the form is developed in a sufficiently clear manner to inform respondents on the data elements required by each type of grantee. Furthermore, we consistently provide outreach and technical assistance to all grantees to ensure that reporting burdens are clear and minimized.

A few respondents provided technical and clerical edits to the OCSE–396 Form to increase accuracy and clarity. We have incorporated many of the requested edits and appreciate the detailed and thoughtful comments.

One respondent was concerned that the instructions to the OCSE–396 may be creating an additional burden by maintaining a 5 percent variance threshold (an increase or decease in any data element of Part 1 compared to that same data element for the previous quarter). While we are understanding of this concern our position is that the form will be used nationally and raising the variance threshold above 5 percent is not justified at this time.

Respondents: State and Tribal agencies (including New York, Texas, Washington, Puyallup Tribe, and Port Gamble S'klallam Tribe) administering a Child Support Enforcement Program.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
OCSE–396	54	4	6	1,296
OCSE–34	114	4	14	6,384

Estimated Total Annual Burden Hours: 7,680.

Additional Information

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *infocollection@acf.hhs.gov.*

OMB Comment

OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Fax: 202–395–7285, Email: *OIRA_SUBMISSION@OMB.EOP.GOV*, Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2017–15348 Filed 7–20–17; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Ryan White HIV/AIDS Program, Part C Early Intervention Services Grant

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of non-competitive, HRSA-initiated supplemental funding award.

SUMMARY: To prevent a lapse in comprehensive HIV primary care services for persons living with HIV, HRSA will provide a one-time non-competitive, HRSA-initiated supplemental award to Cape Cod Hospital. The purpose of the Fiscal Year 2017 RWHAP Part C Early Intervention

Services Program Existing Geographic Service Area (EISEGA) is to provide HIV primary care in the outpatient setting to targeted low income, underinsured, and uninsured people living with HIV.

SUPPLEMENTARY INFORMATION:

Intended Recipient of the Award: Cape Cod Hospital.

Amount of Non-Competitive Award: $158,713.

Period of Funding: April 1, 2017, through March 31, 2018.

CFDA Number: 93.918.

Authority: Sections 2651–2667 of the Public Health Service Act, (42 U.S.C. 300ff–51 through 67) and section 2693 of the Public Health Service Act, as amended by the Ryan White HIV/AIDS Treatment Act of 2009 (P.L. 111–87).

Justification: Outer Cape Health Services, Inc. (OCHS) submitted an official request to relinquish its RWHAP Part C EISEGA grant. Cape Cod Hospital is a current RWHAP Part C EISEGA recipient and provides primary medical care; chronic disease management including HIV care and treatment, counseling, and mental health services; lab work; and dental care to vulnerable and underserved populations. Cape Cod Hospital currently serves the service area of Barnstable County, Massachusetts, with the capacity, capability, and interest to serve OCHS's client base. Cape Cod Hospital has satellite offices located in the middle region of Cape Cod with close proximity to OCHS with comparable medical services provided. OCHS has had previous contractual relationships with Cape Cod Hospital that will ensure familiarity and a seamless transition of RWHAP patients originally served by OCHS. Up to $158,713 will be awarded to Cape Cod Hospital for the budget period of April 1, 2017, through March 31, 2018. The award to Cape Cod Hospital will ensure continuity of comprehensive HIV primary care and support services for low income, underinsured, and uninsured people living with HIV in the service area.

FOR FURTHER INFORMATION CONTACT: CAPT Mahyar Mofidi, DMD, Ph.D., Director, Division of Community HIV/AIDS Programs, HIV/AIDS Bureau, Health Resources and Services Administration, 5600 Fishers Lane, 09N09, Rockville, Maryland 20857, phone: (301) 443–2075, email: *mmofidi@hrsa.gov.*

Dated: July 12, 2017.

George Sigounas,

Administrator.

[FR Doc. 2017–15292 Filed 7–20–17; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Center for Mental Health Services; Notice of Meeting

Pursuant to Public Law 92–463, notice is hereby given that the Substance Abuse and Mental Health Services Administration (SAMHSA), Center for Mental Health Services (CMHS) National Advisory Council (NAC) will meet on August 10, 2017, from 9:00 a.m. to 5:15 p.m. and on August 11, 2017, from 8:30 a.m. to 12:00 p.m. EDT. The NAC will convene in both open and closed sessions on August 10, 2017, and will convene in open session on August 11, 2017.

The closed portion of the meeting will include discussion and evaluation of grant applications reviewed by SAMHSA's Initial Review Groups, and involve an examination of confidential financial and business information as well as personal information concerning the applicants. Therefore, the meeting will be closed to the public from 9:00 a.m. to 10:30 a.m. as determined by the Acting Deputy Assistant Secretary for Mental Health and Substance Use, SAMHSA in accordance with Title 5 U.S.C. 552b(c)(4) and (6) and Title 5 U.S.C. App. 2, 10(d). The remainder of this meeting will be open to the public from 10:45 a.m. to 5:15 p.m. and will continue on Friday, August 11, 2017, from 8:30 a.m. to 12:00 p.m. EDT to include discussion of the Center's policy issues, presentations on SAMHSA's Learning Agenda, Treatment Innovations, Cognitive Behavioral Therapy for Serious Mental Illness, Co-occurring Mental Illness and Opioid Addiction, Continuum of Care for Adults with Serious Mental Illness, Prodromal Care Approaches in Children's Mental Health, Faith-based Approaches, and a conversation with the Acting Deputy Assistant Secretary for Mental Health and Substance Use.

Attendance by the public will be limited to available space. Interested persons may present data, information, or views, orally or in writing, on issues pending before the council. Written submissions should be forwarded to the contact person (below) on or before July 27, 2017. Oral presentations from the public will be scheduled at the conclusion of the meeting on Friday, August 11, 2017. Five minutes will be allotted for each presentation. Meeting information and a roster of Council members may be obtained either by accessing the SAMHSA Council Web site at *http://www.samhsa.gov/about-us/advisory-councils/cmhs-national-advisory-council* or by contacting Ms. Pamela Foote (see contact information below).

The meeting can be accessed via telephone. To obtain the conference call-in number and access code, submit written or brief oral comments, or request special accommodations for persons with disabilities, please register at the SAMHSA's Advisory Council Web site at *http://nac.samhsa.gov/Registration/meetingsRegistration.aspx,* or contact Pamela Foote (see contact information below).

Committee Name: Substance Abuse and Mental Health Services Administration, Center for Mental Health Services National Advisory Council.

Dates/Time/Type:

Thursday, August 10, 2017, 9:00 a.m. to 10:30 a.m. EDT: CLOSED

Thursday, August 10, 2017, 10:45 a.m. to 5:15 p.m. EDT: OPEN

Friday, August 11, 2017, 8:30 a.m. to 12:00 p.m. EDT: OPEN

Place:

SAMHSA, 5600 Fishers Lane, 5th Floor, Conference Room A04, Rockville, Maryland 20857, August 10, 2017

SAMHSA, 5600 Fishers Lane, 5th Floor, Conference Room 5E29, Rockville, Maryland 20857, August 11, 2017

Contact: Pamela Foote, Designated Federal Official, SAMHSA CMHS National Advisory Council, 5600 Fishers Lane, Room 14E53C, Rockville, Maryland 20857, Telephone: (240) 276–1279, Fax: (301) 480–8491, Email: *pamela.foote@samhsa.hhs.gov.*

Summer King,

Statistician, Substance Abuse and Mental Health, Services Administration.

[FR Doc. 2017–15381 Filed 7–20–17; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOMELAND SECURITY

[Docket No. DHS–2017–0041]

Committee management; notice of Federal Advisory Committee meeting

AGENCY: Information Sharing and Services Organization (IS²O)/Office of Chief Information Officer (OCIO), Department of Homeland Security.

ACTION: Committee management; notice of Federal Advisory Committee meeting.

SUMMARY: The Homeland Security Information Network Advisory Committee (HSINAC) will meet on Wednesday, September 6, 2017, to

receive an update from the Homeland Security Information Network (HSIN) Program Office on various HSIN efforts undertaken during the 2017 Fiscal Year (FY) and planned activities for the upcoming quarters.

DATES: The HSINAC will meet on Wednesday, September 6, 2017, from 1:00 p.m. to 2:00 p.m. Eastern Standard Time (EST). Please note that the meeting may close early if the committee has completed its business.

ADDRESSES: The meeting will be held virtually via HSIN Connect, an online web-conferencing tool at *https://share.dhs.gov/hsin-policy,* and available via teleconference at conference number: 1–888–942–9868; conference pin: 390–9971#. To access the web conferencing tool, participants will need to: (1) Go to *https://share.dhs.gov/hsin-policy;* (2) click on ''enter as a guest''; (3) type in their name as a guest; and (4) click ''submit.'' The teleconference line will be open to the public and the meeting brief will be posted beforehand on the HSINAC's Web site (*https://dhs.gov/hsin-advisory-committee*). If the Federal government is closed, the meeting will be rescheduled. For information on services for individuals with disabilities or to request special assistance to attend, please email *sheila.becherer@associates.hq.dhs.gov* by 5:00 p.m. EST on Wednesday, August 30, 2017.

The HSIN Program Office is inviting public comment on the issues to be considered by the HSINAC in order to facilitate public participation in the meeting. Comments must be identified by Docket Number DHS–2017–0041 and may be submitted by *one* of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Email: sheila.becherer@associates.hq.dhs.gov.* Please include Docket Number DHS–2017–0041 in the subject line of the message.
- *Mail:* Designated Federal Officer, 245 Murray Lane SW., Mailstop 0426, 4th Floor, Workstation 82, ATTN: Maria Petrakis, Washington, DC 20828.
- *Fax:* (202) 343–4294, ATTN: Sheila Becherer.
- *Instructions:* All submissions received must include the words ''Department of Homeland Security'' and Docket Number DHS–2017–0041. Comments received will be posted without alteration at *http://www.regulations.gov* including any personal information provided.
- *Docket:* For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and search for Docket Number DHS–2017–0041.

A public comment period is scheduled during the meeting on Wednesday, September 6, 2017, from 1:40 p.m. to 1:55 p.m. EST. Speakers who wish to participate in the public comment period must register in advance and can do so by emailing *sheila.becherer@associates.hq.dhs.gov* by no later than Wednesday, August 30, 2017, at 5:00 p.m. EST. Speakers are requested to limit their comments to three (3) minutes and will speak in order of registration. Please note that the public comment period may begin earlier than the time listed above if the committee concludes its business earlier than expected. Similarly, the period may also end before the time indicated, following the last request for comments.

FOR FURTHER INFORMATION CONTACT: Ms. Maria Petrakis, HSINAC Designated Federal Officer and HSIN Policy Manager, Department of Homeland Security, (202) 343–4280 (office), *maria.petrakis@hq.dhs.gov* (email).

SUPPLEMENTARY INFORMATION: Notice of this meeting is given under the *Federal Advisory Committee Act,* 5 U.S.C. appendix (Pub. L. 92–463). The HSINAC is an advisory body to the HSIN Program Office. This committee provides advice and recommendations to the Department of Homeland Security (DHS) on matters relating to HSIN. These matters include system requirements, operating policies, community organization, knowledge management, interoperability and federation with other systems, and any other aspect of HSIN that supports the operations of DHS and its Federal, State, territorial, local, tribal, international, and private sector mission partners.

Agenda: The HSINAC will hold a virtual meeting on Wednesday, September 6, 2017, to discuss recent HSIN Program efforts, to include an overview of HSIN's migration to the Cloud, significant projects planned for FY 2018, and the impacts of these initiatives on end users. The members will also have the opportunity to discuss upcoming HSINAC activities and provide feedback to the HSIN Program Office on HSINAC future activities.

Responsible DHS Official: Ms. Maria Petrakis, HSINAC Designated Federal Officer.

Dated: July 13, 2017.

James Lanoue,

HSIN Program Manager.

[FR Doc. 2017–15375 Filed 7–20–17; 8:45 am]

BILLING CODE 9110–9B–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[Docket No. FWS–HQ–IA–2017–0040; FXIA16710900000–178–FF09A30000]

Foreign Endangered Species; Receipt of Applications for Permit

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of receipt of applications for permit.

SUMMARY: We, the U.S. Fish and Wildlife Service, invite the public to comment on the following applications to conduct certain activities with endangered species, marine mammals, or both. With some exceptions, the Endangered Species Act (ESA) and Marine Mammal Protection Act (MMPA) prohibit activities with listed species unless Federal authorization is acquired that allows such activities.

DATES: We must receive comments or requests for documents on or before August 21, 2017.

ADDRESSES:

Submitting Comments: You may submit comments by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments on Docket No. FWS–HQ–IA–2017–0040.
- *U.S. mail or hand-delivery:* Public Comments Processing, Attn: Docket No. FWS–HQ–IA–2017–0040; U.S. Fish and Wildlife Service Headquarters, MS: BPHC; 5275 Leesburg Pike, Falls Church, VA 22041–3803.

When submitting comments, please indicate the name of the applicant and the PRT# you are commenting on. We will post all comments on *http://www.regulations.gov.* This generally means that we will post any personal information you provide us (see the Public Comments section for more information).

Viewing Comments: Comments and materials we receive will be available for public inspection on *http://www.regulations.gov,* or by appointment, between 8 a.m. and 4 p.m., Monday through Friday, except Federal holidays, at the U.S. Fish and Wildlife Service, Division of Management Authority, 5275 Leesburg Pike, Falls Church, VA 22041–3803; telephone 703–358–2095.

FOR FURTHER INFORMATION CONTACT: Joyce Russell, Government Information Specialist, Division of Management Authority, U.S. Fish and Wildlife Service Headquarters, MS: IA; 5275 Leesburg Pike, Falls Church, VA 22041–

3803; telephone (703) 358–2023; facsimile (703) 358–2280.

SUPPLEMENTARY INFORMATION:

I. Public Comment Procedures

A. How do I request copies of applications or comment on submitted applications?

Send your request for copies of applications or comments and materials concerning any of the applications to the contact listed under **FOR FURTHER INFORMATION**. Please include the **Federal Register** notice publication date, the PRT-number, and the name of the applicant in your request or submission. We will not consider requests or comments sent to an email or address not listed under **ADDRESSES**. If you provide an email address in your request for copies of applications, we will attempt to respond to your request electronically.

Please make your requests or comments as specific as possible. Please confine your comments to issues for which we seek comments in this notice, and explain the basis for your comments. Include sufficient information with your comments to allow us to authenticate any scientific or commercial data you include.

The comments and recommendations that will be most useful and likely to influence agency decisions are: (1) Those supported by quantitative information or studies; and (2) Those that include citations to, and analyses of, the applicable laws and regulations. We will not consider or include in our administrative record comments we receive after the close of the comment period (see **DATES**) or comments delivered to an address other than those listed above (see **ADDRESSES**).

B. May I review comments submitted by others?

Comments, including names and street addresses of respondents, will be available for public review at the street address listed under **ADDRESSES**. The public may review documents and other information applicants have sent in support of the application unless our allowing viewing would violate the Privacy Act or Freedom of Information Act. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

II. Background

To help us carry out our conservation responsibilities for affected species, and in consideration of section 10(a)(1)(A) of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*), and the Marine Mammal Protection Act of 1972, as amended (16 U.S.C. 1361 *et seq.*), along with Executive Order 13576, ''Delivering an Efficient, Effective, and Accountable Government,'' and the President's Memorandum for the Heads of Executive Departments and Agencies of January 21, 2009—Transparency and Open Government (74 FR 4685; January 26, 2009), which call on all Federal agencies to promote openness and transparency in Government by disclosing information to the public, we invite public comment on these permit applications before final action is taken. Under the MMPA, you may request a hearing on any MMPA application received. If you request a hearing, give specific reasons why a hearing would be appropriate. The holding of such a hearing is at the discretion of the Service Director.

III. Permit Applications

We invite the public to comment on applications to conduct certain activities with endangered species. With some exceptions, the Endangered Species Act (16 U.S.C. 1531 *et seq.;* ESA) prohibits activities with listed species unless Federal authorization is acquired that allows such activities.

Endangered Species

Applicant: Glen Jacobsen, Bird Island, MN; PRT–22069C

The applicant requests a captive-bred wildlife registration under 50 CFR 17.21(g) for radiated tortoise (*Astrochelys radiata*) to enhance the propagation or survival of the species. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: Eric Meffre, New Haven, CT; PRT–187257

The applicant requests a captive-bred wildlife registration under 50 CFR 17.21(g) for radiated tortoise (*Astrochelys radiata*) to enhance the propagation or survival of the species. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: Wildwood Wildlife Park and Nature Center, Inc., Minocqua, WI; PRT–66306A

The applicant requests a renewal of a captive-bred wildlife registration under 50 CFR 17.21(g) to enhance the propagation or survival of the following species: Ring-tailed lemur (*Lemur catta*), brown lemur (*Eulemur fulvus*), black and white ruffed lemur (*Varecia variegata*), red ruffed lemur (*Varecia rubra*), cotton-top tamarin (*Saguinus oedipus*), mandrill (*Mandrillus sphinx*), Japanese macaque (*Macaca fuscata*), lar gibbon (*Hylobates lar*), leopard (*Panthera pardus*), snow leopard (*Uncia uncia*), bontebok (*Damaliscus pygargus*), red lechwe (*Kobus leche*), salmon-crested cockatoo (*Cacatua moluccensis*), Blyth's tragopan (*Tragopan blythii*), Cabot's tragopan (*Tragopan caboti*), spotted pond turtle (*Geoclemys hamiltonii*), Galapagos tortoise (*Chelonoidis nigra*), and radiated tortoise (*Astrochelys radiata*). This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: Farzad Sharim, Encino, CA; PRT–30604C

The applicant requests a captive-bred wildlife registration under 50 CFR 17.21(g) to enhance species propagation or survival of the species for the golden parakeet (*Guarouba guarouba*). This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: Maurice Khoury, Livonia, MI; PRT–28970C

The applicant requests a captive-bred wildlife registration under 50 CFR 17.21(g) for red siskin (*Carduelis cucullata*), to enhance species propagation or survival of the species. This notification covers activities to be conducted by the applicant over a 5-year period.

IV. Next Steps

If the Service decides to issue permits to any of the applicants listed in this notice, we will publish a notice in the **Federal Register**. You may locate the **Federal Register** notice announcing the permit issuance date by searching in *www.regulations.gov* under the permit number listed in this document.

V. Public Comments

You may submit your comments and materials concerning this notice by one of the methods listed in **ADDRESSES**. We will not consider comments sent by email or fax or to an address not listed in **ADDRESSES**.

If you submit a comment via *http://www.regulations.gov,* your entire comment, including any personal identifying information, will be posted on the Web site. If you submit a hardcopy comment that includes personal identifying information, you

may request at the top of your document that we withhold this information from public review. However, we cannot guarantee that we will be able to do so.

We will post all hardcopy comments on *http://www.regulations.gov.*

VI. Authority

Endangered Species Act of 1973, (16 U.S.C. 1531 *et seq.*).

Joyce Russell,

Government Information Specialist, Branch of Permits, Division of Management Authority.

[FR Doc. 2017–15310 Filed 7–20–17; 8:45 am]

BILLING CODE 4333–15–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–579–580 and 731–TA–1369–1372 (Preliminary)]

Fine Denier Polyester Staple Fiber From China, India, Korea, and Taiwan

Determinations

On the basis of the record [1] developed in the subject investigations, the United States International Trade Commission (''Commission'') determines, pursuant to the Tariff Act of 1930 (''the Act''), that there is a reasonable indication that an industry in the United States is materially injured by reason of imports of fine denier polyester staple fiber from China, India, Korea, and Taiwan provided for in subheading 5503.20.00 of the Harmonized Tariff Schedule of the United States, that are allegedly sold in the United States at less than fair value (''LTFV'') and subsidized by the governments of China and India.

Commencement of Final Phase Investigations

Pursuant to section 207.18 of the Commission's rules, the Commission also gives notice of the commencement of the final phase of its investigations. The Commission will issue a final phase notice of scheduling, which will be published in the **Federal Register** as provided in section 207.21 of the Commission's rules, upon notice from the Department of Commerce (''Commerce'') of affirmative preliminary determinations in the investigations under sections 703(b) or 733(b) of the Act, or, if the preliminary determinations are negative, upon notice of affirmative final determinations in those investigations under sections 705(a) or 735(a) of the Act. Parties that filed entries of appearance in the preliminary phase of the investigations need not enter a separate appearance for the final phase of the investigations. Industrial users, and, if the merchandise under investigation is sold at the retail level, representative consumer organizations have the right to appear as parties in Commission antidumping and countervailing duty investigations. The Secretary will prepare a public service list containing the names and addresses of all persons, or their representatives, who are parties to the investigations.

Background

On May 31, 2017, DAK Americas LLC, Charlotte, NC; Nan Ya Plastics Corporation, America, Lake City, SC; and Auriga Polymers Inc., Charlotte, NC filed a petition with the Commission and Commerce, alleging that an industry in the United States is materially injured or threatened with material injury by reason of subsidized imports of fine denier polyester staple fiber from China and India and LTFV imports of fine denier polyester staple fiber from China, India, Korea, Taiwan, and Vietnam. Accordingly, effective May 31, 2017, the Commission, pursuant to sections 703(a) and 733(a) of the Act (19 U.S.C. 1671b(a) and 1673b(a)), instituted countervailing duty investigation Nos. 701–TA–579–580 and antidumping duty investigation Nos. 731–TA–1369–1373 (Preliminary). On July 13, 2017, the Department of Commerce terminated its antidumping duty investigation of imports of fine denier polyester staple fiber from Vietnam, following a request for withdrawal of the petition. Accordingly, the Commission has also terminated its antidumping duty investigation concerning fine denier polyester staple fiber from Vietnam (Investigation No. 731–TA–1373).

Notice of the institution of the Commission's investigations and of a public conference to be held in connection therewith was given by posting copies of the notice in the Office of the Secretary, U.S. International Trade Commission, Washington, DC, and by publishing the notice in the **Federal Register** of June 7, 2017 (82 FR 26512). The conference was held in Washington, DC, on June 21, 2017, and all persons who requested the opportunity were permitted to appear in person or by counsel.

The Commission made these determinations pursuant to sections 703(a) and 733(a) of the Act (19 U.S.C. 1671b(a) and 1673b(a)). It completed and filed its determinations in these investigations on July 17, 2017. The views of the Commission are contained in USITC Publication 4709 (July 2017), entitled *Fine Denier Polyester Staple Fiber from China, India, Korea, and Taiwan: Investigation Nos. 701–TA–579–580 and 731–TA–1369–1372 (Preliminary).*

By order of the Commission.

Issued: July 17, 2017.

Lisa R. Barton,

Secretary to the Commission.

[FR Doc. 2017–15299 Filed 7–20–17; 8:45 am]

BILLING CODE 7020–02–P

[1] The record is defined in sec. 207.2(f) of the Commission's Rules of Practice and Procedure (19 CFR 207.2(f)).

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–581 and 731–TA–1374–1376 (Preliminary)]

Citric Acid and Certain Citrate Salts From Belgium, Colombia, and Thailand

Determinations

On the basis of the record [1] developed in the subject investigations, the United States International Trade Commission (''Commission'') determines, pursuant to the Tariff Act of 1930 (''the Act''), that there is a reasonable indication that an industry in the United States is materially injured by reason of imports of citric acid and certain citrate salts from Belgium, Colombia, and Thailand, provided for in subheadings 2918.14, 2918.15, and 3824.99 of the Harmonized Tariff Schedule of the United States, that are allegedly sold at less than fair value (''LTFV'') and that are allegedly subsidized by the government of Thailand.

Commencement of Final Phase Investigations

Pursuant to section 207.18 of the Commission's rules, the Commission also gives notice of the commencement of the final phase of its investigations. The Commission will issue a final phase notice of scheduling, which will be published in the **Federal Register** as provided in section 207.21 of the Commission's rules, upon notice from the Department of Commerce (''Commerce'') of affirmative preliminary determinations in the investigations under sections 703(b) or 733(b) of the Act, or, if the preliminary determinations are negative, upon notice of affirmative final determinations in those investigations under sections 705(a) or 735(a) of the Act. Parties that filed entries of appearance in the preliminary phase of

[1] The record is defined in sec. 207.2(f) of the Commission's Rules of Practice and Procedure (19 CFR 207.2(f)).

the investigations need not enter a separate appearance for the final phase of the investigations. Industrial users, and, if the merchandise under investigation is sold at the retail level, representative consumer organizations have the right to appear as parties in Commission antidumping and countervailing duty investigations. The Secretary will prepare a public service list containing the names and addresses of all persons, or their representatives, who are parties to the investigations.

Background

On June 2, 2017, Archer Daniels Midland Company (Decatur, Illinois), Cargill, Inc. (Minneapolis, Minnesota), and Tate & Lyle Ingredients Americas LLC (Hoffman Estates, Illinois) filed a petition with the Commission and Commerce, alleging that an industry in the United States is materially injured or threatened with material injury by reason of subsidized imports of citric acid and certain citrate salts from Thailand and LTFV imports of citric acid and certain citrate salts from Belgium, Colombia, and Thailand. Accordingly, effective June 2, 2017, the Commission, pursuant to sections 703(a) and 733(a) of the Act (19 U.S.C. 1671b(a) and 1673b(a)), instituted countervailing duty investigation No. 701–TA–581 and antidumping duty investigation Nos. 731–TA–1374–1376 (Preliminary).

Notice of the institution of the Commission's investigations and of a public conference to be held in connection therewith was given by posting copies of the notice in the Office of the Secretary, U.S. International Trade Commission, Washington, DC, and by publishing the notice in the **Federal Register** of June 8, 2017 (82 FR 26712). The conference was held in Washington, DC, on June 23, 2017, and all persons who requested the opportunity were permitted to appear in person or by counsel.

The Commission made these determinations pursuant to sections 703(a) and 733(a) of the Act (19 U.S.C. 1671b(a) and 1673b(a)). It completed and filed its determinations in these investigations on July 17, 2017. The views of the Commission are contained in USITC Publication 4710 (July 2017), entitled *Citric Acid and Certain Citrate Salts from Belgium, Colombia, and Thailand: Investigation Nos. 701–TA–581 and 731–TA–1374–1376 (Preliminary).*

By order of the Commission.

Issued: July 17, 2017.

Lisa R. Barton,

Secretary to the Commission.

[FR Doc. 2017–15300 Filed 7–20–17; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 731–TA–1373 (Preliminary)]

Fine Denier Polyester Staple Fiber From Vietnam; Termination of Investigation

AGENCY: United States International Trade Commission.

ACTION: Notice of termination of investigation.

SUMMARY: On July 13, 2017, the Department of Commerce terminated its antidumping duty investigation of imports of fine denier polyester staple fiber from Vietnam, following a request for withdrawal of the petition. Accordingly, the Commission is terminating its antidumping duty investigation concerning fine denier polyester staple fiber from Vietnam (Investigation No. 731–TA–1373 (Preliminary)).

DATES: July 13, 2017.

FOR FURTHER INFORMATION CONTACT: Calvin Chang (202–205–3062), Office of Investigations, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436. Hearing-impaired individuals are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its Internet server (*https://www.usitc.gov*). The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.*

Authority: This investigation is being terminated under authority of title VII of the Tariff Act of 1930 and pursuant to section 207.40(a) of the Commission's Rules of Practice and Procedure (19 CFR 207.40(a)). This notice is published pursuant to section 201.10 of the Commission's rules (19 CFR 201.10).

By order of the Commission.

Issued: July 17, 2017.

Lisa R. Barton,

Secretary to the Commission.

[FR Doc. 2017–15301 Filed 7–20–17; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. TA–201–76]

Large Residential Washers; Institution and Scheduling of Safeguard Investigation and Determination That the Investigation Is Extraordinarily Complicated, Amendment

AGENCY: United States International Trade Commission.

ACTION: Notice; amendment.

SUMMARY: The Commission published a notice in the **Federal Register** of June 13, 2017, concerning the institution and scheduling of investigation No. TA–201–76 pursuant to section 202 of the Trade Act of 1974 (''the Act'') to determine whether large residential washers are being imported into the United States in such increased quantities as to be a substantial cause of serious injury, or the threat thereof, to the domestic industry producing an article like or directly competitive with the imported articles. 72 FR 27075. This amended notice provides for limits on page lengths for posthearing briefs.

FOR FURTHER INFORMATION CONTACT: Michael Szustakowski (202–205–3169), Office of Investigations, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (*https://www.usitc.gov*). The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.*

SUPPLEMENTARY INFORMATION:

Amendment.—Pursuant to 19 CFR 206.3(b), in the **Federal Register** of June 13, 2017, in FR Doc. 2017–12160, on page 27077, in the third column, line 23, following the sentence ending with ''October 26, 2017,'' add the following sentences:

No posthearing brief, either in the injury phase or any remedy phase, shall exceed fifteen (15) pages of textual

material, double-spaced and single-sided, when printed out on pages measuring 8.5 x 11 inches. In addition, the presiding official may permit persons to file answers to questions or requests made by the Commission at the hearing for the injury phase, and at any hearing for the remedy phase, within a specified time.

By order of the Commission.

Issued: July 18, 2017.

Lisa R. Barton,

Secretary to the Commission.

[FR Doc. 2017–15356 Filed 7–20–17; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. TA–201–75]

Crystalline Silicon Photovoltaic Cells (Whether or Not Partially or Fully Assembled Into Other Products); Institution and Scheduling of Safeguard Investigation and Determination That the Investigation Is Extraordinarily Complicated, Amendment

AGENCY: United States International Trade Commission.

ACTION: Notice; amendment.

SUMMARY: The Commission published a notice in the **Federal Register** of June 1, 2017, concerning the institution and scheduling of investigation No. TA–201–75 pursuant to section 202 of the Trade Act of 1974 (''the Act'') to determine whether crystalline silicon photovoltaic cells (whether or not partially or fully assembled into other products) are being imported into the United States in such increased quantities as to be a substantial cause of serious injury, or the threat thereof, to the domestic industry producing an article like or directly competitive with the imported articles. 82 FR 25331. This amended notice provides for limits on page lengths for posthearing briefs.

FOR FURTHER INFORMATION CONTACT: Mary Messer (202–205–3193), Office of Investigations, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its Internet server (*https://www.usitc.gov*). The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.*

SUPPLEMENTARY INFORMATION:

Amendment.—Pursuant to 19 CFR 206.3(b), in the **Federal Register** of June 1, 2017, in FR Doc. 2017–11013, on page 25333, in the first column, line 65, following the sentence ending with ''October 10, 2017,'' add the following sentences:

No posthearing brief, either in the injury phase or any remedy phase, shall exceed fifteen (15) pages of textual material, double-spaced and single-sided, when printed out on pages measuring 8.5 x 11 inches. In addition, the presiding official may permit persons to file answers to questions or requests made by the Commission at the hearing for the injury phase, and at any hearing for the remedy phase, within a specified time.

By order of the Commission.

Issued: July 18, 2017.

Lisa R. Barton,

Secretary to the Commission.

[FR Doc. 2017–15355 Filed 7–20–17; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF LABOR

Comment Request for the Extension of a Currently Approved Collection: Evaluation of the Employment First State Leadership Mentoring Program (EFSLMP)

AGENCY: Office of Disability Employment Policy, Department of Labor.

ACTION: 60-Day notice.

SUMMARY: The Department of Labor, as part of its continuing effort to reduce paperwork and respondent burden, conducts a preclearance consultation program to provide the general public and federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA). This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents is properly assessed. Currently, the Department of Labor is soliciting comments concerning the extension of data collection for the Evaluation of the EFSLMP. A copy of the proposed Information Collection Request (ICR) can be obtained by contacting the office listed in the addressee section of this notice.

DATES: Written comments must be submitted to the office listed in the addressee's section below on or before September 19, 2017.

ADDRESSES: You may submit comments by either one of the following methods: Email: *hunter.cherise@dol.gov;* Mail or Courier: Cherise Hunter, Office of Disability Employment Policy, U.S. Department of Labor, Room S–1303, 200 Constitution Avenue NW., Washington, DC 20210. *Instructions:* Please submit one copy of your comments by only one method. All submissions received must include the agency name and OMB Control Number identified below for this information collection. Because we continue to experience delays in receiving mail in the Washington, DC area, commenters are strongly encouraged to transmit their comments electronically via email or to submit them by mail early. Comments, including any personal information provided, become a matter of public record. They will also be summarized and/or included in the request for OMB approval of the information collection request.

FOR FURTHER INFORMATION CONTACT: Cherise Hunter by email at *hunter.cherise@dol.gov* or by phone at (202) 693–7880.

SUPPLEMENTARY INFORMATION:

I. Background

The proposed information collection extension described in this notice will provide ongoing data for an evaluation of the EFSLMP. EFSLMP, a cross-disability and cross-systems change initiative, provides a platform for multi-disciplinary state teams to focus on implementing an employment first (EF) approach when supporting individuals with disabilities. EFSLMP helps the state teams align policies, coordinate resources, and update service delivery models, to facilitate increased competitive integrated employment options for people with the most significant disabilities.

The purpose of this information collection is to gauge, via a Web-based survey, the effectiveness of ODEP's EFSLMP efforts to promote the implementation of EF policies and practices for persons with disabilities and to determine how well remote training and online forums facilitate the implementation of EF activities in each of the 14 participating states. This **Federal Resister** Notice provides the opportunity to comment on the extension of the use of the proposed

data collection instruments that are used in the study:

** The Community of Practice (CoP) Pre/Post Survey.* Community of practice six-part webinar series where participants receive a 'pre-' and a 'post-brief' survey to gauge the effectiveness of the webinar series. Respondents consist of state direct-services staff and managers in disability services and workforce development.

II. Desired Focus of Comments

Currently, DOL is soliciting comments concerning the extension of data collection for the evaluation of the EFSLMP. DOL is particularly interested in comments that do the following:

- Evaluate whether the proposed collection of information is necessary for the proper performance functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's burden estimate of the proposed information collection, including the validity of the methodology and assumptions 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 (for example, permitting electronic submissions of responses).

III. Current Actions

At this time, the Department of Labor is requesting clearance for the extension of data collection to evaluate the EFSLMP via a community of practice pre/post survey.

Type of review: Extension of a currently approved collection.

OMB Control Number: 1230–0007.

Title: Evaluation of the Employment First State Leadership Mentoring Program (EFSLMP).

ESTIMATED TOTAL BURDEN HOURS

Data collection activity	Total number of respondents	Total annual responses	Number of responses per respondent	Average burden hours per response	Total annual estimated burden hours
CoP Pre/Post Survey	300	100	6	0.26	156

Affected Public: State government staff who are members of the EFSLMP Community of Practice.

Form(s): Community of Practice Pre/Post Survey.

Total Respondents: 300.

Annual Frequency: Six times.

Comments submitted will be summarized and/or included in the request for Office of Management and Budget approval of the information collection; they will also become a matter of public record.

Dated: July 12, 2017.

Jennifer Sheehy,

Deputy Assistant Secretary, Office of Disability Employment Policy, U.S. Department of Labor.

[FR Doc. 2017–15315 Filed 7–20–17; 8:45 am]

BILLING CODE 4510–23–P

DEPARTMENT OF LABOR

Bureau of Labor Statistics

Information Collection Activities; Comment Request

AGENCY: Bureau of Labor Statistics, Department of Labor.

ACTION: Notice of information collection; request for comment.

SUMMARY: The Department of Labor, 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 of 1995 (PRA95). This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. The Bureau of Labor Statistics (BLS) is soliciting comments concerning the proposed revision of the Annual Refiling Survey (ARS). A copy of the proposed information collection request (ICR) 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 **ADDRESSES** section of this notice on or before September 19, 2017.

ADDRESSES: Send comments to Carol Rowan, BLS Clearance Officer, Division of Management Systems, Bureau of Labor Statistics, Room 4080, 2 Massachusetts Avenue NE., Washington, DC 20212. Written comments also may be transmitted by fax to 202–691–5111 (this is not a toll free number).

FOR FURTHER INFORMATION CONTACT: Carol Rowan, BLS Clearance Officer, 202–691–7628 (this is not a toll free number). (See **ADDRESSES** section.)

SUPPLEMENTARY INFORMATION:

I. Background

The Quarterly Census of Employment and Wages (QCEW) program is a Federal/State cooperative effort which compiles monthly employment data, quarterly wages data, and business identification information from employers subject to State Unemployment Insurance (UI) laws. These data are collected from State Quarterly Contribution Reports (QCRs) submitted to State Workforce Agencies (SWAs). The States send micro-level employment and wages data, supplemented with the names, addresses, and business identification information of these employers, to the BLS. The State data are used to create the BLS sampling frame, known as the longitudinal QCEW data.

To ensure the continued accuracy of these data, the information supplied by employers must be periodically verified and updated. For this purpose, the ARS is used in conjunction with the UI tax reporting system in each State. The information collected by the ARS is used to review the existing industry code assigned to each establishment as well as the physical location of the business establishment. As a result, changes in the industrial and geographical compositions of our economy are captured in a timely manner and reflected in the BLS statistical programs.

The ARS also asks employers to identify new locations in the State. If these employers meet QCEW program reporting criteria, then a Multiple

Worksite Report (MWR) is sent to the employer requesting employment and wages for each worksite each quarter. Thus, the ARS is also used to identify new potential MWR-eligible employers.

II. Current Action

Office of Management and Budget clearance is being sought for a revision of the ARS. While the primary purpose of the ARS is to verify or to correct the North American Industry Classification System (NAICS) code assigned to establishments, there are other important purposes of the ARS. For example, the BLS and the Census Bureau enhance the quality of their data and reduce costs and respondent burden through increased data sharing. Such sharing improves the quality and the reliability of information for multi-location businesses by developing consistent industrial and geographical classifications for these businesses. The ARS seeks accurate mailing and physical location addresses of establishments as well as geographical codes such as county and township (independent city, parish, or island in some States).

Once every three years, the SWAs survey employers that are covered by the State's UI laws to ensure that State records correctly reflect the business activities and locations of those employers. States survey approximately one-third of their businesses each year and largely take care of the entire universe of covered businesses over a three-year cycle. The selection criterion for surveying establishments is based on the nine-digit Federal Employer Identification Number of the respondent.

BLS constantly pursues a growing number of automated reporting options to reduce employer burden and costs and to take advantage of more efficient methods and procedures. Even given such actions, mailing remains an important part of the survey. The BLS developed a one-page letter rather than mailing forms for ARS solicitation. This letter explains the purpose of the ARS and provides respondents with a unique Web ID and password. Respondents are directed to the BLS online web collection system to verify or to update their geographic and industry information.

Additionally, BLS staff review selected, large multi-worksite national employers rather than surveying these employers with traditional ARS forms. This central review reduces postage costs incurred in sending letters or forms. It also reduces respondent burden, as the selected employers do not have to return forms either.

Finally, BLS continues to use a private contractor to handle various administrative aspects of the survey to reduce the costs associated with the ARS. This initiative is called the Centralized Annual Refiling Survey (CARS). Under CARS, BLS effectively utilizes the commercial advantages related to printing and mailing large volumes of survey letters.

III. Desired Focus of Comments

The Bureau of Labor Statistics is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility.
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used.
- Enhance the quality, utility, and clarity of the information to be collected.
- 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.

Title of Collection: Annual Refiling Survey (ARS).

OMB Number: 1220–0032.

Type of Review: Revision of a currently approved collection.

Affected Public: Business or other for-profit institutions, not-for-profit institutions, and farms.

Frequency: Annually.

ARS collection instrument	Total respondents	Frequency	Total responses	Average time per response (minutes)	Total burden (hours)
BLS 3023–(NVS)	695,969	Once	695,969	5	57,997
BLS 3023–(NVM)	18,328	Once	18,328	15	4,582
BLS 3023–(NCA)	283,810	Once	283,810	10	47,302
Totals	998,107		998,107		109,881

Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget approval of the information collection request; they also will become a matter of public record.

Signed at Washington, DC, this 14th day of July 2017.

Kimberley Hill,

Chief, Division of Management Systems.

[FR Doc. 2017–15323 Filed 7–20–17; 8:45 am]

BILLING CODE 4510–24–P

NATIONAL SCIENCE FOUNDATION

Agency Information Collection Activities: Comment Request

AGENCY: National Science Foundation.

ACTION: Submission for OMB review; comment request.

SUMMARY: Under the Paperwork Reduction Act of 1995, and as part of its continuing effort to reduce paperwork and respondent burden, the National Science Foundation (NSF) is inviting the general public and other Federal agencies to comment on this proposed reinstated information collection. NSF is forwarding the proposed submission to the Office of Management and Budget (OMB) for clearance simultaneously with the publication of this second notice. The full submission may be found at *http://www.reginfo.gov/public/do/PRAMain.*

DATES: Written comments on this notice must be received by August 21, 2017, to be assured consideration. Comments received after that date will be considered to the extent practicable. Send comments to address below.

FOR FURTHER INFORMATION CONTACT: Suzanne H. Plimpton, Reports Clearance Officer, National Science Foundation,

4201 Wilson Boulevard, Suite 1265, Arlington, Virginia 22230; telephone (703) 292–7556; or send email to *splimpto@nsf.gov.* Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339, which is accessible 24 hours a day, 7 days a week, 365 days a year (including federal holidays).

SUPPLEMENTARY INFORMATION: This is the second notice for public comment; the first was published in the **Federal Register** at 81 FR 35805 and no comments were received. Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Foundation, including whether the information will have practical utility; (b) the accuracy of the Foundation'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; and (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of automated collection techniques or other forms of information technology.

Title of Collection: 2017 Early Career Doctorates Survey.

OMB Approval Number: 3145–0235.

Type of Request: Intent to seek approval to reinstate an information collection for three years.

Abstract: Established within the NSF by the America COMPETES Reauthorization Act of 2010 § 505, codified in the National Science Foundation Act of 1950, as amended, the National Center for Science and Engineering Statistics (NCSES) serves as a central Federal clearinghouse for the collection, interpretation, analysis, and dissemination of objective data on science, engineering, technology, and research and development for use by practitioners, researchers, policymakers, and the public. The Early Career Doctorates Survey (ECDS) will become part of an integrated survey system that meets the human resources statistics part of this mission.

The Early Career Doctorates Project was established to gather in-depth information about early career doctorates (ECD), including postdoctoral researchers (postdocs). Early career doctorates are critical to the success of the U.S. scientific enterprise and will influence U.S. and global scientific markets for years to come. Despite their importance, current surveys of this population are limited, and extant workforce studies are insufficient for covering all doctorates who contribute to the U.S. economy. The NSF's Survey of Earned Doctorates and the Survey of Doctorate Recipients are limited to individuals who received research doctorates from U.S. academic institutions, thereby excluding individuals who earned professional doctorates and those who earned doctorates from institutions outside the United States but are currently employed in the United States. The NSF's Survey of Graduate Students and Postdoctorates in Science and Engineering (GSS) provides aggregate level data for all postdocs and nonfaculty researchers regardless of where they earned the degree. However, the GSS is limited to science, engineering, and selected health (SEH) fields in U.S. academic institutions and their related research facilities and is collected at the program rather than the individual level.

Through its multi-year Postdoc Data Project, NCSES determined the need for and the feasibility of gathering information about postdocs working in the United States. However, efforts to reliably identify and gather information about postdocs proved difficult due to substantial variation in how institutions characterize postdoc appointments. As a result, NCSES expanded the target population to include all individuals who earned their first doctorate within the past 10-years. Expanding the population to doctoral degree holders ensures a larger, more consistent and reliable target population. Unique in scope, the key goals of the ECD Project are:

- To broaden the scope and depth of national statistics on the ECD population both U.S. degreed and non-U.S. degreed, across employment sectors and fields of discipline
- To collect nationally representative data from ECD that can be used by funding agencies, policy makers, and other researchers to better understand the labor market and work experiences of recent doctorate recipients
- To gather the diverse definitions for ECD to allow for analysis within and across employment sectors

The current focus of the ECD Project is to conduct a survey of ECD working in three areas of employment: U.S. academic institutions in the GSS, Federally Funded Research and Development Centers, and the National Institutes of Health Intramural Research Programs. NCSES, under full clearance (OMB #3145–0235), has conducted a pilot survey with data collection period spanning July 2014 to March 2015. The Pilot ECDS data was released in January 2017.

Beginning in August 2017, NSF will request lists of ECD from approximately 350 institutions nationwide, and sample 22,855 individuals from these lists. Sample members will be invited to participate in a 32-minute web-based questionnaire. The survey topics cover: educational achievement, professional activities, employer demographics, professional and personal life balance, mentoring, training and research opportunities, and career paths and plans. Participation in the survey is voluntary.

The survey will be collected in conformance with the Privacy Act of 1974, the Confidential Information Protection and Statistical Efficiency Act (CIPSEA) of 2002, and the Federal Cybersecurity Enhancement Act of 2015. The NSF will ensure that all individually identifiable information collected will be kept strictly confidential and will be used for research or statistical purposes.

Use of the Information: The NSF will publish statistics from the survey in several reports, including the National Science Board's *Science and Engineering Indicators* and NCSES's *Women, Minorities, and Persons with Disabilities in Science and Engineering.* These reports will be made available electronically on the NSF Web site. Restricted-use and public use data files will also be developed, and will be made available to interested researchers from government, professional associations, and other organizations. Restricted-use data may be obtained under a license agreement.

Expected Respondents: There are five groups who contribute to the estimated total burden hours of the 2017 ECDS data collection. Three groups assist in the development of an accurate list of ECD: Institutional high authority (HA), communication coordinator (CC), and list coordinator (LC). The fourth and fifth groups consist of the individual early career doctorates (ECD) and ineligible respondents. At the first stage of sampling, the 2017 ECDS will select approximately 350 institutions. At each institution, a high authority (HA) will authorize the institution's participation in the study, designate a list coordinator (LC) and a communication coordinator (CC), and provide a letter of support for the survey. The primary responsibility of the LC is to prepare a list of ECD working at the institution. The LC will provide a list of all ECD, that is, individuals working at their institution who earned their first doctorate or doctorate-equivalent degree within the past 10 years, including postdocs, non-faculty researchers, tenured or tenure-track faculty members. The primary

responsibility of the CC is to coordinate all ECDS-related institutional communications. In the second stage, the 2017 ECDS will select a sample of up to 22,855 ECD to participate in the survey with the goal of attaining 18,000 eligible ECD respondents. The HA, with the help of the CC, will notify the sampled individuals of their selection and NSF will survey these individuals.

Estimate of Burden: In the 2017 ECDS, taking into account all five respondent types (HA, CC, LC, ECD, and ineligible respondents), we estimate the total respondent burden to be 12,641 hours. We estimate a total burden of 157 hours for HAs, 470 hours for CCs, 2,400 hours for list coordinators, 9,600 hours for ECD, and 14 hours for ineligible respondents. These estimates use the burden information collected during the Pilot ECDS and assume that 300 institutions will participate (approximately 86%) during stage 1 of the 2017 ECDS data collection, 240 of the participating institutions (80%) will send pre-notification emails to potential respondents in stage 2 of data collection, and that the 22,855 sample size will result in 18,000 eligible responding ECD and 410 ineligible respondents. The amount of time for eligible responding ECD to complete the 2017 ECDS questionnaire may vary depending on an individual's circumstances; however, NCSES estimate it will take approximately 32 minutes. The below table shows the estimated burden by stage and respondent type.

ESTIMATED BURDEN BY STAGE AND RESPONDENT TYPE: 2017 ECDS

Respondent type	Sample members	Minutes per respondent	Estimated total burden hours
Stage 1: Frame Creation:			
High Authority (HA)	350	20	117
Communication Coordinator (CC)	350	60	350
List Coordinator (LC)	300	480	2,400
Subtotal			*2,867*
Stage 2: Individual Survey			
High Authority (HA) Communication	240	10	40
Coordinator (CC)	240	30	120
Early Career Doctorate (ECD)	18,000	32	9,600
Ineligible Respondents	410	2	14
Subtotal			*9,774*
Total			12,641

Updates: Relative to the first notice, there are three substantive changes: (1) The first notice included the statement that ''NSF will request lists of ECD from approximately 390 institutions nationwide, and sample 24,000 individuals from these lists'' was based on the initial sample design plan. Based on additional analysis, the final sample sizes decreased to a sample of approximately 350 institutions and 22,855 individuals. (2) The first notice also stated ''Sample members will be invited to participate in a 40-minute web-based questionnaire.'' Since the first notice, NCSES further revised the Pilot ECDS questionnaire to reduce the time needed to complete the survey to 32 minutes. (3) NCSES reduced the estimated burden to 12,641 hours from the 19,900 hours provided in the first notice. This reduction in the estimated burden was a result of the smaller sample sizes, a reduction in the time to complete the survey, and a change in the expected response rate.

NSF 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.

Dated: July 17, 2017.

Suzanne H. Plimpton,

Reports Clearance Officer.

[FR Doc. 2017–15326 Filed 7–20–17; 8:45 am]

BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2016–0174]

Information Collection: DOE/NRC Form 740M, Concise Note; DOE/NRC Form 741, Nuclear Material Transaction Report; DOE/NRC Form 742, Material Balance Report; DOE/NRC Form 742C, Physical Inventory Listing

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of submission to the Office of Management and Budget; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) has recently submitted a request for renewal of an existing collection of information to the Office of Management and Budget (OMB) for review. The information collections are entitled, ''DOE/NRC Form 740M, Concise Note; DOE/NRC Form 741, Nuclear Material Transaction Report; DOE/NRC Form 742, Material Balance Report and, DOE/NRC Form 742C, Physical Inventory Listing.''

DATES: Submit comments by August 21, 2017.

ADDRESSES: Submit comments directly to the OMB reviewer at: Aaron Szabo, Desk Officer, Office of Information and Regulatory Affairs (3150–0057, 3150–0003, 3150–0004, 3150–0058), NEOB–10202, Office of Management and Budget, Washington, DC 20503; telephone: 202–395–3621, email: *oira_submission@omb.eop.gov.*

FOR FURTHER INFORMATION CONTACT: David Cullison, NRC Clearance Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2084; email: *INFOCOLLECTS.Resource@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID: NRC–2016–0174 when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

• *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID: NRC–2016–0174. A copy of the collection of information and related instructions may be obtained without charge by accessing Docket ID NRC–2016–0174.

• *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.* A copy of the collection of information and related instructions may be obtained without charge by accessing the following ADAMS Accession No. ML17173A237. Guidance documents are available for the forms in ADAMS as follows: NUREG/BR–0006, Revision 7, ADAMS Accession No. ML111740924, and NUREG/BR–0007 ADAMS Accession No. ML090120288. The supporting statements for each DOE/NRC Form and the forms themselves are available in ADAMS as follows: DOE/NRC Form 740M, ''Concise Note'' ADAMS Accession Nos. ML17173A239 and ML16252A189; DOE/NRC Form 741, ''Nuclear Material Transaction Report'' ADAMS Accession Nos. ML17173A240 and ML16252A191; DOE/NRC Form 742, ''Material Balance Report'' ADAMS Accession numbers ML17173A241 and ML16252A192; and DOE/NRC Form 742C, ''Physical Inventory Listing'' ADAMS Accession Nos. ML17173A242 and ML16252A193.

• *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.

• *NRC's Clearance Officer:* A copy of the collections of information and related instructions may be obtained without charge by contacting the NRC's Clearance Officer, David Cullison, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2084; email: *INFOCOLLECTS.Resource@NRC.GOV.*

B. Submitting Comments

The NRC cautions you not to include identifying or contact information in comment submissions that you do not want to be publicly disclosed in your comment submission. All comment submissions are posted at *http://www.regulations.gov* and entered into ADAMS. Comment submissions are not routinely edited to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the OMB, 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 comment submissions are not routinely edited to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Background

Under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the NRC recently submitted an extension of four collections of information to OMB for review entitled, ''DOE/NRC Form 740M, Concise Note; DOE/NRC Form 741, Nuclear Material Transaction Report; DOE/NRC Form 742, Material Balance Report; DOE/NRC Form 742C, Physical Inventory Listing.'' The NRC hereby informs potential respondents that an agency may not conduct or sponsor, and that a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

The NRC published a **Federal Register** notice with a 60-day comment period on this information collection on October 28, 2016, 81 FR 75167.

1. *The title of the information collection:* DOE/NRC Form 740M, Concise Note; DOE/NRC Form 741, Nuclear Material Transaction Report; DOE/NRC Form 742, Material Balance Report; DOE/NRC Form 742C, Physical Inventory Listing.

2. *OMB approval numbers:*

DOE/NRC Form 740M: 3150–0057.
DOE/NRC Form 741: 3150–0003.
DOE/NRC Form 742: 3150–0004.
DOE/NRC Form 742C: 3150–0058.

3. *Type of submission:* Extension.

4. *The form number if applicable:* DOE/NRC Forms 740M, 741, 742, and 742C.

5. *How often the collection is required or requested:* DOE/NRC Form 741, Nuclear Material Transaction Reports will be collected whenever nuclear material is shipped or received into the Material Balance Area; DOE/NRC Form 742, Material Balance Report will be collected on an annual basis; DOE/NRC Form 742C, Physical Inventory Listing will be collected on an annual basis; DOE/NRC Form 740M, Concise Note Forms are used when needed.

6. *Who will be required or asked to respond:* Any licensee who ships, receives, or otherwise undergoes an inventory change of nuclear material is required to submit a DOE/NRC Form 741 to document the change. Additional information regarding these transactions shall be submitted through Form 740M, with Safeguards Information identified and handled in accordance with § 73.21 of Title of the *Code of Federal Regulations* (10 CFR), ''Protection of Safeguards Information: Performance requirements.''

Any licensee who had possessed in the previous reporting period, at any one time and location, nuclear material in a quantity totaling one gram or more shall complete DOE/NRC Form 742. In addition, each licensee, Federal or State, who is authorized to possess, at any one time or location, one kilogram of foreign obligated source material, is required to file with the NRC an annual statement of source material inventory which is foreign obligated.

Any licensee, who had possessed in the previous reporting period, at any one time and location, special nuclear material in a quantity totaling one gram or more shall complete DOE/NRC Form 742C.

7. *The estimated number of annual responses:*

DOE/NRC Form 740M: 150
DOE/NRC Form 741: 10,000
DOE/NRC Form 742: 360
DOE/NRC Form 742C: 360

8. *The estimated number of annual respondents:*

DOE/NRC Form 740M: 15
DOE/NRC Form 741: 340
DOE/NRC Form 742: 360
DOE/NRC Form 742C: 360

9. *An estimate of the total number of hours needed annually to comply with the information collection requirement or request:*

DOE/NRC Form 740M: 113
DOE/NRC Form 741: 12,500
DOE/NRC Form 742: 1,260
DOE/NRC Form 742C: 1,440

10. *Abstract:* Persons licensed to possess specified quantities of nuclear material currently report inventory and transaction of material to the Nuclear Materials Management and Safeguards System via the DOE/NRC Forms: DOE/NRC Form 740M, Concise Note; DOE/NRC Form 741, Nuclear Material Transaction Report; DOE/NRC Form 742, Material Balance Report; DOE/NRC Form 742C, Physical Inventory Listing. The NRC uses these forms to collect, retrieve, analyze, and maintain relevant inventory data. The NRC is not submitting the information collections

associated with the modified Small Quantities Protocol to OMB at this time. A separate 30-day notice will be published prior to submitting the information collections associated with the final rule.

Dated at Rockville, Maryland, this 14th day of July 2017.

For the Nuclear Regulatory Commission.

David Cullison,

NRC Clearance Officer, Office of the Chief Information Officer.

[FR Doc. 2017–15354 Filed 7–20–17; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2017–0161]

Assessment of the Assumption of Normality (Employing Individual Observed Values)

AGENCY: Nuclear Regulatory Commission.

ACTION: Regulatory guide; withdrawal.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is withdrawing Regulatory Guide (RG) 5.22, ''Assessment of the Assumption of Normality (Employing Individual Observed Values).'' This RG is being withdrawn because the guidance for licensees to develop written procedures describing statistical analyses of nuclear material accounting data, specifically when assessing the assumption of normality in a data set, is no longer needed.

DATES: The effective date of the withdrawal of RG 5.22 is July 21, 2017.

ADDRESSES: Please refer to Docket ID NRC–2017–0161 when contacting the NRC about the availability of information regarding this document. You may obtain publicly-available information related to this document, using the following methods:

- *Federal Rulemaking Web site*: Go to *http://www.regulations.gov* and search for Docket ID NRC–2017–0161. 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.
- *NRC's Agencywide Documents Access and Management System (ADAMS)*: You may obtain publicly-available documents online in the ADAMS Public Document 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 in this notice (if that document is available in ADAMS) is provided the first time that a document is referenced. The basis for the withdrawal of this guide is found in ADAMS under Accession No. ML16225A659.
- *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.

Regulatory guides are not copyrighted, and NRC approval is not required to reproduce them.

FOR FURTHER INFORMATION CONTACT: Glenn Tuttle, Office of Nuclear Materials Safety and Safeguards, telephone: 301–415–7230; email: *Glenn.Tuttle@nrc.gov; and* Harriet Karagiannis, Office of Nuclear Regulatory Research, telephone: 301–415–2493; email: *Harriet.Karagiannis@nrc.gov.* Both are staff of the U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

SUPPLEMENTARY INFORMATION: Regulatory Guide 5.22 was published in April 1974 to provide guidance on meeting the requirements related to material control and accounting (MC&A) statistical control procedures in § 70.22(b) of title 10 of the *Code of Federal Regulations* (10 CFR), ''Contents of applications.'' This requirement, regarding submittal of the licensees' description of its MC&A procedures, did not specifically require the methodology that the guidance in RG 5.22 addressed and no longer exists in 10 CFR 70.22(b). The MC&A requirements have all been moved to 10 CFR part 74 and no specific requirements exist for assessing the assumption of normality.

Regulatory Guide 5.22 endorsed the American National Standards Institute (ANSI) Standard N15.15–1973, ''Assessment of the Assumption of Normality (Employing Individual Observed Values),'' with qualifications. The ANSI Standard N15.15–1973 provided a common method used in assessing the assumption of normality in a data set. However, the NRC is not aware that any licensee ever used this particular RG or the ANSI standard it endorsed since the method is not required by NRC regulations. Instructions on performing such an analysis, if a licensee chose to test their MC&A data for the assumption of normality, can be found in NUREG/CR–4604 (PNL–5849), ''Statistical Methods for Nuclear Material Management'' (ADAMS Accession No. ML103430339). NUREG/CR–4604 was developed to be a comprehensive guidance document on statistical methods that licensees may use in evaluating MC&A data.

Withdrawal of a RG means that the guide no longer provides useful information or has been superseded by other guidance, technological innovations, congressional actions, or other events. The NRC is withdrawing RG 5.22 because it is no longer needed. The withdrawal of RG 5.22 does not alter any prior or existing NRC licensing approvals or the acceptability of licensee commitments to RG 5.22. Although RG 5.22 is withdrawn, current licensees may continue to use it, and withdrawal does not affect any existing licenses or agreements. However, by withdrawing RG 5.22, the NRC will no longer approve its use in future requests or applications for NRC licensing actions.

Dated at Rockville, Maryland, this 17th day of July, 2017.

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. 2017–15336 Filed 7–20–17; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2017–0066]

Information Collection: NRC Form 4, Cumulative Occupational Exposure History

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of submission to the Office of Management and Budget; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) has recently submitted a request for renewal of an existing collection of information to the Office of Management and Budget (OMB) for review. The information collection is entitled, ''NRC Form 4, Cumulative Occupational Exposure History''.

DATES: Submit comments by August 21, 2017.

ADDRESSES: Submit comments directly to the OMB reviewer at: Aaron Szabo, Desk Officer, Office of Information and Regulatory Affairs (3150–0005), NEOB–10202, Office of Management and

Budget, Washington, DC 20503; telephone: 202–395–3621, email: *oira_submission@omb.eop.gov.*

FOR FURTHER INFORMATION CONTACT: David Cullison, NRC Clearance Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2084; email: *INFOCOLLECTS.Resource@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2017–0066 when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2017–0066.
- *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.* A copy of the collection of information and related instructions may be obtained without charge by accessing ADAMS Accession No. ML17171A265. The supporting statement and Cumulative Occupational Exposure History is available in ADAMS under Accession No. ML17163A038.
- *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.
- *NRC's Clearance Officer:* A copy of the collection of information and related instructions may be obtained without charge by contacting the NRC's Clearance Officer, David Cullison, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2084; email: *INFOCOLLECTS.Resource@NRC.GOV.*

B. Submitting Comments

The NRC cautions you not to include identifying or contact information in comment submissions that you do not want to be publicly disclosed in your comment submission. All comment submissions are posted at *http://www.regulations.gov* and entered into ADAMS. Comment submissions are not routinely edited to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the OMB, 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 comment submissions are not routinely edited to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Background

Under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the NRC recently submitted a request for renewal of an existing collection of information to OMB for review entitled, ''NRC Form 4, Cumulative Occupational Exposure History.'' The NRC hereby informs potential respondents that an agency may not conduct or sponsor, and that a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

The NRC published a **Federal Register** notice with a 60-day comment period on this information collection on March 28, 2017 (82 FR 15376).

1. *The title of the information collection:* NRC Form 4, ''Cumulative Occupational Exposure History.''
2. *OMB approval number:* 3150–0005.
3. *Type of submission:* Extension.
4. *The form number if applicable:* NRC Form 4.
5. *How often the collection is required or requested:* On occasion. The NRC does not collect NRC Form 4. However, NRC inspects the NRC Form 4 records at NRC-licensed facilities.
6. *Who will be required or asked to respond:* NRC licensees who are required to comply with part 20 of title 10 of the *Code of Federal Regulations* (10 CFR).
7. *The estimated number of annual responses:* 227,841 (223,700 third party disclosure + 4,141 recordkeepers).
8. *The estimated number of annual respondents:* 4,146.
9. *An estimate of the total number of hours needed annually to comply with the information collection requirement or request:* 30,348.
10. *Abstract:* The NRC Form 4 is used to record the summary of an occupational worker's cumulative occupational radiation dose, including prior occupational exposure and the current year's occupational radiation exposure. The NRC Form 4 is used by licensees, and inspected by the NRC, to ensure that occupational radiation doses do not exceed the regulatory limits specified in 10 CFR 20.1501.

Dated at Rockville, Maryland, this 18th day of July 2017.

For the Nuclear Regulatory Commission.

David Cullison,

NRC Clearance Officer, Office of the Chief Information Officer.

[FR Doc. 2017–15342 Filed 7–20–17; 8:45 am]

BILLING CODE 7590–01–P

SECURITIES AND EXCHANGE COMMISSION

Proposed Collection; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE., Washington, DC 20549–2736

Extension:

Regulation S–X; SEC File No. 270–003, OMB Control No. 3235–0009

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') is soliciting comments on the collection of information summarized below. The Commission plans to submit this existing collection of information to the Office of Management and Budget for extension and approval.

Information collected and information prepared pursuant to Regulation S–X focus on the form and content of, and requirements for, financial statements filed with periodic reports and in connection with the offer and sale of securities. Investors need reasonably current financial statements to make informed investment and voting decisions.

The potential respondents include all entities that file registration statements or reports pursuant to the Securities Act of 1933 (15 U.S.C. 77a, *et seq.*), the Securities Exchange Act of 1934 (15 U.S.C. 78a, *et seq.*) or the Investment Company Act of 1940 (15 U.S.C. 80a–1, *et seq.*).

Regulation S–X specifies the form and content of financial statements when those financial statements are required to be filed by other rules and forms under the federal securities laws. Compliance burdens associated with the financial statements are assigned to the rule or form that directly requires the financial statements to be filed, not to Regulation S–X. Instead, an estimated

burden of one hour traditionally has been assigned to Regulation S–X for incidental reading of the regulation. The estimated average burden hours are solely for purposes of the Paperwork Reduction Act and are not derived from a comprehensive or even a representative survey or study of the costs of SEC rules or forms.

Written 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 will have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication.

Please direct your written comments to Pamela Dyson, Chief Information Officer, Securities and Exchange Commission, c/o Remi Pavlik-Simon, 100 F Street NE., Washington, DC 20549. or send an email to: *PRA_Mailbox@sec.gov*.

Dated: July 17, 2017.

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2017–15349 Filed 7–20–17; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–520, OMB Control No. 3235–0577]

Submission for OMB Review; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of Investor Education and Advocacy, Washington, DC 20549–2833

Extension:
Rule 30b1–5.

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (the ''Commission'') has submitted to the Office of Management and Budget (''OMB'') a request for extension of the previously approved collection of information discussed below.

Rule 30b1–5 (17 CFR 270.30b1–5) under the Investment Company Act of 1940 (15 U.S.C. 80a–1 *et seq.*) (the ''Investment Company Act'') requires registered management investment companies, other than small business investment companies registered on Form N–5 (17 CFR 239.24 and 274.5) (''funds''), to file a quarterly report via the Commission's EDGAR system on Form N–Q (17 CFR 249.332 and 274.130), not more than sixty calendar days after the close of each first and third fiscal quarter, containing their complete portfolio holdings. The purpose of the collection of information required by rule 30b1–5 is to meet the disclosure requirements of the Investment Company Act and to provide investors with information necessary to evaluate an interest in the fund by improving the transparency of information about the fund's portfolio holdings.

The Commission estimates that there are 2,380 management investment companies, with a total of approximately 11,757 portfolios, that are governed by the rule. For purposes of this analysis, the burden associated with the requirements of rule 30b1–5 has been included in the collection of information requirements of Form N–Q, rather than the rule.

The collection of information under rule 30b1–5 is mandatory. The information provided under rule 30b1–5 is not kept confidential. 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 public may view the background documentation for this information collection at the following Web site, *www.reginfo.gov.* Comments should be directed to: (i) Desk Officer for the Securities and Exchange Commission, Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10102, New Executive Office Building, Washington, DC 20503, or by sending an email to: *Shagufta_Ahmed@omb.eop.gov;* and (ii) Thomas Bayer, Chief Information Officer, Securities and Exchange Commission, c/o Remi Pavlik-Simon, 100 F Street NE., Washington, DC 20549 or send an email to: *PRA_Mailbox@sec.gov.* Comments must be submitted to OMB within 30 days of this notice.

Dated: July 17, 2017.

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2017–15294 Filed 7–20–17; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

Submission for OMB Review; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE., Washington, DC 20549–0213

Extension:
Rule 17g–2; SEC File No. 270–564, OMB Control No. 3235–0628

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') has submitted to the Office of Management and Budget (''OMB'') a request for approval of extension of the previously approved collection of information provided for in Rule 17g–2 (17 CFR 240.17g–2) under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*) (''Exchange Act'').

Rule 17g–2, ''Records to be made and retained by nationally recognized statistical rating organizations,'' implements the Commission's recordkeeping rulemaking authority under Section 17(a) of the Exchange Act.[1] The rule requires a Nationally Recognized Statistical Rating Organization (''NRSRO'') to make and retain certain records relating to its business and to retain certain other business records, if such records are made. The rule also prescribes the time periods and manner in which all these records must be retained. There are 10 credit rating agencies registered with the Commission as NRSROs under section 15E of the Exchange Act, which have already established the recordkeeping policies and procedures required by Rule 17g–2. Based on staff experience, NRSROs are estimated to spend a total industry-wide burden of 2,390 annual hours to make and retain the appropriate records.

The Commission 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.

Background documentation for this information collection may be viewed at the following Web site: *www.reginfo.gov.* Comments should be directed to: (i) Desk Officer for the Securities and Exchange Commission, Office of Information and Regulatory Affairs, Office of Management and

[1] 15 U.S.C 78q.

Budget, Room 10102, New Executive Office Building, Washington, DC 20503, or by sending an email to: *Shagufta_Ahmed@omb.eop.gov;* and (ii) Pamela Dyson, Director/Chief Information Officer, Securities and Exchange Commission, c/o Remi Pavlik-Simon, 100 F St NE., Washington, DC 20549 or send an email to: *PRA_Mailbox@sec.gov.* Comments must be submitted to OMB within 30 days of this notice.

Dated: July 17, 2017.

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2017–15295 Filed 7–20–17; 8:45 am]

BILLING CODE P

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–203, OMB Control No. 3235–0195]

Proposed Collection; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE., Washington, DC 20549–2736

Extension:

Rule 17Ab2–1, Form CA–1.

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (''PRA'') (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') is soliciting comments on the collection of information provided for Rule 17Ab2–1 (17 CFR 240.17Ab2–1) and Form CA–1: Registration of Clearing Agencies (17 CFR 249b.200) under the Securities Exchange Act of 1934 (''Exchange Act'') (15 U.S.C. 78a *et seq.*). The Commission plans to submit this existing collection of information to the Office of Management and Budget (''OMB'') for extension and approval.

Rule 17Ab2–1 and Form CA–1 require clearing agencies to register with the Commission and to meet certain requirements with regard to, among other things, the clearing agency's organization, capacities, and rules. The information is collected from the clearing agency upon the initial application for registration on Form CA–1. Thereafter, information is collected by amendment to the initial Form CA–1 when changes in circumstances that render certain information on Form CA–1 inaccurate, misleading, or incomplete necessitate modification of the information previously provided to the Commission.

The Commission uses the information disclosed on Form CA–1 to (i) determine whether an applicant meets the standards for registration set forth in Section 17A of the Exchange Act, (ii) enforce compliance with the Exchange Act's registration requirement, and (iii) provide information about specific registered clearing agencies for compliance and investigatory purposes. Without Rule 17Ab2–1, the Commission could not perform these duties as statutorily required.

The Commission staff estimates that the average Form CA–1 requires approximately 130 hours to complete and submit for approval. This burden is composed primarily of a one-time reporting burden that reflects the applicant's staff time (*i.e.* internal labor costs) to prepare and submit the Form to the Commission. This estimate includes the burden associated with filing amendments to Form CA–1, which is required when certain information contained in an applicant's or registrant's Form CA–1 becomes inaccurate, misleading, or incomplete. (The time burden related to preparing and submitting an amendment widely varies depending on the nature of the information that needs to be updated.) The Commission staff estimates that compliance staff work at applicant or registrant clearing agencies to comply with Rule 17Ab2–1 and complete Form CA–1 will result in an internal cost of compliance, at an estimated hourly wage of $283, of $36,790 per year per clearing agency (130 hours × $283 per hour = $36,790 per year). Therefore, the aggregate annual internal cost of compliance for the approximately one clearing agency each year to comply with Rule 17Ab2–1 is also $36,790. The external costs associated with work on Form CA–1 include fees charged by outside lawyers and accountants to assist the applicant or registrant collect and prepare the information sought by the form (though such consultations are not required by the Commission) and are estimated to be approximately a total amount of $19,029 ($19,029 times one registrant per year).

Written comments are invited on: (a) 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; (b) the accuracy of the Commission's estimates of the burden 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. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information under the PRA unless it displays a currently valid OMB control number.

Please direct your written comments to: Pamela Dyson, Director/Chief Information Officer, Securities and Exchange Commission, c/o Remi Pavlik-Simon, 100 F Street NE., Washington, DC 20549, or send an email to: *PRA_Mailbox@sec.gov.*

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2017–15296 Filed 7–20–17; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–81153; File No. SR–BOX–2017–24]

Self-Regulatory Organizations; BOX Options Exchange LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the BOX Fee Schedule

July 17, 2017.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on July 6, 2017, BOX Options Exchange LLC (the ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Exchange filed the proposed rule change pursuant to Section 19(b)(3)(A)(ii) of the Act,[3] and Rule 19b–4(f)(2) thereunder,[4] which renders the proposal effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of the Substance of the Proposed Rule Change

The Exchange is filing with the Securities and Exchange Commission (''Commission'') a proposed rule change to amend the Fee Schedule. The text of the proposed rule change is available from the principal office of the Exchange, at the Commission's Public

[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).

Reference Room and also on the Exchange's Internet Web site at *http://boxexchange.com.*

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend the Fee Schedule for trading on BOX to adopt transactions fees for Qualified Contingent Cross (''QCC'') transactions. A QCC Order is an originating order (Agency Order) to buy or sell at least 1,000 standard option contracts, or 10,000 mini-option contracts, that is identified as being part of a qualified contingent trade, coupled with a contra side order to buy or sell an equal number of contracts. The Exchange is proposing to establish fees for QCC Orders to coincide with the launch of QCC Orders on the Exchange beginning July 10, 2017.[5]

The Exchange proposes to establish a transaction fee for all Public Customer QCC Orders of $0.00 per contract side. Further, the Exchange proposes to establish a transaction fee for all non-Public Customer (Professional Customers, Broker Dealers and Market Makers) QCC Orders of $0.20 per contract side.[6] In addition, the Exchange is proposing to adopt a $0.15 per contract rebate that will be applied to the Agency Order[7] where at least one party to the QCC transaction is a Non-Public Customer. The rebate will be paid to the Participant that entered the order into the BOX system. However, no rebates will be paid for QCC transactions in which both the Agency Order and the contra-side orders are Public Customers.

Additionally, the Exchange proposes to state explicitly in the Fee Schedule that a QCC transaction must be comprised of an originating order to buy or sell at least 1,000 contracts or 10,000 mini-option contracts,[8] coupled with a contra-side order or orders totaling an equal number of contracts as the originating order.[9] The Exchange notes that with regard to order entry, the first order submitted into the BOX system is marked as the Agency Order and the second order received by the BOX system is marked as the contra side order.

Lastly, the Exchange proposes to specify that QCC Orders will be exempt from the Liquidity Fees and Credits outlined in Section II of the BOX Fee Schedule.

The purpose of these changes is to incentivize the sending of QCC Orders to the Exchange. The Exchange notes that other competing exchanges similarly provide fees and rebates on QCC Orders.[10]

2. Statutory Basis

The Exchange believes that the proposal is consistent with the requirements of Section 6(b) of the Act, in general, and Section 6(b)(4) and 6(b)(5)of the Act,[11] in particular, in that it provides for the equitable allocation of reasonable dues, fees, and other charges among BOX Participants and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers or dealers.

The Exchange believes the proposed transaction fees for QCC Orders are reasonable and in line with the amount assessed at other Exchanges for similar transactions.[12] Additionally, the same proposed fee would be charged to all non-Public Customer QCC Orders. The Exchange believes that charging Professional Customers and Broker Dealers and Market Makers more than Public Customers for QCC Orders is reasonable, equitable and not unfairly discriminatory. The securities markets generally, and BOX in particular, have historically aimed to improve markets for investors and develop various features within the market structure for Public Customer benefit. The Exchange believes that charging no fees to Public Customers in QCC transactions is reasonable and, ultimately, will benefit all Participants trading on the Exchange by attracting Public Customer order flow.

The Exchange believes the proposed rebate for the originating side of a QCC transaction is reasonable, as other competing exchanges also provide a rebate on the originating side of a QCC order. Additionally, the proposed rebate amount is in line with the rebates offered at other competing exchanges.[13] The Exchange believes the proposed rebate is equitable and not unfairly discriminatory because it potentially applies to all Participants that enter the originating order (except for when both the agency order and contra-side orders are Public Customers) and because it is intended to incentivize the sending of more QCC Orders to the Exchange. The Exchange believes it is reasonable, equitable and not unfairly discriminatory to not provide a rebate for the originating order for QCC transactions when both the originating order and contra side orders are from Public Customers, since Public Customers are already incentivized by having no transaction fee for QCC Orders.

The Exchange believes that exempting QCC Orders from Section II (Liquidity Fees and Credits) is reasonable, equitable and not unfairly discriminatory. The Exchange's Liquidity Fees and Credits are intended to attract order flow to the Exchange by offering incentives to all market participants to submit orders to the Exchange and the Exchange believes that the proposed QCC fee structure will provide appropriate incentives to encourage Participants to submit QCC Orders to the Exchange. The Exchange believes that exempting QCC Orders from liquidity fees and credits is reasonable compared to similar fees and credits offered by another exchange.[14] The Exchange believes that exempting QCC Orders from liquidity fees and credits is not unfairly discriminatory as the exemption from the liquidity fees and credits applies equally to all Participants on the Exchange.

[5] *See* Securities Exchange Act Release No. 80661 (May 11, 2017), 82 FR 22682 (May 17, 2017) (Notice of Filing and Immediate Effectiveness SR–BOX–2017–14).

[6] The Exchange notes that all QCC Orders will count toward Participant tier volume calculations.

[7] For QCC transactions, an Agency Order is the originating order to buy or sell at least 1,000 contracts or 10,000 mini-contracts.

[8] The Exchange notes that mini-options are not currently traded on BOX and are therefore not present in the BOX Fee Schedule.

[9] *See* BOX Rule 7110(c)(6).

[10] *See* Chicago Board Options Exchange (''CBOE''), Fees Schedule, ''QCC Rate Table,'' Page 5; Miami International Securities Exchange LLC (''MIAX''), Fee Schedule, Section 1(a)(vi).

[11] 15 U.S.C. 78f(b)(4) and (5).

[12] *See* CBOE Fee Schedule. CBOE charges non-Public Customers $0.17 per contract and does not charge Public Customers. *See also* MIAX Fee Schedule. MIAX charges Non-Priority Customers $0.15 per contract and does not charge Priority Customers. (Priority Customers on MIAX are the equivalent to Public Customers on BOX).

[13] CBOE and MIAX offer a $0.10 per contract credit or rebate paid on the initiating side of the QCC transaction.

[14] CBOE does not apply Taker fees and Maker rebates to QCC orders. *See* CBOE Fee Schedule Footnote 44.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The Exchange believes this proposal will not cause unnecessary burden on intermarket competition because the proposed changes will actually enhance the competiveness of the Exchange relative to other exchanges which offer comparable fees and rebates for QCC transactions. To the extent that the proposed changes make the Exchange a more attractive marketplace for market participants at other exchanges, such market participants are welcome to become market participants on the Exchange.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Exchange Act [15] and Rule 19b–4(f)(2) thereunder,[16] because it establishes or changes a due, or fee.

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend the rule change if it appears to the Commission that the action is necessary or appropriate in the public interest, for the protection of investors, or would otherwise further the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–BOX–2017–24 on the subject line.

Paper comments:

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–BOX–2017–24. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–BOX–2017–24, and should be submitted on or before August 11, 2017.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[17]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2017–15321 Filed 7–20–17; 8:45 am]

BILLING CODE 8011–01–P

[15] 15 U.S.C. 78s(b)(3)(A)(ii).

[16] 17 CFR 240.19b–4(f)(2).

[17] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–81155; File No. SR–NYSEArca–2016–176]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Designation of a Longer Period for Commission Action on Proceedings To Determine Whether To Approve or Disapprove a Proposed Rule Change Relating to the Listing and Trading of Shares of the EtherIndex Ether Trust Under NYSE Arca Equities Rule 8.201

July 17, 2017.

On December 30, 2016, NYSE Arca, Inc. 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 shares of the EtherIndex Ether Trust under NYSE Arca Equities Rule 8.201. The proposed rule change was published for comment in the **Federal Register** on January 23, 2017.[3]

On February 23, 2017, 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 April 21, 2017, the Commission instituted proceedings to determine whether to approve or disapprove the proposed rule change.[6] The Commission has received nine comments on the proposed rule change.[7]

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 79792 (Jan. 13, 2017), 82 FR 7891.

[4] 15 U.S.C. 78s(b)(2).

[5] *See* Securities Exchange Act Release No. 80094, 82 FR 12268 (Mar. 1, 2017).

[6] *See* Securities Exchange Act Release No. 80501, 82 FR 19397 (Apr. 27, 2017). Specifically, the Commission instituted proceedings to allow for additional analysis of the proposed rule change's consistency 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.* at 19397.

[7] *See* Letters from Andrew Quentson (Apr. 26, 2017); Charles K. Massey, III, Venture Private Equity Investment (Apr. 26, 2017); Anita Desai (Apr. 29, 2017); Luc Jean (May 3, 2017); Tisho P. (May 10, 2017); Kevin McSheehan (May 14, 2017); Bruce Granger (May 16, 2017); Bruce Granger (May 16, 2017); and Alen Lee (May 18, 2017). All comments on the proposed rule change are available on the Commission's Web site at: *https://www.sec.gov/comments/sr-nysearca-2016-176/nysearca2016176.htm.*

Section 19(b)(2) of the Act[8] provides that, after initiating disapproval proceedings, the Commission shall issue an order approving or disapproving the proposed rule change not later than 180 days after the date of publication of notice of filing of the proposed rule change. The Commission may extend the period for issuing an order approving or disapproving the proposed rule change by not more than 60 days if the Commission determines that a longer period is appropriate and publishes the reasons for such determination. The proposed rule change was published for notice and comment in the **Federal Register** on January 23, 2017. July 22, 2017 is 180 days from that date, and September 20, 2017 is 240 days from that date.

The Commission finds it appropriate to designate a longer period within which to issue an order approving or disapproving the proposed rule change so that it has sufficient time to consider this proposed rule change. Accordingly, the Commission, pursuant to Section 19(b)(2) of the Act,[9] designates September 20, 2017 as the date by which the Commission shall either approve or disapprove the proposed rule change (File No. SR–NYSEArca–2016–176).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[10]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2017–15320 Filed 7–20–17; 8:45 am]

BILLING CODE 8011–01–P

[8] 15 U.S.C. 78s(b)(2).

[9] *Id.*

[10] 17 CFR 200.30–3(a)(57).

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #15151 and #15152]

Missouri Disaster Number MO–00081

AGENCY: U.S. Small Business Administration.

ACTION: Amendment 1.

SUMMARY: This is an amendment of the Presidential declaration of a major disaster for the State of MISSOURI (FEMA–4317–DR), dated 06/02/2017.

Incident: Severe Storms, Tornadoes, Straight-line Winds, and Flooding.

Incident Period: 04/28/2017 through 05/11/2017.

DATES: Applicable 07/13/2017.

Physical Loan Application Deadline Date: 08/01/2017.

EIDL Loan Application Deadline Date: 03/02/2018.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW., Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: The notice of the Presidential disaster declaration for the State of MISSOURI, dated 06/02/2017 is hereby amended to include the following areas as adversely affected by the disaster:

Primary Counties: (Physical Damage and Economic Injury Loans): Christian, Crawford, Dent, Greene, Iron, Sainte Genevieve, Wayne, Wright.

Contiguous Counties: (Economic Injury Loans Only):

Illinois: Randolph

Missouri: Dallas, Polk

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Numbers 59002 and 59008)

Rafaela Monchek

Acting Associate Administrator for Disaster Assistance.

[FR Doc. 2017–15360 Filed 7–20–17; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #15153 and #15154]

Missouri Disaster Number MO–00082

AGENCY: U.S. Small Business Administration.

ACTION: Amendment 1.

SUMMARY: This is an amendment of the Presidential declaration of a major disaster for Public Assistance Only for the State of MISSOURI (FEMA–4317–DR), dated 06/02/2017.

Incident: Severe Storms, Tornadoes, Straight-line Winds, and Flooding.

Incident Period: 04/28/2017 through 05/11/2017.

DATES: Applicable 07/13/2017.

Physical Loan Application Deadline Date: 08/01/2017.

Economic Injury (EIDL) Loan Application Deadline Date: 03/02/2018.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW., Suite 6050, Washington, DC 20416.

SUPPLEMENTARY INFORMATION: The notice of the President's major disaster declaration for Private Non-Profit organizations in the State of MISSOURI, dated 06/02/2017, is hereby amended to include the following areas as adversely affected by the disaster.

Primary Counties: Boone, Cape Girardeau, Mississippi, New Madrid, Pemiscot, Sainte Genevieve, Scott.

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Numbers 59002 and 59008)

Rafaela Monchek,

Acting Associate Administrator for Disaster Assistance.

[FR Doc. 2017–15358 Filed 7–20–17; 8:45 am]

BILLING CODE 8025–01–P

DEPARTMENT OF STATE

[Public Notice: 10064]

Defense Trade Advisory Group; Notice of Open Meeting

The Defense Trade Advisory Group (DTAG) will meet in open session from 1:00 p.m. until 5:00 p.m. on Friday, September 8, 2017 at 1777 F Street NW., Washington DC 20006. Entry and registration will begin at 12:30 p.m. The membership of this advisory committee consists of private sector defense trade representatives, appointed by the Assistant Secretary of State for Political-Military Affairs, who advise the Department on policies, regulations, and technical issues affecting defense trade. The purpose of the meeting will be to discuss current defense trade issues and topics for further study.

The following agenda topics will be discussed: (1) One-Form electronic filing, review and discuss recommendations for making electronic filing more cost-effective and efficient for industry; (2) Identify key areas of concern with the proposed definition for defense services in 80 FR 31525 (June 3, 2015); (3) Review and provide feedback to accurately and effectively define ''manufacturing'' and distinguish it from other related activities like assembly, integration, installment and various services; (4) Examine and discuss the current rules regarding the release of technical data to foreign dual-nationals and identify alternative options which sufficiently facilitates risk assessment and risk mitigation and (5) Discuss and provide assessment, including a cost-benefit analysis, of

DDTC standardizing the expiration date for all new agreements to a fixed 10 year period from the date of initial approval.

Members of the public may attend this open session and will be permitted to participate in the discussion in accordance with the Chair's instructions. Members of the public may, if they wish, submit a brief statement to the committee in writing.

As seating is limited to 125 persons, each member of the public or DTAG member that wishes to attend this plenary session should provide: His/her name and contact information such as email address and/or phone number and any request for reasonable accommodation to the DTAG Alternate Designated Federal Officer (DFO), Anthony Dearth, via email at *DTAG@state.gov* by COB Monday, August 28, 2017. If notified after this date, the Department might be unable to accommodate requests due to requirements at the meeting location. One of the following forms of valid photo identification will be required for admission to the meeting: U.S. driver's license, passport, U.S. Government ID or other valid photo ID. For additional information, contact Ms. Glennis Gross-Peyton, PM/DDTC, SA–1, 12th Floor, Directorate of Defense Trade Controls, Bureau of Political-Military Affairs, U.S. Department of State, Washington, DC 20522–0112; telephone (202) 663–2862; FAX (202) 261–8199; or email *DTAG@state.gov.*

Anthony Dearth,

Alternate Designated Federal Officer, Defense Trade Advisory Group, Department of State.

[FR Doc. 2017–15316 Filed 7–20–17; 8:45 am]

BILLING CODE 4710–25–P

SURFACE TRANSPORTATION BOARD

[Docket No. FD 36126]

Chicago Rail & Port, LLC— Lease and Operation Exemption—Rail Line of South Chicago Property Development, LLC

Chicago Rail & Port, LLC (CRP), a noncarrier, has filed a verified notice of exemption under 49 CFR 1150.31 to acquire by lease from South Chicago Property Development, LLC (SCPD) and to operate,[1] approximately 3,797 linear feet (0.72 mile) of railroad right-of-way and trackage and transloading facilities located at the northeast corner of the intersection of 106th Street and the Calumet River in Chicago, Ill. (the Chicago Transload Facility trackage), pursuant to an agreement.

According to CRP, there are no mileposts associated with the Chicago Transload Facility trackage. CRP states that the trackage is used to transload gravel and other stone products (including railroad stone ballast), and aggregate materials from water to rail. The trackage is used in conjunction with interchanging to and from the Indiana Harbor Belt Railroad Company.

CRP asserts that because the trackage in question will constitute the entire line of railroad of CRP, this trackage is a line of railroad under 49 U.S.C. 10901, rather than spur, switching or side tracks excepted from Board acquisition and operation authority by virtue of 49 U.S.C. 10906.[2]

Although CRP states in its verified notice that the operations were proposed to be consummated on or about June 1, 2017, this transaction may not be consummated until August 5, 2017 (30 days after the verified notice was officially filed).[3]

CRP certifies that its projected annual revenues as a result of this transaction do not exceed those that would qualify it as a Class III rail carrier and will not exceed $5 million. CRP also certifies that there are no provisions or agreements that may limit future interchange commitments.

If the verified notice contains false or misleading information, the exemption is void ab initio. Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the effectiveness of the exemption. Petitions to stay must be filed no later than July 28, 2017 (at least seven days before the exemption becomes effective).

An original and 10 copies of all pleadings, referring to Docket No. FD 36126, must be filed with the Surface Transportation Board, 395 E Street SW., Washington, DC 20423–0001. In addition, a copy of each pleading must be served on CRP's representative, David C. Dillon, Dillon & Nash, Ltd., 3100 Dundee Road, Suite 508, Northbrook, IL 60062.

According to CRP, this action is categorically excluded from environmental review under 49 CFR 1105.6(c).

Board decisions and notices are available on our Web site at "*WWW.STB.GOV.*"

Decided: July 18, 2017.

By the Board, Rachel D. Campbell, Director, Office of Proceedings.

Kenyatta Clay,

Clearance Clerk.

[FR Doc. 2017–15365 Filed 7–20–17; 8:45 am]

BILLING CODE 4915–01–P

[1] A draft copy of the operating agreement was submitted with the notice of exemption.

[2] *See Effingham R.R.—Pet. for Declaratory Order—Constr. at Effingham, IL,* NOR 41986 *et al.* (STB served Sept. 18, 1998), *aff'd sub nom. United Transp. Union-Ill. Legislative Bd.* v. *STB,* 183 F.3d 606 (7th Cir. 1999).

[3] CRP initially filed its verified notice of exemption on June 14, 2017. CRP filed letters supplementing and clarifying its verified notice on June 20, 2017, and July 6, 2017, respectively. Therefore, July 6, 2017, is the official filing date.

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. 2017–0423]

Petition for Exemption; Summary of Petition Received; Lauren Pelicano: Child Restraint System

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Notice.

SUMMARY: This notice contains a summary of a petition seeking relief from specified requirements of Federal Aviation Regulations. The purpose of this notice is to improve the public's awareness of, and participation in, the FAA's exemption process. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

DATES: Comments on this petition must identify the petition docket number and must be received on or before August 10, 2017.

ADDRESSES: Send comments identified by docket number FAA–2017–0423 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov* and follow the online instructions for sending your comments electronically.
- *Mail:* Send comments to Docket Operations, M–30; U.S. Department of Transportation (DOT), 1200 New Jersey Avenue SE., Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC 20590–0001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* Fax comments to Docket Operations at 202–493–2251.

Privacy: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the

public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *http://www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *http://www.dot.gov/privacy.*

Docket: Background documents or comments received may be read at *http://www.regulations.gov* at any time. Follow the online instructions for accessing the docket or go to the Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Brittany Newton (202) 267–6691, Office of Rulemaking, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591.

This notice is published pursuant to 14 CFR 11.85.

Issued in Washington, DC, on July 7, 2017.

Dale Bouffiou,

Deputy Director, Office of Rulemaking.

Petition for Exemption

Docket No.: FAA–2017–0423.

Petitioner: Lauren Pelicano: Child Restraint System.

Section(s) of 14 CFR Affected: 121.311.

Description of Relief Sought: Petitioner seeks an exemption from § 121.311 to the extent necessary to allow her daughter to use the Convaid Carrot 3 booster seat on U.S.-registered aircraft in commercial air carrier operations under part 121. The petitioner states that this seat supports her daughter's trunk and easily accommodates her height and weight. The manufacturer (Convaid) has labeled the restraint as being certified for use in motor vehicles and aircraft. However, the manufacturer also notes in the user manual that the Convaid Carrot 3 is not ''FAA certified'' and that the Convaid Carrot 3 must always be secured with a lap shoulder (3-point) safety belt to secure the child restraint and the child. The manufacturer further notes that not using a lap shoulder (3-point) safety belt could cause the child restraint to not perform as intended and increase the potential of serious injury or death. Most commercial air carriers operating under part 121 do not operate aircraft (certificated under part 25) with a lap shoulder (3-point) safety belt restraint system in the passenger seats on their aircraft. It is novel for a child restraint system (CRS) to have labeling that indicates it is certificated for use on aircraft but to also have a manufacturer's limitation on the type of installed restraints in the passenger seat that, in effect, prohibits use on most large commercial aircraft in air carrier operations under part 121. Therefore, the FAA seeks public comment on whether the FAA should grant the petitioner's request for an exemption from 14 CFR 121.311 for CRS that are approved under FMVSS 209, which must always be secured with lap shoulder (3-point) safety belts to secure the child restraints in passenger seats, to permit their use on U.S.-registered aircraft in commercial air carrier operations under part 121.

[FR Doc. 2017–15087 Filed 7–20–17; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. 2017–41]

Petition for Exemption; Summary of Petition Received; CSA Ocean Sciences, Inc.

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Notice.

SUMMARY: This notice contains a summary of a petition seeking relief from specified requirements of Federal Aviation Regulations. The purpose of this notice is to improve the public's awareness of, and participation in, the FAA's exemption process. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

DATES: Comments on this petition must identify the petition docket number and must be received on or before August 10, 2017.

ADDRESSES: Send comments identified by docket number FAA–2016–2215 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov* and follow the online instructions for sending your comments electronically.
- *Mail:* Send comments to Docket Operations, M–30; U.S. Department of Transportation (DOT), 1200 New Jersey Avenue SE., Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC 20590–0001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* Fax comments to Docket Operations at (202) 493–2251.

Privacy: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *http://www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *http://www.dot.gov/privacy.*

Docket: Background documents or comments received may be read at *http://www.regulations.gov* at any time. Follow the online instructions for accessing the docket or go to the Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC 20590–0001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Jake Troutman (202) 683–7788, Office of Rulemaking, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591.

This notice is published pursuant to 14 CFR 11.85.

Issued in Washington, DC.

Lirio Liu,

Director, Office of Rulemaking.

Petition for Exemption

Docket No.: FAA–2016–2215.

Petitioner: CSA Ocean Sciences, Inc.

Section(s) of 14 CFR Affected: part 21, Subpart H; §§ 91.203(a)(1), 45.23(b), 91.7(a), 91.9, 61.113, 61.133, 91.109, 91.119, 91.121, 91.151, and 91.401, 91.403, 91.405, 91.407, 91.409, 91.411, 91.413, 91.415, 91.417, 91.419, 91.421.

Description of Relief Sought: The petitioner is seeking an exemption to commercially operate small unmanned aircraft systems (UAS) for aerial imaging, inspections, search and rescue, and education purposes beyond visual line of sight (BVLOS) near shore and over water.

[FR Doc. 2017–15317 Filed 7–20–17; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. 2017–38]

Petition for Exemption; Summary of Petition Received; Phoenix Air UNMANNED, LLC

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Notice.

SUMMARY: This notice contains a summary of a petition seeking relief from specified requirements of Federal Aviation Regulations. The purpose of this notice is to improve the public's awareness of, and participation in, the FAA's exemption process. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

DATES: Comments on this petition must identify the petition docket number and must be received on or before August 10, 2017.

ADDRESSES: Send comments identified by docket number FAA–2014–0692 using any of the following methods:

- *Federal eRulemaking Portal*: Go to *http://www.regulations.gov* and follow the online instructions for sending your comments electronically.
- *Mail*: Send comments to Docket Operations, M–30; U.S. Department of Transportation (DOT), 1200 New Jersey Avenue SE., Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.
- *Hand Delivery or Courier*: Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC20590–0001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax*: Fax comments to Docket Operations at (202) 493–2251.

Privacy: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *http://www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *http://www.dot.gov/privacy.*

Docket: Background documents or comments received may be read at *http://www.regulations.gov* at any time. Follow the online instructions for accessing the docket or go to the Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC 20590–0001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Jake Troutman (202) 683–7788, Office of Rulemaking, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591.

This notice is published pursuant to 14 CFR 11.85.

Issued in Washington, DC.

Lirio Liu

Director, Office of Rulemaking.

Petition for Exemption

Docket No.: FAA–2014–0692.

Petitioner: Phoenix Air UNMANNED, LLC.

Section(s) of 14 CFR Affected: 61.23(a) and (c), 61.101(e)(4) and (5), 61.113(a), 61.315(a), 91.7(a), 91.119(c), 91.121, 91.151(a)(1), 91.405(a), 91.407(a)(1), 91.409(a)(1) and (2), and 91.417(a) and (b).

Description of Relief Sought: The petitioner, a member of the Phoenix Air Group family of companies, is seeking an exemption to commercially operate the Pulse Vapor 65, weighing more than 55 pounds with payload, for on-demand service to a host of industries and applications including: Flare stack inspections, utility-power generation system inspections and patrolling, pipeline inspection and patrolling, filmmaking, cinematography, videography, precision agriculture, wildlife and forestry monitoring, aerial surveying, construction site inspection and monitoring, and public entity support operations.

[FR Doc. 2017–15314 Filed 7–20–17; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Notice of Final Federal Agency Actions on Proposed Highway in California

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of Limitation on Claims for Judicial Review of Actions by FHWA, the U.S. Army Corps of Engineers, and the U.S. Fish and Wildlife Service.

SUMMARY: The FHWA is issuing this notice to announce actions taken by FHWA, the U.S. Army Corps of Engineers, and the U.S. Fish and Wildlife Service that are final within the meaning of applicable law. The FHWA is issuing this notice to announce to the public that FHWA, as NEPA lead agency, has prepared and approved (May 26, 2017) a Final Environmental Assessment (EA) with a Finding of No Significant Impact (FONSI) and Section 4(f) Evaluation. The actions relate to a proposed highway project: Widen approximately 12.6 miles of U.S. Highway 395 from two lanes to four lanes from the existing four-lane highway segment just south of the Los Angeles Aqueduct Bridge No. 48–10 at post mile 29.2 north to the four-lane segment at the Ash Creek Bridge No. 48–068R, post mile 41.8, in the County of Inyo, State of California. Those actions grant licenses, permits, and approvals for the project.

DATES: By this notice, the FHWA, is advising the public of final agency actions subject to 23 U.S.C. 139(*l*)(1). A claim seeking judicial review of the Federal agency actions on the highway project will be barred unless the claim is filed on or before December 18, 2017. If the Federal law that authorizes judicial review of a claim provides a time period of less than 150 days for filing such claim, then that shorter time period still applies.

FOR FURTHER INFORMATION CONTACT:

For FHWA: David Tedrick, Senior Environmental Specialist, Federal Highway Administration, 650 Capitol Mall, Suite 4–100, Sacramento, CA 95814, (916) 498–5014, or email: *david.tedrick@dot.gov.*

For Caltrans: John Thomas, Associate Environmental Planner, California Department of Transportation, 855 M Street, Suite 200, Fresno, CA 93721, (559) 445–6451, or email: *john.q.thomas@dot.ca.gov.*

SUPPLEMENTARY INFORMATION: The Final EA/EIR is a joint project by the California Department of Transportation (Caltrans) and the Federal Highway Administration (FHWA) and is subject to state and federal environmental review requirements. FHWA and Caltrans jointly prepared the Final EA/EIR pursuant to the requirements of the National Environmental Policy Act and the California Environmental Quality Act. Caltrans is the lead agency under the CEQA. The Federal Highway Administration is the lead agency under the NEPA.

The project proposes to widen approximately 12.6 miles of U.S. Highway 395 from two lanes to four lanes from the existing four-lane highway segment just south of the Los Angeles Aqueduct Bridge No. 48–10 at post mile 29.2 north to the four-lane segment at the Ash Creek Bridge No.

48–068R, post mile 41.8, in the County of Inyo, State of California. The actions by the Federal agencies, and the laws under which such actions were taken, are described in the Final Environmental Assessment (FEA) for the project, approved on May 26, 2017, in the FHWA Finding of No Significant Impacts (FONSI), also issued on May 26 2017, and in other documents in the FHWA project records. The FEA, FONSI, and other project records are available by contacting FHWA, at the address provided above. The FHWA FEA and FONSI can be viewed and downloaded from the project Web site at: *http://www.dot.ca.gov/d9/projects/olancha/index.html.*

The U.S. Army Corps of Engineers decision and permit SPL–2009–00965–TS, and the U.S. Fish and Wildlife biological opinion FWS–INY–13B0156–14F0013 are available by contacting FHWA, at the address provided above. This notice applies to all Federal agency decisions as of the issuance date of this notice and all laws under which such actions were taken, including but not limited to:

1. Council on Environmental Quality regulations (40 CFR 1500 *et seq.;* 23 CFR 771);
2. National Environmental Policy Act (NEPA) (42 U.S.C. 4321–4351 *et seq.*);
3. Clean Air Act of 1963, as amended (42 U.S.C. 7401 *et seq.*);
4. Noise Control Act of 1979 (42 U.S.C. 4901 *et seq.*);
5. FHWA Noise Standards, Policies, and Procedures (23 CFR 772);
6. Department of Transportation Act of 1966, Section 4(f) (49 U.S.C. 303);
7. Clean Water Act of 1977 (33 U.S.C. 1344);
8. Endangered Species Act of 1973 (16 U.S.C. 1531–1543);
9. Migratory Bird Treaty Act (16 U.S.C. 703–712);
10. National Historic Preservation Act of 1966, as amended (54 U.S.C. 306108 *et seq.*);
11. Executive Order 11990, Protection of Wetlands;
12. Executive Order 11988, Floodplain Management;
13. Executive Order 13112, Invasive Species;
14. Executive Order 12898, Federal Actions to Address Environmental Justice and Low-Income Populations;
15. Title VI of Civil Rights Act 1964 (42 U.S.C. 2000d *et seq.*), as amended.

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program.)

Authority: 23 U.S.C.139(*l*)(1).

David Tedrick,

Senior Environmental Specialist, Federal Highway Administration, Sacramento, California.

[FR Doc. 2017–15347 Filed 7–20–17; 8:45 am]

BILLING CODE 4910–RY–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Notice of OFAC Sanctions Actions

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice.

SUMMARY: The U.S. Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing the names of one or more persons that have been placed on OFAC's Specially Designated National and Blocked Persons List based on OFAC's determination that one or more applicable legal criteria were satisfied. All property and interests in property subject to U.S. jurisdiction of these persons are blocked, and U.S. persons are generally prohibited from engaging in transactions with them.

DATES: See **SUPPLEMENTARY INFORMATION** section for date(s).

FOR FURTHER INFORMATION CONTACT: *OFAC:* Associate Director for Global Targeting, tel.: 202–622–2420; Assistant Director for Sanctions Compliance & Evaluation, tel.: 202–622–2490; Assistant Director for Licensing, tel.: 202–622–2480; or the Department of the Treasury's Office of the General Counsel: Office of the Chief Counsel (Foreign Assets Control), tel.: 202–622–2410 (not toll free numbers).

SUPPLEMENTARY INFORMATION:

Electronic Availability

The Specially Designated Nationals and Blocked Persons List and additional information concerning OFAC sanctions programs are available on OFAC's Web site (*www.treas.gov/ofac*).

Notice of OFAC Actions

On July 18, 2017, OFAC determined that the property and interests in property subject to U.S. jurisdiction of the following persons are blocked under the relevant sanctions authorities listed below.

Individuals

1. LIU, Emily (a.k.a. BAOXIA, Liu; a.k.a. LAU, Emily), China; DOB 10 Sep 1981; POB Shandong, China; nationality China; Additional Sanctions Information—Subject to Secondary Sanctions; Gender Female; Passport G28882492 (China) expires 04 May 2018 (individual) [NPWMD] [IFSR] (Linked To: SHIRAZ ELECTRONICS INDUSTRIES).

Designated pursuant to section 1(a)(iii) of Executive Order 13382 of June 28, 2005, ''Blocking Property of Weapons of Mass Destruction Proliferators and Their Supporters'' (''E.O. 13382'') for having provided, or attempted to provide, financial, material, technological, or other support for, or goods or services in support of, SHIRAZ ELECTRONICS INDUSTRIES, a person whose property and interests in property are blocked pursuant to E.O. 13382.

2. GHASEMI, Seyyed Reza (a.k.a. QASEMI, Seyed Reza); Additional Sanctions Information—Subject to Secondary Sanctions; National ID No. 004–3–94558–9 (Iran); Chief Executive Officer, Rayan Roshd Afzar Company; Managing Director, Rayan Roshd Afzar Company (individual) [NPWMD] [IFSR] (Linked To: RAYAN ROSHD AFZAR COMPANY).

Designated pursuant to section 1(a)(iv) of E.O. 13382 for acting or purporting to act for or on behalf of, directly or indirectly, RAYAN ROSHD AFZAR COMPANY, a person whose property or interests in property are blocked pursuant to E.O. 13382.

3. HAKEMZADEH, Farshad; Additional Sanctions Information—Subject to Secondary Sanctions; National ID No. 005–1–61706–4 (Iran) (individual) [NPWMD] [IFSR] (Linked To: RAYAN ROSHD AFZAR COMPANY).

Designated pursuant to section 1(a)(iv) of E.O. 13382 for acting or purporting to act for or on behalf of, directly or indirectly, RAYAN ROSHD AFZAR COMPANY, a person whose property or interests in property are blocked pursuant to E.O. 13382.

4. PARSAJAM, Mohsen (a.k.a. HODJATABADI, Mohsen Kargar; a.k.a. HODJAT ABADI, Mohsen Kargar; a.k.a. ''KARGAR, Mohsen''); DOB 23 Aug 1964; POB Qom, Iran; nationality Iran; Additional Sanctions Information—Subject to Secondary Sanctions; Gender Male; Passport N95873956 (Iran) expires 05 May 2020; National ID No. 038–1–57690–6 (Iran); Chairman of the Board, Rayan Roshd Afzar Company (individual) [NPWMD] [IFSR] (Linked To: RAYAN ROSHD AFZAR COMPANY).

Designated pursuant to section 1(a)(iv) of E.O. 13382 for acting or purporting to act for or on behalf of, directly or indirectly, RAYAN ROSHD AFZAR COMPANY, a person whose property or interests in property are blocked pursuant to E.O. 13382.

5. TAVAN, Resit (a.k.a. TAVAN, Reshit); DOB 01 Jan 1977; nationality Turkey; Additional Sanctions Information—Subject to Secondary Sanctions; Passport U06314813 (Turkey) (individual) [NPWMD] [IFSR] (Linked To: QESHM MADKANDALOO SHIPBUILDING COOPERATIVE CO).

Designated pursuant to section 1(a)(iii) of E.O. 13382 for having provided, or attempted to provide, financial, material, technological, or other support for, or goods or services in support of, QESHM MADKANDALOO SHIPBUILDING COOPERATIVE CO, a person whose property and interests in property are blocked pursuant to E.O. 13382.

6. AJILY, Mohammed Saeed (a.k.a. AJILI, Sa'id); DOB 03 Sep 1982; nationality Iran (individual) [TCO] (Linked To: AJILY SOFTWARE PROCUREMENT GROUP).

Designated pursuant to sections 1(a)(ii)(C) of E.O. 13581, ''Blocking Property of Transnational Criminal Organizations'' (''E.O. 13581'') for having acted or purported to act for or on behalf of, directly or indirectly, the AJILY SOFTWARE PROCUREMENT GROUP, a person whose property and interests in property are blocked pursuant to E.O. 13581.

7. REZAKHAH, Mohammed Reza (a.k.a. REZAKHAH, Mohammad Reza); DOB 04 Aug 1978; nationality Iran (individual) [TCO] (Linked To: AJILY SOFTWARE PROCUREMENT GROUP).

Designated pursuant to sections 1(a)(ii)(C) of E.O. 13581 for having acted or purported to act for or on behalf of, directly or indirectly, the AJILY SOFTWARE PROCUREMENT GROUP, a person whose property and interests in property are blocked pursuant to E.O. 13581.

Entities

1. ABASCIENCE TECH CO. LTD., Room 1724, Si Fang Building No. 5, Xiao Ying Road, ChaoYang District, Beijing 100101, China; 14C, Hung Shui Kiu Main Street, Yuen Long, N.T., Hong Kong; Additional Sanctions Information—Subject to Secondary Sanctions [NPWMD] [IFSR] (Linked To: SHIRAZ ELECTRONICS INDUSTRIES; Linked To: LIU, Emily).

Designated pursuant to sections 1(a)(iii) and 1(a)(iv) of E.O. 13382 for having provided, or attempted to provide, financial, material, technological, or other support for, or goods or services in support of, SHIRAZ ELECTRONICS INDUSTRIES, a person whose property and interests in property are blocked pursuant to E.O. 13382, and for being owned or controlled by EMILY LIU, a person whose property and interests in property are blocked pursuant to E.O. 13382.

2. RAYBEAM OPTRONICS CO. LTD., 10–D, Blessgo Industrial Park, Yanjiao High and New Tech Zone, Beijing 101601, China; 10–D Blessgo Industrial Park, Yanjiao Economic Development Zone, Sanhe, Hebei Province, China; Additional Sanctions Information—Subject to Secondary Sanctions [NPWMD] [IFSR] (Linked To: LIU, Emily).

Designated pursuant to section 1(a)(iv) of E.O. 13382 for being owned or controlled by EMILY LIU, a person whose property and interests in property are blocked pursuant to E.O. 13382.

3. RAYTRONIC CORPORATION, LIMITED, No. 901, Jing Shu Dong Li, Haidian Dist, Beijing 100083, China; Additional Sanctions Information—Subject to Secondary Sanctions [NPWMD] [IFSR] (Linked To: LIU, Emily).

Designated pursuant to section 1(a)(iii) of E.O. 13382 for having provided, or attempted to provide, financial, material, technological, or other support for, or goods or services in support of, EMILY LIU, a person whose property and interests in property are blocked pursuant to E.O. 13382.

4. SUNWAY TECH CO., LTD, No. 1724, Xiao Ying Rd, Si Fang Building, Chao Yang District, Beijing, China; Additional Sanctions Information—Subject to Secondary Sanctions [NPWMD] [IFSR] (Linked To: SHIRAZ ELECTRONICS INDUSTRIES; Linked To: LIU, Emily).

Designated pursuant to sections 1(a)(iii) and 1(a)(iv) of E.O. 13382 for having provided, or attempted to provide, financial, material, technological, or other support for, or goods or services in support of, SHIRAZ ELECTRONICS INDUSTRIES, a person whose property and interests in property are blocked pursuant to E.O. 13382, and for being owned or controlled by EMILY LIU, a person whose property and interests in property are blocked pursuant to E.O. 13382.

5. RAYAN ROSHD AFZAR COMPANY (a.k.a. RAYAN ROSHD COMPANY; a.k.a. ''RAYAN ROSHD''), No. 16, Barazandeh St., North Sohrevardi St., Seyed Khandan, Tehran, Iran; Number 24 Barzandeh St., North Sohrevardi Ave., Tehran, Iran; Additional Sanctions Information—Subject to Secondary Sanctions [NPWMD] [IFSR] (Linked To: ISLAMIC REVOLUTIONARY GUARD CORPS).

Designated pursuant to section 1(a)(iii) of E.O. 13382 for having provided, or attempted to provide, financial, material, technological, or other support for, or goods or services in support of, the ISLAMIC REVOLUTIONARY GUARD CORPS, a person whose property and interests in property are blocked pursuant to E.O. 13382.

6. QESHM MADKANDALOO SHIPBUILDING COOPERATIVE CO (a.k.a. MAD KANDALU COMPANY; a.k.a. MAD KANDALU SHIPBUILDING COOPERATIVE; a.k.a. MAD KANDALU SHIPBUILDING COOPERATIVE QESHM; a.k.a. MADKANDALOU COMPANY), Qeshm Island, Iran; Web site *www.madkandaloo.com;* Additional Sanctions Information—Subject to Secondary Sanctions [NPWMD] [IFSR] (Linked To: ISLAMIC REVOLUTIONARY GUARD CORPS).

Designated pursuant to section 1(a)(iii) of E.O. 13382 for having provided, or attempted to provide, financial, material, technological, or other support for, or goods or services in support of, the ISLAMIC REVOLUTIONARY GUARD CORPS, a person whose property and interests in property are blocked pursuant to E.O. 13382.

7. RAMOR GROUP (a.k.a. RAMOR DIS TICARET VE INSAAT YATIRIM ANONIM SIRKETI), Ataturk mah. 42 Ada Gardenya 7/1 Kat. 12 D.77 Atasehir, Istanbul, Turkey; 42A ADA Kat: 12, Daire: 77, No: 7/1, Gardenya Plaza, Atasehir, Istanbul 34758, Turkey; Web site *www.ramor.com.tr;* Additional Sanctions Information—Subject to Secondary Sanctions [NPWMD] [IFSR] (Linked To: TAVAN, Resit).

Designated pursuant to section 1(a)(iv) of E.O. 13382 for being owned or controlled by RESIT TAVAN, a person whose property and interests in property are blocked pursuant to E.O. 13382.

8. AJILY SOFTWARE PROCUREMENT GROUP, Iran [TCO].

Designated pursuant to sections 1(a)(ii)(A) of E.O. 13581 for being a foreign person that constitutes a significant transnational criminal organization.

9. ANDISHEH VESAL MIDDLE EAST COMPANY, No. 3, Unit 6, Daroos Building, Qanat Crossroad, Dolat St, Pasdaran Ave., Tehran, Iran [TCO] (Linked To: AJILY SOFTWARE PROCUREMENT GROUP).

Designated pursuant to sections 1(a)(ii)(C) of E.O. 13581 for having acted or purported to act for or on behalf of, directly or indirectly, the AJILY SOFTWARE PROCUREMENT GROUP, a person whose property and interests in

property are blocked pursuant to E.O. 13581.

Dated: July 18, 2017.

John E. Smith,

Director, Office of Foreign Assets Control.

[FR Doc. 2017–15364 Filed 7–20–17; 8:45 am]

BILLING CODE 4810–AL–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Information Collection; Comment Request

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Internal Revenue Service, 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 continuing information collections, as required by the Paperwork Reduction Act of 1995.

DATES: Written comments should be received on or before September 19, 2017 to be assured of consideration.

ADDRESSES: Direct all written comments to L. Brimmer, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW., Washington, DC 20224, or at *Elaine.H.Christophe@irs.gov.*

Please send separate comments for each specific information collection listed below. You must reference the information collection's title, form number, reporting or record-keeping requirement number, and OMB number (if any) in your comment. Requests for additional information, or copies of the information collection and instructions, or copies of any comments received, contact Elaine Christophe, at Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW., Washington, DC 20224, or through the Internet, at *Elaine.H.Christophe@irs.gov.*

SUPPLEMENTARY INFORMATION:

Request for Comments

The Internal Revenue Service, as part of their continuing effort to reduce paperwork and respondent burden, invite the general public and other Federal agencies to take this opportunity to comment on these continuing information collections listed below in this notice, as required by the Paperwork Reduction Act of 1995.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in our request for Office of Management and Budget (OMB) approval of the relevant information collection. All comments will become a matter of public record. Please do not include any confidential or inappropriate material in your comments.

We invite comments on: (a) Whether the collection of information is necessary for the proper performance of the agency's functions, including whether the information has practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including 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 the requested information. The IRS is seeking comments concerning the following forms, and reporting and record-keeping requirements:

1. *Title:* Claim for Refund of Excise Taxes.

OMB Number: 1545–1420.

Form Number: 8849 and Schedule 1, Schedule 2, Schedule 3, Schedule 5, Schedule 6, Schedule 8.

Abstract: The regulations allow for refunds of taxes (except income taxes) or refund, abatement, or credit or interest, penalties, and additions to tax in the event of errors or certain actions by the IRS. Form 8849 is used by taxpayers to claim refunds of excise taxes.

Current Actions: There are no significant changes to the form previously approved by OMB.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations, individuals or households, and not-for-profit institutions, farms, and Federal, state, local or tribal governments.

Estimated Number of Responses: 8,838.

Estimated Total Annual Burden Hours: 76,890.

Estimated Time per Response: 8.68 hours.

2. *Title:* Form 8944, Preparer Hardship Waiver Request; Form 8948, Preparer Explanation for Not Filing Electronically.

OMB Number: 1545–2200.

Form Numbers: 8944 and 8948.

Abstract Form 8944: A tax preparer uses Form 8944 to request a waiver from the requirement to file tax returns on magnetic media when the filing of tax returns on magnetic media would cause a hardship.

Abstract, Form 8948: A specified tax return preparer uses Form 8948 to explain which exception applies when a covered return is prepared and filed on paper.

Current Actions: There is no change in the paperwork burden previously approved by OMB. This form is being submitted for renewal purposes only.

Type of Review: Extension of a currently approved collection.

Affected Public: Businesses and other for-profit organizations.

Estimated Number of Respondents: 8,910,000.

Estimated Total Annual Burden Hours: 18,270,900.

Estimated Time per Response: 2.05 hours.

3. *Title:* Notice of Intent to Operate Under Section 501(c)(4).

OMB Number: 1545–2268.

Form Number: 8976.

Abstract: The Protecting Americans from Tax Hikes Act of 2015 (the PATH Act) section 506 to the Internal Revenue Code (Code) requires an organization described in section 501(c)(4), no later than 60 days after the organization is established, to notify the Secretary that it is operating as a section 501(c)(4) organization (the notification). Section 506(b) provides that the notification must include: (1) The name, address, and taxpayer identification number of the organization; (2) the date on which, and the State under the laws of which, the organization was organized; and (3) a statement of the purpose of the organization.

Current Actions: There are no changes being made to the collection.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations, not-for-profit institutions.

Estimated Number of Respondents: 2,500.

Estimated Time per Respondent: 45 minutes.

Estimated Total Annual Burden Hours: 1,875.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Approved: July 14, 2017.

L. Brimmer,

Senior Tax Analyst.

[FR Doc. 2017–15306 Filed 7–20–17; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection: Comment Request for Forms 945, 945–A, and, 945–X

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Internal Revenue Service, 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 information collections, as required by the Paperwork Reduction Act of 1995. The IRS is soliciting comments concerning Form 945 Annual Return of Withheld Federal Income Tax, Form 945–A Annual Record of Federal Tax Liability, and Form 945–X Adjusted Annual Return of Withheld Federal Income Tax or Claim for Refund.

DATES: Written comments should be received on or before September 19, 2017 to be assured of consideration.

ADDRESSES: Direct all written comments to L. Brimmer, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW., Washington, DC 20224. Requests for additional information or copies of the forms and instructions should be directed to Sara Covington, at Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW., Washington, DC 20224, or through the internet at *Sara.L.Covington@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Annual Return of Withheld Federal Income Tax.

OMB Number: 1545–1430.

Form Number: 945.

Abstract: Form 945 is used to report income tax withholding on non payroll payments including backup withholding and withholding on pensions, annuities, IRAs, military retirement and gambling winnings.

Form Number: 945–A.

Abstract: Form 945–A is used by employers who deposit non-payroll income tax withheld (such as from pensions and gambling) on a semiweekly schedule, or whose tax liability on any day is $100,000 or more, use Form 945–A with Form 945 or CT–1 to report their tax liability.

Form Number: 945–X.

Abstract: Form 945–X is used to correct errors made on Form 945, Annual Return of Withheld Federal Income Tax.

Current Actions: There are no changes being made to the forms approved under this collection. However, changes to the estimated number of filers (236,818 to 220,851), will result in a total burden decrease of 110,013 (1,619,603 to 1,509,590).

Type of Review: Revision of a current OMB approval.

Affected Public: Business, or other for-profit organizations, individuals, or households, not-for-profit institutions, farms, and, Federal, state, local, or tribal governments.

Estimated Number of Respondents: 220,851.

Estimated Time per Respondent: 6 hrs., 50 min.

Estimated Total Annual Burden Hours: 1,509,590.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: July 13, 2017.

L. Brimmer,

Senior Tax Analyst.

[FR Doc. 2017–15307 Filed 7–20–17; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF VETERANS AFFAIRS

Solicitation of Nominations for Appointment to the VA Prevention of Fraud, Waste, and Abuse Advisory Committee

ACTION: Notice, amended.

SUMMARY: The Department of Veterans Affairs (VA) is seeking nominations of qualified candidates to be considered for appointment to the VA Prevention of Fraud, Waste, and Abuse Advisor Committee (herein-after in this section referred to as ''the Committee'').

DATES: Nominations for membership on the Committee must be received no later than 5:00 p.m. EST on July 24, 2017.

ADDRESSES: All nominations should be sent electronically to the Advisory Committee Management Office mailbox at *vaadvisorycmte@va.gov.*

FOR FURTHER INFORMATION CONTACT: Gregory Woskow, Designated Federal Officer, Office of Finance, Department of Veterans Affairs, 810 Vermont Avenue NW., (047), Washington, DC 20420, telephone (720) 471–1235.

SUPPLEMENTARY INFORMATION: In carrying out the duties set forth, the activities of the Committee include, but are not limited to:

(1) Identifying best practices and lessons learned from private industry and other Federal agencies that VA can leverage to maximize the effectiveness and efficiency of Department-wide activities to detect and prevent fraud, waste, and abuse in VA programs at significant risk;

(2) Providing advice on leveraging cutting-edge fraud detection and prevention tools and technologies used by other Federal agencies and private industry, including the identification of ways to utilize such tools in the short-term, as well as in the future, given VA's current Financial Management Business Transformation break-thru initiative; and

(3) Providing advice on leveraging partnerships and experience to assist in maximizing the efficiency and effectiveness of VA's ''Seek to Prevent Fraud, Waste, and Abuse (STOP FWA)'' initiative, which is designed to increase activities that prevent fraud, waste, and abuse and to reduce improper payments.

Authority: The Committee is being established by the directive of the Secretary of VA, in accordance with the provisions of the Federal Advisory Committee Act (FACA), as amended, 5 U.S.C. App. 2. The Committee will provide the Secretary of Veterans Affairs with advice related to improving and enhancing VA's efforts to identify, prevent, and mitigate fraud, waste, and abuse across VA in order to improve the integrity of VA's payments and the efficiency of VA's programs and activities.

Membership Criteria and Qualifications: VA is seeking nominations for Committee membership. The Committee is composed of twelve members and several ex-officio members.

The members of the Committee are appointed by the Secretary of Veteran Affairs from the general public, from various sectors and organizations, including but not limited to:

a. Veteran-focused organizations;
b. Academic communities;
c. Health care providers;
d. Other Federal agencies;
e. Insurance;
f. Former Inspectors General;
g. Veteran Service Organizations;
h. Military service organizations;
i. Academic communities; and
j. Leaders of key stakeholder associations and organizations.

In accordance with the Committee Charter, the Secretary shall determine the number, terms of service, and pay and allowances of Committee members, except that a term of service of any such member may not exceed two years. The Secretary may reappoint any Committee member for additional terms of service.

To the extent possible, the Secretary seeks members who have diverse professional and personal qualifications including but not limited to subject matter experts in the areas described above. We ask that nominations include any relevant experience information so that VA can ensure diverse Committee membership.

Requirements for Nomination Submission

Nominations should be typed (one nomination per nominator). Nomination package should include:

(1) A letter of nomination that clearly states the name and affiliation of the nominee, the basis for the nomination (*i.e.* specific attributes which qualify the nominee for service in this capacity), and a statement from the nominee indicating the willingness to serve as a member of the Committee;

(2) The nominee's contact information, including name, mailing address, telephone numbers, and email address;

(3) The nominee's curriculum vitae; and

(4) A summary of the nominee's experience and qualifications relative to the membership considerations described above.

Individuals selected for appointment to the Committee shall be invited to serve a two-year term. Committee members will receive a stipend for attending Committee meetings, including per diem and reimbursement for eligible travel expenses incurred.

The Department makes every effort to ensure that the membership of VA Federal advisory committees is diverse in terms of points of view represented and the committee's capabilities. Appointments to this Committee shall be made without discrimination because of a person's race, color, religion, sex, sexual orientation, gender identify, national origin, age, disability, or genetic information. Nominations must state that the nominee is willing to serve as a member of the Committee and appears to have no conflict of interest that would preclude membership. An ethics review is conducted for each selected nominee.

Dated: July 18, 2017.

Jelessa M. Burney,

Federal Advisory Committee Management Officer.

[FR Doc. 2017–15337 Filed 7–20–17; 8:45 am]

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Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 410, 414, et al.

Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2018; Medicare Shared Savings Program Requirements; and Medicare Diabetes Prevention Program; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 410, 414, 424, and 425

[CMS–1676–P]

RIN 0938–AT02

Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2018; Medicare Shared Savings Program Requirements; and Medicare Diabetes Prevention Program

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This major proposed rule addresses changes to the Medicare physician fee schedule (PFS) and other Medicare Part B payment policies.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on September 11, 2017. (See the **SUPPLEMENTARY INFORMATION** section of this final rule with comment period for a list of provisions open for comment.)

ADDRESSES: In commenting, please refer to file code CMS–1676–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *www.regulations.gov.* Follow the instructions for ''submitting a comment.''

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1676–P, P.O. Box 8016, Baltimore, MD 21244–8013.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1676–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–7195 in advance to schedule your arrival with one of our staff members. Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

FOR FURTHER INFORMATION CONTACT:

Jamie Hermansen, (410) 786–2064, for issues related to the valuation of anesthesia services and any physician payment issues not identified below.

Lindsey Baldwin, (410) 786–1694, and Emily Yoder, (410) 786–1804, for issues related to telehealth services and primary care.

Roberta Epps, (410) 786–4503, for issues related to PAMA section 218(a) policy and transition from traditional X-ray imaging to digital radiography.

Isadora Gil, (410) 786–4532, for issues related to the valuation of cardiovascular services, bone marrow services, surgical respiratory services, dermatological procedures, and payment rates for nonexcepted items and services furnished by nonexcepted off-campus provider-based departments of a hospital.

Donta Henson, (410) 786–1947, for issues related to ophthalmology services.

Tourette Jackson, (410) 786–4735, for issues related to the valuation of musculoskeletal services, allergy and clinical immunology services, endocrinology services, genital surgical services, nervous system services, INR monitoring services, injections and infusions, and chemotherapy services.

Ann Marshall, (410) 786–3059, for issues related to primary care, chronic care management (CCM), and evaluation and management (E/M) services.

Geri Mondowney, (410) 786–4584, for issues related to malpractice RVUs.

Patrick Sartini, (410) 786–9252, for issues related to the valuation of imaging services and malpractice RVUs.

Michael Soracoe, (410) 786–6312, for issues related to the practice expense methodology, impacts, conversion factor, and valuation of pathology and surgical procedures.

Pamela West, (410) 786–2302, for issues related to therapy services.

Corinne Axelrod, (410) 786–5620, for issues related to rural health clinics or federally qualified health centers.

Felicia Eggleston, (410) 786–9287, for issues related to DME infusion drugs.

Rasheeda Johnson, (410) 786–3434, for issues related to initial data collection and reporting periods for the clinical laboratory fee schedule.

Edmund Kasaitis, (410) 786–0477, for issues related to biosimilars.

JoAnna Baldwin, (410) 786–7205, or Sarah Fulton, (410) 786–2749, for issues related to appropriate use criteria for advanced diagnostic imaging services.

Alesia Hovatter, (410) 786–6861, for issues related to PQRS.

Alexandra Mugge, (410) 786–4457, or Elizabeth Holland, (410) 786–1309, for issues related to the EHR incentive program.

Rabia Khan or Terri Postma, (410) 786–8084 or *ACO@cms.hhs.gov,* for issues related to the Medicare Shared Savings Program.

Kimberly Spalding Bush, (410) 786–3232, or Fiona Larbi, (410) 786–7224, for issues related to Value-based Payment Modifier and Physician Feedback Program.

Wilbert Agbenyikey, (410) 786–4399, for issues related to MACRA patient relationship categories and codes.

Carlye Burd, (410) 786–1972, or Albert Wesley, (410) 786–4204, for issues related to diabetes prevention program.

SUPPLEMENTARY INFORMATION:

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Acronyms

In addition, because of the many organizations and terms to which we refer by acronym in this final rule, we are listing these acronyms and their corresponding terms in alphabetical order below:

A1c Hemoglobin A1c
AAA Abdominal aortic aneurysms
ACO Accountable care organization
AMA American Medical Association
ASC Ambulatory surgical center
ATA American Telehealth Association
ATRA American Taxpayer Relief Act (Pub. L. 112–240)
AWV Annual wellness visit
BBA Balanced Budget Act of 1997 (Pub. L. 105–33)
BBRA [Medicare, Medicaid and State Child Health Insurance Program] Balanced Budget Refinement Act of 1999 (Pub. L. 106–113)
BLS Bureau of Labor Statistics
CAD Coronary artery disease
CAH Critical access hospital
CBSA Core-Based Statistical Area
CCM Chronic care management
CEHRT Certified EHR technology
CF Conversion factor
CG–CAHPS Clinician and Group Consumer Assessment of Healthcare Providers and Systems
CLFS Clinical Laboratory Fee Schedule
CoA Certificate of Accreditation
CoC Certificate of Compliance
CoR Certificate of Registration
CNM Certified nurse-midwife
CP Clinical psychologist
CPC Comprehensive Primary Care
CPEP Clinical Practice Expert Panel
CPT [Physicians] Current Procedural Terminology (*CPT codes, descriptions and other data only are copyright 2015 American Medical Association. All rights reserved.*)
CQM Clinical quality measure
CSW Clinical social worker
CT Computed tomography
CW Certificate of Waiver
CY Calendar year
DFAR Defense Federal Acquisition Regulations
DHS Designated health services
DM Diabetes mellitus
DSMT Diabetes self-management training
eCQM Electronic clinical quality measures
ED Emergency Department
EHR Electronic health record
E/M Evaluation and management
EMT Emergency Medical Technician
EP Eligible professional
eRx Electronic prescribing
ESRD End-stage renal disease
FAR Federal Acquisition Regulations
FDA Food and Drug Administration
FFS Fee-for-service
FQHC Federally qualified health center
FR Federal Register
FSHCAA Federally Supported Health Centers Assistance Act
GAF Geographic adjustment factor
GAO Government Accountability Office
GPCI Geographic practice cost index
GPO Group purchasing organization
GPRO Group practice reporting option
GTR Genetic Testing Registry
HCPCS Healthcare Common Procedure Coding System
HHS [Department of] Health and Human Services
HOPD Hospital outpatient department
HPSA Health professional shortage area
IDTF Independent diagnostic testing facility
IPPE Initial preventive physical exam
IPPS Inpatient Prospective Payment System
IQR Inpatient Quality Reporting
ISO Insurance service office
IT Information technology
IWPUT Intensity of work per unit of time
LCD Local coverage determination
MA Medicare Advantage
MAC Medicare Administrative Contractor
MACRA Medicare Access and CHIP Reauthorization Act of 2015 (Pub. L. 114–10)
MAP Measure Applications Partnership
MAPCP Multi-payer Advanced Primary Care Practice
MAV Measure application validity [process]
MCP Monthly capitation payment
MedPAC Medicare Payment Advisory Commission
MEI Medicare Economic Index
MFP Multi-Factor Productivity
MIPPA Medicare Improvements for Patients and Providers Act (Pub. L. 110–275)
MMA Medicare Prescription Drug, Improvement and Modernization Act of 2003 (Pub. L. 108–173, enacted on December 8, 2003)
MP Malpractice
MPPR Multiple procedure payment reduction
MRA Magnetic resonance angiography
MRI Magnetic resonance imaging
MSA Metropolitan Statistical Areas
MSPB Medicare Spending per Beneficiary
MU Meaningful use
NCD National coverage determination
NCQDIS National Coalition of Quality Diagnostic Imaging Services
NP Nurse practitioner
NPI National Provider Identifier
NPP Nonphysician practitioner
NQS National Quality Strategy
OACT CMS's Office of the Actuary
OBRA '89 Omnibus Budget Reconciliation Act of 1989 (Pub. L. 101–239)
OBRA '90 Omnibus Budget Reconciliation Act of 1990 (Pub. L. 101–508)
OES Occupational Employment Statistics
OMB Office of Management and Budget
OPPS Outpatient prospective payment system
OT Occupational therapy
PA Physician assistant
PAMA Protecting Access to Medicare Act of 2014 (Pub. L. 113–93)
PAMPA Patient Access and Medicare Protection Act (Pub. L. 114–115)
PC Professional component
PCIP Primary Care Incentive Payment
PE Practice expense
PE/HR Practice expense per hour
PEAC Practice Expense Advisory Committee
PECOS Provider Enrollment, Chain, and Ownership System
PFS Physician Fee Schedule
PLI Professional Liability Insurance
PMA Premarket approval
PPM Provider-Performed Microscopy
PQRS Physician Quality Reporting System
PPIS Physician Practice Expense Information Survey
PPS Prospective Payment System
PT Physical therapy
PT Proficiency Testing
PT/INR Prothrombin Time/International Normalized Ratio
PY Performance year
QA Quality Assessment
QC Quality Control
QCDR Qualified clinical data registry
QRUR Quality and Resources Use Report
RBRVS Resource-based relative value scale
RFA Regulatory Flexibility Act
RHC Rural health clinic
RIA Regulatory impact analysis
RUC American Medical Association/ Specialty Society Relative Value Scale Update Committee
RUCA Rural Urban Commuting Area
RVU Relative value unit
SBA Small Business Administration
SGR Sustainable growth rate
SIM State Innovation Model
SLP Speech-language pathology
SMS Socioeconomic Monitoring System
SNF Skilled nursing facility
TAP Technical Advisory Panel
TC Technical component
TIN Tax identification number
TCM Transitional Care Management
UAF Update adjustment factor
UPIN Unique Physician Identification Number
USPSTF United States Preventive Services Task Force
VBP Value-based purchasing
VM Value-Based Payment Modifier

Addenda Available Only Through the Internet on the CMS Web site

The PFS Addenda along with other supporting documents and tables referenced in this proposed rule are available on the CMS Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.* Click on the link on the left side of the screen titled, ''PFS Federal Regulations Notices'' for a chronological list of PFS **Federal Register** and other related documents. For the CY 2018 PFS Proposed Rule, refer to item CMS–1676–P. Readers with questions related to accessing any of the Addenda or other supporting documents referenced in this proposed rule and posted on the CMS Web site identified above should contact Jamie Hermansen at (410) 786–2064.

CPT (Current Procedural Terminology) Copyright Notice

Throughout this proposed rule, we use CPT codes and descriptions to refer to a variety of services. We note that CPT codes and descriptions are copyright 2016 American Medical Association. All Rights Reserved. CPT is a registered trademark of the American Medical Association (AMA). Applicable Federal Acquisition Regulations (FAR) and Defense Federal Acquisition Regulations (DFAR) apply.

I. Executive Summary

A. Purpose

This major proposed rule proposes to revise payment polices under the Medicare PFS and make other policy changes related to Medicare Part B payment, applicable to services furnished in CY 2018. In addition, this proposed rule includes proposals related to payment policy changes that are addressed in section III. of this proposed rule.

1. Summary of the Major Provisions

The statute requires us to establish payments under the PFS based on national uniform relative value units (RVUs) that account for the relative resources used in furnishing a service. The statute requires that RVUs be established for three categories of resources: Work, practice expense (PE); and malpractice (MP) expense; and, that we establish by regulation each year's payment amounts for all physicians' services paid under the PFS, incorporating geographic adjustments to reflect the variations in the costs of furnishing services in different geographic areas. In this major proposed rule, we are proposing to establish RVUs for CY 2018 for the PFS, and other Medicare Part B payment policies, to ensure that our payment systems are updated to reflect changes in medical practice and the relative value of services, as well as changes in the statute. In addition, this proposed rule includes discussions and proposals regarding:

- Potentially Misvalued Codes.
- Telehealth Services.
- Establishing Values for New, Revised, and Misvalued Codes.
- Establishing Payment Rates under the PFS for Nonexcepted Items and Services Furnished by Nonexcepted Off-Campus Provider-Based Departments of a Hospital.
- Evaluation & Management (E/M) Guidelines and Care Management Services.
- Care Coordination Services and Payment for Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs).
- Payment for DME Infusion Drugs.
- Solicitation of Public Comments on Initial Data Collection and Reporting Periods for Clinical Laboratory Fee Schedule.
- Solicitation of Public Comments on Payment for Biosimilar Biological Products under Section 1847A of the Act.
- Appropriate Use Criteria for Advanced Diagnostic Imaging Services.
- PQRS Criteria for Satisfactory Reporting for Individual EPs and Group Practices for the 2018 PQRS Payment Adjustment.
- Medicare EHR Incentive Program.
- Medicare Shared Savings Program.
- Value-Based Payment Modifier and the Physician Feedback Program.
- MACRA Patient Relationship Categories and Codes.
- Medicare Diabetes Prevention Program.

2. Summary of Costs and Benefits

We have determined that this major proposed rule is economically significant. For a detailed discussion of the economic impacts, see section VI. of this proposed rule.

II. Provisions of the Proposed Rule for PFS

A. Background

Since January 1, 1992, Medicare has paid for physicians' services under section 1848 of the Act, ''Payment for Physicians' Services.'' The PFS relies on national relative values that are established for work, PE, and MP, which are adjusted for geographic cost variations. These values are multiplied by a conversion factor (CF) to convert the RVUs into payment rates. The concepts and methodology underlying the PFS were enacted as part of the Omnibus Budget Reconciliation Act of 1989 (Pub. L. 101–239, enacted on December 19, 1989) (OBRA '89), and the Omnibus Budget Reconciliation Act of 1990 (Pub. L. 101–508, enacted on November 5, 1990) (OBRA '90). The final rule published on November 25, 1991 (56 FR 59502) set forth the first fee schedule used for payment for physicians' services.

We note that throughout this major proposed rule, unless otherwise noted, the term ''practitioner'' is used to describe both physicians and nonphysician practitioners (NPPs) who are permitted to bill Medicare under the PFS for services furnished to Medicare beneficiaries.

1. Development of the Relative Values

a. Work RVUs

The work RVUs established for the initial fee schedule, which was implemented on January 1, 1992, were developed with extensive input from the physician community. A research team at the Harvard School of Public Health developed the original work RVUs for most codes under a cooperative agreement with the Department of Health and Human Services (HHS). In constructing the code-specific vignettes used in determining the original physician work RVUs, Harvard worked with panels of experts, both inside and outside the federal government, and obtained input from numerous physician specialty groups.

As specified in section 1848(c)(1)(A) of the Act, the work component of physicians' services means the portion of the resources used in furnishing the service that reflects physician time and intensity. We establish work RVUs for new, revised and potentially misvalued codes based on our review of information that generally includes, but is not limited to, recommendations received from the American Medical Association/Specialty Society Relative Value Scale Update Committee (RUC), the Health Care Professionals Advisory Committee (HCPAC), the Medicare Payment Advisory Commission (MedPAC), and other public commenters; medical literature and comparative databases; as well as a comparison of the work for other codes within the Medicare PFS, and consultation with other physicians and health care professionals within CMS and the federal government. We also assess the methodology and data used to develop the recommendations

submitted to us by the RUC and other public commenters, and the rationale for their recommendations. In the CY 2011 PFS final rule with comment period (75 FR 73328 through 73329), we discussed a variety of methodologies and approaches used to develop work RVUs, including survey data, building blocks, crosswalk to key reference or similar codes, and magnitude estimation. More information on these issues is available in that rule.

b. Practice Expense RVUs

Initially, only the work RVUs were resource-based, and the PE and MP RVUs were based on average allowable charges. Section 121 of the Social Security Act Amendments of 1994 (Pub. L. 103–432, enacted on October 31, 1994), amended section 1848(c)(2)(C)(ii) of the Act and required us to develop resource-based PE RVUs for each physicians' service beginning in 1998. We were required to consider general categories of expenses (such as office rent and wages of personnel, but excluding malpractice expenses) comprising PEs. The PE RVUs continue to represent the portion of these resources involved in furnishing PFS services.

Originally, the resource-based method was to be used beginning in 1998, but section 4505(a) of the Balanced Budget Act of 1997 (Pub. L. 105–33, enacted on August 5, 1997) (BBA) delayed implementation of the resource-based PE RVU system until January 1, 1999. In addition, section 4505(b) of the BBA provided for a 4-year transition period from the charge-based PE RVUs to the resource-based PE RVUs.

We established the resource-based PE RVUs for each physicians' service in a final rule, published on November 2, 1998 (63 FR 58814), effective for services furnished in CY 1999. Based on the requirement to transition to a resource-based system for PE over a 4-year period, payment rates were not fully based upon resource-based PE RVUs until CY 2002. This resource-based system was based on two significant sources of actual PE data: The Clinical Practice Expert Panel (CPEP) data; and the AMA's Socioeconomic Monitoring System (SMS) data. These data sources are described in greater detail in the CY 2012 final rule with comment period (76 FR 73033).

Separate PE RVUs are established for services furnished in facility settings, such as a hospital outpatient department (HOPD) or an ambulatory surgical center (ASC), and in nonfacility settings, such as a physician's office. The nonfacility RVUs reflect all of the direct and indirect PEs involved in furnishing a service described by a particular HCPCS code. The difference, if any, in these PE RVUs generally results in a higher payment in the nonfacility setting because in the facility settings some costs are borne by the facility. Medicare's payment to the facility (such as the outpatient prospective payment system (OPPS) payment to the hospital outpatient department (HOPD)) would reflect costs typically incurred by the facility. Thus, payment associated with those facility resources is not made under the PFS.

Section 212 of the Balanced Budget Refinement Act of 1999 (Pub. L. 106–113, enacted on November 29, 1999) (BBRA) directed the Secretary of Health and Human Services (the Secretary) to establish a process under which we accept and use, to the maximum extent practicable and consistent with sound data practices, data collected or developed by entities and organizations to supplement the data we normally collect in determining the PE component. On May 3, 2000, we published the interim final rule (65 FR 25664) that set forth the criteria for the submission of these supplemental PE survey data. The criteria were modified in response to comments received, and published in the **Federal Register** (65 FR 65376) as part of a November 1, 2000 final rule. The PFS final rules published in 2001 and 2003, respectively, (66 FR 55246 and 68 FR 63196) extended the period during which we would accept these supplemental data through March 1, 2005.

In the CY 2007 PFS final rule with comment period (71 FR 69624), we revised the methodology for calculating direct PE RVUs from the top-down to the bottom-up methodology beginning in CY 2007. We adopted a 4-year transition to the new PE RVUs. This transition was completed for CY 2010. In the CY 2010 PFS final rule with comment period, we updated the practice expense per hour (PE/HR) data that are used in the calculation of PE RVUs for most specialties (74 FR 61749). In CY 2010, we began a 4-year transition to the new PE RVUs using the updated PE/HR data, which was completed for CY 2013.

c. Malpractice RVUs

Section 4505(f) of the BBA amended section 1848(c) of the Act to require that we implement resource-based MP RVUs for services furnished on or after CY 2000. The resource-based MP RVUs were implemented in the PFS final rule with comment period published November 2, 1999 (64 FR 59380). The MP RVUs are based on commercial and physician-owned insurers' malpractice insurance premium data from all the states, the District of Columbia, and Puerto Rico. For more information on MP RVUs, see section II.C. of this proposed rule.

d. Refinements to the RVUs

Section 1848(c)(2)(B)(i) of the Act requires that we review RVUs no less often than every 5 years. Prior to CY 2013, we conducted periodic reviews of work RVUs and PE RVUs independently. We completed five-year reviews of work RVUs that were effective for calendar years 1997, 2002, 2007, and 2012.

Although refinements to the direct PE inputs initially relied heavily on input from the RUC Practice Expense Advisory Committee (PEAC), the shifts to the bottom-up PE methodology in CY 2007 and to the use of the updated PE/HR data in CY 2010 have resulted in significant refinements to the PE RVUs in recent years.

In the CY 2012 PFS final rule with comment period (76 FR 73057), we finalized a proposal to consolidate reviews of work and PE RVUs under section 1848(c)(2)(B) of the Act and reviews of potentially misvalued codes under section 1848(c)(2)(K) of the Act into one annual process.

In addition to the 5-year reviews, beginning for CY 2009, CMS and the RUC have identified and reviewed a number of potentially misvalued codes on an annual basis based on various identification screens. This annual review of work and PE RVUs for potentially misvalued codes was supplemented by the amendments to section 1848 of the Act, as enacted by section 3134 of the Affordable Care Act, that require the agency to periodically identify, review and adjust values for potentially misvalued codes.

e. Application of Budget Neutrality to Adjustments of RVUs

As described in section VI.C. of this proposed rule, in accordance with section 1848(c)(2)(B)(ii)(II) of the Act, if revisions to the RVUs cause expenditures for the year to change by more than $20 million, we make adjustments to ensure that expenditures do not increase or decrease by more than $20 million.

2. Calculation of Payments Based on RVUs

To calculate the payment for each service, the components of the fee schedule (work, PE, and MP RVUs) are adjusted by geographic practice cost indices (GPCIs) to reflect the variations in the costs of furnishing the services.

The GPCIs reflect the relative costs of work, PE, and MP in an area compared to the national average costs for each component.

RVUs are converted to dollar amounts through the application of a conversion factor (CF), which is calculated based on a statutory formula by CMS's Office of the Actuary (OACT). The formula for calculating the Medicare PFS payment amount for a given service and fee schedule area can be expressed as:

Payment = [(RVU work × GPCI work) + (RVU PE × GPCI PE) + (RVU MP × GPCI MP)] × CF

3. Separate Fee Schedule Methodology for Anesthesia Services

Section 1848(b)(2)(B) of the Act specifies that the fee schedule amounts for anesthesia services are to be based on a uniform relative value guide, with appropriate adjustment of an anesthesia conversion factor, in a manner to ensure that fee schedule amounts for anesthesia services are consistent with those for other services of comparable value. Therefore, there is a separate fee schedule methodology for anesthesia services. Specifically, we establish a separate conversion factor for anesthesia services and we utilize the uniform relative value guide, or base units, as well as time units, to calculate the fee schedule amounts for anesthesia services. Since anesthesia services are not valued using RVUs, a separate methodology for locality adjustments is also necessary. This involves an adjustment to the national anesthesia CF for each payment locality.

B. Determination of Proposed Practice Expense (PE) Relative Value Units (RVUs)

1. Overview

Practice expense (PE) is the portion of the resources used in furnishing a service that reflects the general categories of physician and practitioner expenses, such as office rent and personnel wages, but excluding malpractice expenses, as specified in section 1848(c)(1)(B) of the Act. As required by section 1848(c)(2)(C)(ii) of the Act, we use a resource-based system for determining PE RVUs for each physicians' service. We develop PE RVUs by considering the direct and indirect practice resources involved in furnishing each service. Direct expense categories include clinical labor, medical supplies, and medical equipment. Indirect expenses include administrative labor, office expense, and all other expenses. The sections that follow provide more detailed information about the methodology for translating the resources involved in furnishing each service into service-specific PE RVUs. We refer readers to the CY 2010 PFS final rule with comment period (74 FR 61743 through 61748) for a more detailed explanation of the PE methodology.

2. Practice Expense Methodology

a. Direct Practice Expense

We determine the direct PE for a specific service by adding the costs of the direct resources (that is, the clinical staff, medical supplies, and medical equipment) typically involved with furnishing that service. The costs of the resources are calculated using the refined direct PE inputs assigned to each CPT code in our PE database, which are generally based on our review of recommendations received from the RUC and those provided in response to public comment periods. For a detailed explanation of the direct PE methodology, including examples, we refer readers to the 5 Year Review of Work Relative Value Units under the PFS and Proposed Changes to the Practice Expense Methodology proposed notice (71 FR 37242) and the CY 2007 PFS final rule with comment period (71 FR 69629).

b. Indirect Practice Expense per Hour Data

We use survey data on indirect PEs incurred per hour worked in developing the indirect portion of the PE RVUs. Prior to CY 2010, we primarily used the practice expense per hour (PE/HR) by specialty that was obtained from the AMA's Socioeconomic Monitoring Surveys (SMS). The AMA administered a new survey in CY 2007 and CY 2008, the Physician Practice Expense Information Survey (PPIS). The PPIS is a multispecialty, nationally representative, PE survey of both physicians and nonphysician practitioners (NPPs) paid under the PFS using a survey instrument and methods highly consistent with those used for the SMS and the supplemental surveys. The PPIS gathered information from 3,656 respondents across 51 physician specialty and health care professional groups. We believe the PPIS is the most comprehensive source of PE survey information available. We used the PPIS data to update the PE/HR data for the CY 2010 PFS for almost all of the Medicare-recognized specialties that participated in the survey.

When we began using the PPIS data in CY 2010, we did not change the PE RVU methodology itself or the manner in which the PE/HR data are used in that methodology. We only updated the PE/HR data based on the new survey. Furthermore, as we explained in the CY 2010 PFS final rule with comment period (74 FR 61751), because of the magnitude of payment reductions for some specialties resulting from the use of the PPIS data, we transitioned its use over a 4-year period from the previous PE RVUs to the PE RVUs developed using the new PPIS data. As provided in the CY 2010 PFS final rule with comment period (74 FR 61751), the transition to the PPIS data was complete for CY 2013. Therefore, PE RVUs from CY 2013 forward are developed based entirely on the PPIS data, except as noted in this section.

Section 1848(c)(2)(H)(i) of the Act requires us to use the medical oncology supplemental survey data submitted in 2003 for oncology drug administration services. Therefore, the PE/HR for medical oncology, hematology, and hematology/oncology reflects the continued use of these supplemental survey data.

Supplemental survey data on independent labs from the College of American Pathologists were implemented for payments beginning in CY 2005. Supplemental survey data from the National Coalition of Quality Diagnostic Imaging Services (NCQDIS), representing independent diagnostic testing facilities (IDTFs), were blended with supplementary survey data from the American College of Radiology (ACR) and implemented for payments beginning in CY 2007. Neither IDTFs, nor independent labs, participated in the PPIS. Therefore, we continue to use the PE/HR that was developed from their supplemental survey data.

Consistent with our past practice, the previous indirect PE/HR values from the supplemental surveys for these specialties were updated to CY 2006 using the Medicare Economic Index (MEI) to put them on a comparable basis with the PPIS data.

We also do not use the PPIS data for reproductive endocrinology and spine surgery since these specialties currently are not separately recognized by Medicare, nor do we have a method to blend the PPIS data with Medicare-recognized specialty data.

Previously, we established PE/HR values for various specialties without SMS or supplemental survey data by crosswalking them to other similar specialties to estimate a proxy PE/HR. For specialties that were part of the PPIS for which we previously used a crosswalked PE/HR, we instead used the PPIS-based PE/HR. We use crosswalks for specialties that did not participate in the PPIS. These crosswalks have been generally established through notice and

comment rulemaking and are available in the file called ''CY 2018 PFS Proposed Rule PE/HR'' on the CMS Web site under downloads for the CY 2018 PFS proposed rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.*

c. Allocation of PE to Services

To establish PE RVUs for specific services, it is necessary to establish the direct and indirect PE associated with each service.

(1) Direct Costs

The relative relationship between the direct cost portions of the PE RVUs for any two services is determined by the relative relationship between the sum of the direct cost resources (that is, the clinical staff, medical supplies, and medical equipment) typically involved with furnishing each of the services. The costs of these resources are calculated from the refined direct PE inputs in our PE database. For example, if one service has a direct cost sum of $400 from our PE database and another service has a direct cost sum of $200, the direct portion of the PE RVUs of the first service would be twice as much as the direct portion of the PE RVUs for the second service.

(2) Indirect Costs

We allocate the indirect costs to the code level on the basis of the direct costs specifically associated with a code and the greater of either the clinical labor costs or the work RVUs. We also incorporate the survey data described earlier in the PE/HR discussion (see section II.B.2.b of this proposed rule). The general approach to developing the indirect portion of the PE RVUs is as follows:

- For a given service, we use the direct portion of the PE RVUs calculated as previously described and the average percentage that direct costs represent of total costs (based on survey data) across the specialties that furnish the service to determine an initial indirect allocator. That is, the initial indirect allocator is calculated so that the direct costs equal the average percentage of direct costs of those specialties furnishing the service. For example, if the direct portion of the PE RVUs for a given service is 2.00 and direct costs, on average, represent 25 percent of total costs for the specialties that furnish the service, the initial indirect allocator would be calculated so that it equals 75 percent of the total PE RVUs. Thus, in this example, the initial indirect allocator would equal 6.00, resulting in a total PE RVU of 8.00 (2.00 is 25 percent of 8.00 and 6.00 is 75 percent of 8.00).
- Next, we add the greater of the work RVUs or clinical labor portion of the direct portion of the PE RVUs to this initial indirect allocator. In our example, if this service had a work RVU of 4.00 and the clinical labor portion of the direct PE RVU was 1.50, we would add 4.00 (since the 4.00 work RVUs are greater than the 1.50 clinical labor portion) to the initial indirect allocator of 6.00 to get an indirect allocator of 10.00. In the absence of any further use of the survey data, the relative relationship between the indirect cost portions of the PE RVUs for any two services would be determined by the relative relationship between these indirect cost allocators. For example, if one service had an indirect cost allocator of 10.00 and another service had an indirect cost allocator of 5.00, the indirect portion of the PE RVUs of the first service would be twice as great as the indirect portion of the PE RVUs for the second service.
- Next, we incorporated the specialty-specific indirect PE/HR data into the calculation. In our example, if, based on the survey data, the average indirect cost of the specialties furnishing the first service with an allocator of 10.00 was half of the average indirect cost of the specialties furnishing the second service with an indirect allocator of 5.00, the indirect portion of the PE RVUs of the first service would be equal to that of the second service.

(3) Facility and Nonfacility Costs

For procedures that can be furnished in a physician's office, as well as in a facility setting, where Medicare makes a separate payment to the facility for its costs in furnishing a service, we establish two PE RVUs: Facility, and nonfacility. The methodology for calculating PE RVUs is the same for both the facility and nonfacility RVUs, but is applied independently to yield two separate PE RVUs. In calculating the PE RVUs for services furnished in a facility, we do not include resources that would generally not be provided by physicians when furnishing the service. For this reason, the facility PE RVUs are generally lower than the nonfacility PE RVUs.

(4) Services With Technical Components and Professional Components

Diagnostic services are generally comprised of two components: A professional component (PC) and a technical component (TC). The PC and TC may be furnished independently or by different providers, or they may be furnished together as a global service. When services have separately billable PC and TC components, the payment for the global service equals the sum of the payment for the TC and PC. To achieve this, we use a weighted average of the ratio of indirect to direct costs across all the specialties that furnish the global service, TCs, and PCs; that is, we apply the same weighted average indirect percentage factor to allocate indirect expenses to the global service, PCs, and TCs for a service. (The direct PE RVUs for the TC and PC sum to the global.)

(5) PE RVU Methodology

For a more detailed description of the PE RVU methodology, we refer readers to the CY 2010 PFS final rule with comment period (74 FR 61745 through 61746). We also direct interested readers to the file called ''Calculation of PE RVUs under Methodology for Selected Codes'' which is available on our Web site under downloads for the CY 2018 PFS proposed rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.* This file contains a table that illustrates the calculation of PE RVUs as described in this proposed rule for individual codes.

(a) Setup File

First, we create a setup file for the PE methodology. The setup file contains the direct cost inputs, the utilization for each procedure code at the specialty and facility/nonfacility place of service level, and the specialty-specific PE/HR data calculated from the surveys.

(b) Calculate the Direct Cost PE RVUs

Sum the costs of each direct input.

Step 1: Sum the direct costs of the inputs for each service.

Step 2: Calculate the aggregate pool of direct PE costs for the current year. We set the aggregate pool of PE costs equal to the product of the ratio of the current aggregate PE RVUs to current aggregate work RVUs and the proposed aggregate work RVUs.

Step 3: Calculate the aggregate pool of direct PE costs for use in ratesetting. This is the product of the aggregate direct costs for all services from Step 1 and the utilization data for that service.

Step 4: Using the results of Step 2 and Step 3, use the conversion factor to calculate a direct PE scaling adjustment to ensure that the aggregate pool of direct PE costs calculated in Step 3 does not vary from the aggregate pool of direct PE costs for the current year. Apply the scaling adjustment to the direct costs for each service (as calculated in Step 1).

Step 5: Convert the results of Step 4 to a RVU scale for each service. To do this, divide the results of Step 4 by the conversion factor (CF). Note that the actual value of the CF used in this calculation does not influence the final direct cost PE RVUs as long as the same CF is used in Step 4 and Step 5. Different CFs would result in different direct PE scaling adjustments, but this has no effect on the final direct cost PE RVUs since changes in the CFs and changes in the associated direct scaling adjustments offset one another.

(c) Create the Indirect Cost PE RVUs

Create indirect allocators.

Step 6: Based on the survey data, calculate direct and indirect PE percentages for each physician specialty.

Step 7: Calculate direct and indirect PE percentages at the service level by taking a weighted average of the results of Step 6 for the specialties that furnish the service. Note that for services with TCs and PCs, the direct and indirect percentages for a given service do not vary by the PC, TC, and global service.

We generally use an average of the 3 most recent years of available Medicare claims data to determine the specialty mix assigned to each code. Prior to implementing that policy, we used the most recent year of available claims data to determine the specialty mix assigned to each code.

Under either of these approaches, codes with low Medicare service volume require special attention since billing or enrollment irregularities for a given year can result in significant changes in specialty mix assignment. Prior to adopting the 3-year average of data, for low-volume services (fewer than 100 Medicare allowed services), we assigned the values associated with the specialty that most frequently reported the service in the most recent claims data (dominant specialty). For some time, stakeholders, including the RUC, have requested that we use a recommended ''expected'' specialty for all low volume services instead of the information contained in the claims data. Currently, in the development of PE RVUs we use ''expected specialty'' overrides for only several dozen services based on several code-specific policies we established in prior rulemaking. As we stated in the CY 2016 final rule with comment period (80 FR 70894), we hoped that the 3-year average would mitigate the need to use dominant or expected specialty instead of the specialty identified using claims data. Because we incorporated CY 2015 claims data for use in the CY 2017 proposed rates, we believe that the finalized PE RVUs associated with the CY 2017 PFS final rule provided a first opportunity to determine whether service-level overrides of claims data are necessary.

Although we believe that the use of the 3-year average of claims data to determine specialty mix has led to an improvement in the stability of PE and MP RVUs from year to year, after reviewing the RVUs for low volume services, we continue to see possible distortions and wide variability from year to year in PE and MP RVUs for low volume services. Several stakeholders have suggested that CMS implement service-level overrides based on the expected specialty in order to determine the specialty mix for these low volume procedures. The RUC previously supplied us with a list of nearly 2,000 lower volume codes and their suggested specialty overrides. After reviewing the finalized PE RVUs for the CY 2017 PFS final rule, we agree that the use of service-level overrides for low volume services would help mitigate annual fluctuations and provide greater stability in the valuation of these services. While the use of the 3-year average of claims data to determine specialty mix has helped to mitigate some of the year-to-year variability for low volume services, it has not fully mitigated what appear to be anomalies for many of these lower volume codes.

We are, therefore, proposing to use the most recent year of claims data to determine which codes are low volume for the coming year (those that have fewer than 100 allowed services in the Medicare claims data). For codes that fall into this category, instead of assigning specialty mix based on the specialties of the practitioners reporting the services in the claims data, we are proposing to instead use the expected specialty that we identify on a list. For CY 2018, we are proposing to use a list that was developed based on our medical review of the list most recently recommended by the RUC, in addition to our own proposed expected specialty for certain other low-volume codes for which we have historically used expected specialty assignments. We would display this list as part of the annual set of data files we make available as part of notice and comment rulemaking. We propose to consider recommendations from the RUC and other stakeholders on changes to this list on an annual basis.

We are also proposing to apply these service-level overrides for both PE and MP, rather than one or the other category. We believe that this would simplify the implementation of service-level overrides for PE and MP, and would also address stakeholder concerns about the year-to-year variability for low volume services. We are soliciting public comment on the proposal to use service-level overrides to determine the specialty mix for low volume procedures, as well as on the proposed list of expected specialty overrides itself, which is largely based on the recommendations submitted by the RUC last year. The proposed list of expected specialty assignments for individual low volume services is available on our Web site under downloads for the CY 2018 PFS proposed rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.* Services for which the specialty is automatically assigned based on previously finalized policies under our established methodology (for example, ''always therapy'' services) would be unaffected by this proposal.

Step 8: Calculate the service level allocators for the indirect PEs based on the percentages calculated in Step 7. The indirect PEs are allocated based on the three components: the direct PE RVUs; the clinical labor PE RVUs; and the work RVUs.

For most services the indirect allocator is: indirect PE percentage * (direct PE RVUs/direct percentage) + work RVUs.

There are two situations where this formula is modified:

- If the service is a global service (that is, a service with global, professional, and technical components), then the indirect PE allocator is: indirect percentage (direct PE RVUs/direct percentage) + clinical labor PE RVUs + work RVUs.
- If the clinical labor PE RVUs exceed the work RVUs (and the service is not a global service), then the indirect allocator is: indirect PE percentage (direct PE RVUs/direct percentage) + clinical labor PE RVUs.

(*Note:* For global services, the indirect PE allocator is based on both the work RVUs and the clinical labor PE RVUs. We do this to recognize that, for the PC service, indirect PEs would be allocated using the work RVUs, and for the TC service, indirect PEs would be allocated using the direct PE RVUs and the clinical labor PE RVUs. This also allows the global component RVUs to equal the sum of the PC and TC RVUs.)

For presentation purposes, in the examples in the download file called ''Calculation of PE RVUs under Methodology for Selected Codes'', the formulas were divided into two parts for each service.

• The first part does not vary by service and is the indirect percentage (direct PE RVUs/direct percentage).

• The second part is either the work RVU, clinical labor PE RVU, or both depending on whether the service is a global service and whether the clinical PE RVUs exceed the work RVUs (as described earlier in this step).

Apply a scaling adjustment to the indirect allocators.

Step 9: Calculate the current aggregate pool of indirect PE RVUs by multiplying the result of Step 8 by the average indirect PE percentage from the survey data.

Step 10: Calculate an aggregate pool of indirect PE RVUs for all PFS services by adding the product of the indirect PE allocators for a service from Step 8 and the utilization data for that service.

Step 11: Using the results of Step 9 and Step 10, calculate an indirect PE adjustment so that the aggregate indirect allocation does not exceed the available aggregate indirect PE RVUs and apply it to indirect allocators calculated in Step 8.

Calculate the indirect practice cost index.

Step 12: Using the results of Step 11, calculate aggregate pools of specialty-specific adjusted indirect PE allocators for all PFS services for a specialty by adding the product of the adjusted indirect PE allocator for each service and the utilization data for that service.

Step 13: Using the specialty-specific indirect PE/HR data, calculate specialty-specific aggregate pools of indirect PE for all PFS services for that specialty by adding the product of the indirect PE/HR for the specialty, the work time for the service, and the specialty's utilization for the service across all services furnished by the specialty.

Step 14: Using the results of Step 12 and Step 13, calculate the specialty-specific indirect PE scaling factors.

Step 15: Using the results of Step 14, calculate an indirect practice cost index at the specialty level by dividing each specialty-specific indirect scaling factor by the average indirect scaling factor for the entire PFS.

Step 16: Calculate the indirect practice cost index at the service level to ensure the capture of all indirect costs. Calculate a weighted average of the practice cost index values for the specialties that furnish the service. (Note: For services with TCs and PCs, we calculate the indirect practice cost index across the global service, PCs, and TCs. Under this method, the indirect practice cost index for a given service (for example, echocardiogram) does not vary by the PC, TC, and global service.)

Step 17: Apply the service level indirect practice cost index calculated in Step 16 to the service level adjusted indirect allocators calculated in Step 11 to get the indirect PE RVUs.

(d) Calculate the Final PE RVUs

Step 18: Add the direct PE RVUs from Step 5 to the indirect PE RVUs from Step 17 and apply the final PE budget neutrality (BN) adjustment. The final PE BN adjustment is calculated by comparing the sum of steps 5 and 17 to the proposed aggregate work RVUs scaled by the ratio of current aggregate PE and work RVUs. This adjustment ensures that all PE RVUs in the PFS account for the fact that certain specialties are excluded from the calculation of PE RVUs but included in maintaining overall PFS budget neutrality. (See ''Specialties excluded from ratesetting calculation'' later in this proposed rule.)

Step 19: Apply the phase-in of significant RVU reductions and its associated adjustment. Section 1848(c)(7) of the Act specifies that for services that are not new or revised codes, if the total RVUs for a service for a year would otherwise be decreased by an estimated 20 percent or more as compared to the total RVUs for the previous year, the applicable adjustments in work, PE, and MP RVUs shall be phased in over a 2-year period. In implementing the phase-in, we consider a 19 percent reduction as the maximum 1-year reduction for any service not described by a new or revised code. This approach limits the year one reduction for the service to the maximum allowed amount (that is, 19 percent), and then phases in the remainder of the reduction. To comply with section 1848(c)(7) of the Act, we adjust the PE RVUs to ensure that the total RVUs for all services that are not new or revised codes decrease by no more than 19 percent, and then apply a relativity adjustment to ensure that the total pool of aggregate PE RVUs remains relative to the pool of work and MP RVUs. For a more detailed description of the methodology for the phase-in of significant RVU changes, we refer readers to the CY 2016 PFS final rule with comment period (80 FR 70927 through 70931).

(e) Setup File Information

• *Specialties excluded from ratesetting calculation:* For the purposes of calculating the PE RVUs, we exclude certain specialties, such as certain NPPs paid at a percentage of the PFS and low-volume specialties, from the calculation. These specialties are included for the purposes of calculating the BN adjustment. They are displayed in Table 1.

TABLE 1—SPECIALTIES EXCLUDED FROM RATESETTING CALCULATION

Specialty code	Specialty description
49	Ambulatory surgical center.
50	Nurse practitioner.
51	Medical supply company with certified orthotist.
52	Medical supply company with certified prosthetist.
53	Medical supply company with certified prosthetist-orthotist.
54	Medical supply company not included in 51, 52, or 53.
55	Individual certified orthotist.
56	Individual certified prosthetist.
57	Individual certified prosthetist-orthotist.
58	Medical supply company with registered pharmacist.
59	Ambulance service supplier, *e.g.*, private ambulance companies, funeral homes, etc.
60	Public health or welfare agencies.
61	Voluntary health or charitable agencies.
73	Mass immunization roster biller.
74	Radiation therapy centers.
87	All other suppliers (*e.g.*, drug and department stores).
88	Unknown supplier/provider specialty.
89	Certified clinical nurse specialist.
96	Optician.

TABLE 1—SPECIALTIES EXCLUDED FROM RATESETTING CALCULATION—Continued

Specialty code	Specialty description
97	Physician assistant.
A0	Hospital.
A1	SNF.
A2	Intermediate care nursing facility.
A3	Nursing facility, other.
A4	HHA.
A5	Pharmacy.
A6	Medical supply company with respiratory therapist.
A7	Department store.
B2	Pedorthic personnel.
B3	Medical supply company with pedorthic personnel.

• *Crosswalk certain low volume physician specialties:* Crosswalk the utilization of certain specialties with relatively low PFS utilization to the associated specialties.

• *Physical therapy utilization:* Crosswalk the utilization associated with all physical therapy services to the specialty of physical therapy.

• *Identify professional and technical services not identified under the usual TC and 26 modifiers:* Flag the services that are PC and TC services but do not use TC and 26 modifiers (for example, electrocardiograms). This flag associates the PC and TC with the associated global code for use in creating the indirect PE RVUs. For example, the professional service, CPT code 93010 (Electrocardiogram, routine ECG with at least 12 leads; interpretation and report only), is associated with the global service, CPT code 93000 (Electrocardiogram, routine ECG with at least 12 leads; with interpretation and report).

• *Payment modifiers:* Payment modifiers are accounted for in the creation of the file consistent with current payment policy as implemented in claims processing. For example, services billed with the assistant at surgery modifier are paid 16 percent of the PFS amount for that service; therefore, the utilization file is modified to only account for 16 percent of any service that contains the assistant at surgery modifier. Similarly, for those services to which volume adjustments are made to account for the payment modifiers, time adjustments are applied as well. For time adjustments to surgical services, the intraoperative portion in the work time file is used; where it is not present, the intraoperative percentage from the payment files used by contractors to process Medicare claims is used instead. Where neither is available, we use the payment adjustment ratio to adjust the time accordingly. Table 2 details the manner in which the modifiers are applied.

TABLE 2—APPLICATION OF PAYMENT MODIFIERS TO UTILIZATION FILES

Modifier	Description	Volume adjustment	Time adjustment
80,81,82	Assistant at Surgery	16%	Intraoperative portion.
AS	Assistant at Surgery—Physician Assistant.	14% (85% * 16%)	Intraoperative portion.
50 or LT and RT	Bilateral Surgery	150%	150% of work time.
51	Multiple Procedure	50%	Intraoperative portion.
52	Reduced Services	50%	50%.
53	Discontinued Procedure	50%	50%.
54	Intraoperative Care only	Preoperative + Intraoperative Percentages on the payment files used by Medicare contractors to process Medicare claims.	Preoperative + Intraoperative portion.
55	Postoperative Care only	Postoperative Percentage on the payment files used by Medicare contractors to process Medicare claims.	Postoperative portion.
62	Co-surgeons	62.5%	50%.
66	Team Surgeons	33%	33%.

We also make adjustments to volume and time that correspond to other payment rules, including special multiple procedure endoscopy rules and multiple procedure payment reductions (MPPRs). We note that section 1848(c)(2)(B)(v) of the Act exempts certain reduced payments for multiple imaging procedures and multiple therapy services from the BN calculation under section 1848(c)(2)(B)(ii)(II) of the Act. These MPPRs are not included in the development of the RVUs.

For anesthesia services, we do not apply adjustments to volume since we use the average allowed charge when simulating RVUs; therefore, the RVUs as calculated already reflect the payments as adjusted by modifiers, and no volume adjustments are necessary. However, a time adjustment of 33 percent is made only for medical direction of two to four cases since that is the only situation where a single practitioner is involved with multiple beneficiaries concurrently, so that counting each service without regard to the overlap with other services would overstate the amount of time spent by the practitioner furnishing these services.

• *Work RVUs:* The setup file contains the work RVUs from this proposed rule.

(6) Equipment Cost per Minute

The equipment cost per minute is calculated as:

(1/(minutes per year * usage)) * price * ((interest rate/(1 − (1/((1 + interest rate)^ life of equipment)))) + maintenance)

Where:

minutes per year = maximum minutes per year if usage were continuous (that is, usage=1); generally 150,000 minutes.
usage = variable, see discussion in this proposed rule.
price = price of the particular piece of equipment.
life of equipment = useful life of the particular piece of equipment.
maintenance = factor for maintenance; 0.05.
interest rate = variable, see discussion in this proposed rule.

Usage: We currently use an equipment utilization rate assumption of 50 percent for most equipment, with the exception of expensive diagnostic imaging equipment, for which we use a 90 percent assumption as required by section 1848(b)(4)(C) of the Act.

Stakeholders have often suggested that particular equipment items are used less frequently than 50 percent of the time in the typical setting and that CMS should reduce the equipment utilization rate based on these recommendations. We appreciate and share stakeholders' interest in using the most accurate assumption regarding the equipment utilization rate for particular equipment items. However, we believe that absent robust, objective, auditable data regarding the use of particular items, the 50 percent assumption is the most appropriate within the relative value system. We welcome the submission of data that illustrates an alternative rate.

Maintenance: This factor for maintenance was finalized in the CY 1998 PFS final rule with comment period (62 FR 33164). We continue to investigate potential avenues for determining equipment maintenance costs across a broad range of equipment items.

Interest Rate: In the CY 2013 PFS final rule with comment period (77 FR 68902), we updated the interest rates used in developing an equipment cost per minute calculation (see 77 FR 68902 for a thorough discussion of this issue). The interest rate was based on the Small Business Administration (SBA) maximum interest rates for different categories of loan size (equipment cost) and maturity (useful life). We are not proposing any changes to these interest rates for CY 2018. The interest rates are listed in Table 3.

TABLE 3—SBA MAXIMUM INTEREST RATES

Price	Useful life	Interest rate (%)
<$25K	<7 Years	7.50
$25K to $50K	<7 Years	6.50
>$50K	<7 Years	5.50
<$25K	7+ Years	8.00
$25K to $50K	7+ Years	7.00
>$50K	7+ Years	6.00

3. Changes to Direct PE Inputs for Specific Services

This section focuses on specific PE inputs. The direct PE inputs are included in the CY 2018 direct PE input database, which is available on the CMS Web site under downloads for the CY 2018 PFS proposed rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.*

(a) PE Inputs for Digital Imaging Services

In the CY 2017 PFS final rule (81 FR 80179 through 80184), we finalized our proposal to add a professional PACS workstation (ED053) used for interpretation of digital images to a series of CPT codes and to address costs related to the use of film that had previously been incorporated as direct PE inputs for these services. We finalized the following criteria for the inclusion of a professional PACS workstation:

- We did not add the professional PACS workstation to any code that currently lacks a technical PACS workstation (ED050) or lacks a work RVU. We continue to believe that procedures that do not include a technical workstation, or do not have physician work, would not require a professional workstation.
- We did not add the professional PACS workstation to add-on codes. Because the base codes include equipment minutes for the professional PACS workstation, we continue to believe it would be duplicative to add additional equipment time for the professional PACS workstation in the add-on code.
- We also did not add the professional PACS workstation to image guidance codes where the dominant provider is not a radiologist according to the most recent year of claims data, because we believe a single technical PACS workstation would be more typical in those cases.
- We agreed with commenters that because the clinical utility of the PACS workstation is not necessarily limited to diagnostic services, there may be therapeutic codes where it would be reasonable to assume its use to be typical. Based on information provided by commenters and our own medical review, we stated that we believe that the use of the professional PACS workstation is typical for many of the specific codes that were identified. We added the workstation to many of the therapeutic codes requested by commenters, specifically CPT codes listed outside the 70000 series, where we agreed that use of the professional PACS workstation was typical.
- For CPT codes in the 80000 and 90000 series, we expressed our concerns about whether it is appropriate to include the technical PACS workstation in many of these services. PACS workstations were created for imaging purposes, but many of these services that include a technical PACS workstation do not appear to make use of imaging. Although we did not remove the technical PACS workstation from these codes at that time, we did not believe that a professional PACS workstation should be added to these procedures.

Prior to the publication of this CY 2018 PFS proposed rule, a stakeholder expressed concern about our decision not to include the professional PACS workstation in a series of vascular ultrasound codes that use technical PACS workstations. The stakeholder indicated that the vascular ultrasound codes in question do make use of a professional PACS workstation, and that the dominant specialty provider requirement (that is, that the code's dominant specialty provider being diagnostic radiology) would exclude codes for which the professional PACS workstation is typical based on a mistaken assumption. The stakeholder stated that to furnish vascular ultrasound services following the transition from film to digital imaging, both a technical and a professional PACS workstation are required, regardless of whether the practitioner furnishing the service is a radiologist, cardiologist, neurologist, or vascular surgeon.

We appreciate the submission of this additional information regarding the use of the professional PACS workstation in vascular ultrasound codes. Therefore, we seek comments regarding whether or not the use of the professional PACS workstation would be typical in the following list of CPT and HCPCS codes. The codes brought to our attention by the stakeholder are CPT codes 93880, 93882, 93886, 93888, 93890, 93892, 93893, 93922, 93923, 93924, 93925, 93926, 93930, 93931, 93965, 93970, 93971, 93975, 93976, 93978, 93979, 93980, 93981, 93990, and 76706, and HCPCS code G0365. We will consider information submitted in comments to determine whether the professional

PACS workstation should be included as a direct PE input for these codes.

(2) Standardization of Clinical Labor Tasks

As we noted in the CY 2015 PFS final rule with comment period (79 FR 67640–67641), we continue to make improvements to the direct PE input database to provide the number of clinical labor minutes assigned for each task for every code in the database instead of only including the number of clinical labor minutes for the preservice, service, and postservice periods for each code. In addition to increasing the transparency of the information used to set PE RVUs, this improvement would allow us to compare clinical labor times for activities associated with services across the PFS, which we believe is important to maintaining the relativity of the direct PE inputs. This information would facilitate the identification of the usual numbers of minutes for clinical labor tasks and the identification of exceptions to the usual values. It would also allow for greater transparency and consistency in the assignment of equipment minutes based on clinical labor times. Finally, we believe that the information can be useful in maintaining standard times for particular clinical labor tasks that can be applied consistently to many codes as they are valued over several years, similar in principle to the use of physician preservice time packages. We believe such standards would provide greater consistency among codes that share the same clinical labor tasks and could improve relativity of values among codes. For example, as medical practice and technologies change over time, changes in the standards could be updated simultaneously for all codes with the applicable clinical labor tasks, instead of waiting for individual codes to be reviewed.

In the following paragraphs, we address a series of issues related to clinical labor tasks, particularly relevant to services currently being reviewed under the misvalued code initiative.

a. Preservice Clinical Labor for 0-Day and 10-Day Global Services

Several years ago, the RUC's PE Subcommittee reviewed the preservice clinical labor times for CPT codes with 0-day and 10-day global periods. The RUC concluded that these codes are assumed to have no preservice clinical staff time (standard time of 0 minutes) unless the specialty can provide evidence that the preservice time is appropriate. In other words, for minor procedures, it is assumed that there is no clinical staff time typically spent preparing for the specific procedure prior to the patient's arrival. However, we note that for CY 2018, 41 of the 53 reviewed codes with 0-day or 10-day global periods include preservice clinical labor of some kind, suggesting that it is typical for clinical staff to prepare for the procedure prior to the patient's arrival. As we review misvalued codes, we believe that the general adherence to values that we have established as standards supports relativity within the PFS. Because 77 percent of the reviewed codes for the current calendar year deviate from the ''standard,'' we are seeking comment on the value and appropriate application of the standard in our review of RUC recommendations in future rulemaking. In reviewing the inputs included in the direct PE inputs database, we found that for the 1,142 total 0-day global codes, 741 of them had preservice clinical labor of some kind (65 percent). We also noticed a general correlation between preservice clinical labor time and the recent review. We are seeking comment specifically on whether the standard preservice clinical labor time of 0 minutes should be consistently applied for 0-day and 10-day global codes in future rulemaking.

b. Obtain Vital Signs Clinical Labor

The direct PE inputs for each CPT code paid under the PFS include minutes assigned to a series of standard clinical labor tasks assumed to be typical for the service in question. The minutes assigned to each of these tasks for each CPT code have been developed over several decades, and what was previously considered to be a standard value in the review of the codes has changed over time. Because each year we perform a detailed review of all of the inputs for only several hundred of the over 7,000 CPT codes paid under the PFS, valuation for individual services can be influenced by shifts in review standards over time rather than purely based on changes in practice.

For example, we traditionally assigned a clinical labor time of 3 minutes for the ''Obtain vital signs'' clinical labor activity, based on the amount of time typically required to check a patient's vitals. Over time, that number of minutes has increased as codes are reviewed. For example, many of the reviewed codes for the current CY 2018 rulemaking cycle have a recommended clinical labor time of 5 minutes for ''Obtain vital signs,'' based on the understanding that these services are measuring two additional vital signs: The patient's height and weight. We do not have any reason to believe that measuring a patient's height and weight is only typical for services described by recently reviewed codes. Instead, we believe that the review standards have changed, perhaps in conjunction with changes in medical practice, and that the change in the minutes assigned for the ''Obtain vital signs'' task for newer-reviewed services is detrimental to relativity among PFS services.

Therefore, to preserve relativity among the PFS codes, we are proposing to assign 5 minutes of clinical labor time for all codes that include the ''Obtain vital signs'' task, regardless of the date of last review. We are proposing to assign this 5 minutes of clinical labor time for all codes that include at least 1 minute previously assigned to this task. We are also proposing to update the equipment times of the codes with this clinical labor task accordingly to match the changes in clinical labor time. For codes that were not recently reviewed and for which we lacked a breakdown of how the equipment time was derived from the clinical labor tasks, we could not determine if the equipment time included time assigned for the ''Obtain vital signs'' task. In these cases, we are proposing to adjust the equipment time of any equipment item that matched the clinical labor time of the full service period to match the change in the ''Obtain vital signs'' clinical labor time. The proposed list of all codes affected by these proposed vital signs changes to direct PE inputs is available on the CMS Web site under downloads for the CY 2018 PFS proposed rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.*

c. Establishment of Clinical Labor Activity Codes

Historically, the RUC has submitted a ''PE worksheet'' that details the recommended direct PE inputs for our use in developing PE RVUs. The format of the PE worksheet has varied over time and among the medical specialties developing the recommendations. These variations have made it difficult for both the RUC's development and our review of code values for individual codes. Beginning for the CY 2019 PFS rulemaking cycle, we understand that the RUC intends to mandate the use of a new PE worksheet for purposes of their recommendation development process that standardizes the clinical labor tasks and assigns them a clinical labor activity code. We believe the RUC's use of the new PE worksheet in developing and submitting recommendations to us would, in turn, help us to simplify and standardize the hundreds of different clinical labor tasks

currently listed in our direct PE database.

To help facilitate this transition to the new clinical labor activity codes, we have developed a crosswalk to link the old clinical labor tasks to the new clinical labor activity codes. Our crosswalk is for informational purposes only, and would not change either the direct PE input values or the PE RVUs for codes. Instead, we hope that the crosswalk would help us to translate the sprawling, existing data set into a condensed version that would significantly improve the standardization of clinical labor recommendations and improve the ability of commenters to identify concerns with our proposed valuation. For CY 2018 rulemaking, we are displaying two versions of the Labor Task Detail public use file: One version with the old listing of clinical labor tasks, and one with the same tasks as described by the new listing of clinical labor activity codes. These lists are available on the CMS Web site under downloads for the CY 2018 PFS proposed rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.*

(3) Equipment Recommendations for Scope Systems

During our routine reviews of direct PE input recommendations, we have regularly found unexplained inconsistencies involving the use of scopes and the video systems associated with them. Some of the scopes include video systems bundled into the equipment item, some of them include scope accessories as part of their price, and some of them are standalone scopes with no other equipment included. It is not always clear which equipment items related to scopes fall into which of these categories. We have also frequently found anomalies in the equipment recommendations, with equipment items that consist of a scope and video system bundle recommended, along with a separate scope video system. Based on our review, the variations do not appear to be consistent with the different code descriptions.

To promote appropriate relativity among the services and facilitate the transparency of our review process, during review of recommended direct PE inputs for the CY 2017 PFS proposed rule, we developed a structure that separates the scope and the associated video system as distinct equipment items for each code. Under this approach, we proposed standalone prices for each scope, and separate prices for the video systems that are used with scopes. We proposed to define the scope video system as including: (1) A monitor; (2) a processor; (3) a form of digital capture; (4) a cart; and (5) a printer. We believe that these equipment components represent the typical case for a scope video system. Our model for this system was the ''video system, endoscopy (processor, digital capture, monitor, printer, cart)'' equipment item (ES031), which we proposed to re-price as part of this separate pricing approach. We obtained current pricing invoices for the endoscopy video system as part of our investigation of these issues involving scopes, which we proposed to use for this re-pricing. We understand that there may be other accessories associated with the use of scopes; we proposed to separately price any scope accessories, and individually evaluate their inclusion or exclusion as direct PE inputs for particular codes as usual under our current policy based on whether they are typically used in furnishing the services described by the particular codes.

We also proposed standardizing refinements to the way scopes have been defined in the direct PE input database. We believe that there are four general types of scopes: non-video scopes; flexible scopes; semi-rigid scopes, and rigid scopes. Flexible scopes, semi-rigid scopes, and rigid scopes would typically be paired with one of the scope video systems, while the non-video scopes would not. The flexible scopes can be further divided into diagnostic (or non-channeled) and therapeutic (or channeled) scopes. We proposed to identify for each anatomical application: (1) A rigid scope; (2) a semi-rigid scope; (3) a non-video flexible scope; (4) a non-channeled flexible video scope; and (5) a channeled flexible video scope. We proposed to classify the existing scopes in our direct PE database under this classification system, to improve the transparency of our review process and improve appropriate relativity among the services. We planned to propose input prices for these equipment items through future rulemaking.

We proposed these changes only for the reviewed codes for CY 2017 that made use of scopes, along with updated prices for the equipment items related to scopes utilized by these services. But, we did not propose to apply these policies to codes with inputs reviewed prior to CY 2017. We also solicited comment on this separate pricing structure for scopes, scope video systems, and scope accessories, which we could consider proposing to apply to other codes in future rulemaking. In response to comments, we finalized the addition of a digital capture device to the endoscopy video system (ES031) in the CY 2017 PFS final rule. We finalized our proposal to price the system at $33,391, based on component prices of $9,000 for the processor, $18,346 for the digital capture device, $2,000 for the monitor, $2,295 for the printer, and $1,750 for the cart. We also finalized a price of $16,843.87 for the stroboscopy system scope accessory (ES065). We did not finalize price increases for a series of other scopes and scope accessories, as the invoices submitted for these components indicated that they are different forms of equipment with different product IDs and different prices. We did not receive any data to indicate that the equipment on the newly submitted invoices was more typical in its use than the equipment that we were currently using for pricing.

We did not make further changes to existing scope equipment in CY 2017 in order to allow the RUC's PE Subcommittee the opportunity to provide feedback. However, we believe there was some miscommunication on this point, as the RUC's PE Subcommittee workgroup that was created to address scope systems stated that no further action was required following the finalization of our proposal. We are making further proposals to continue clarifying scope equipment inputs, and seek comments regarding the new set of scope proposals. We welcome feedback from all stakeholders, including practitioners with direct experience in the use of scope equipment.

We are seeking comment on several potential categories of scope system PE inputs. We are considering creating a single scope equipment code for each of the five categories detailed in this proposed rule: (1) A rigid scope; (2) a semi-rigid scope; (3) a non-video flexible scope; (4) a non-channeled flexible video scope; and (5) a channeled flexible video scope. Under the current classification system, there are many different scopes in each category depending on the medical specialty furnishing the service and the part of the body affected. We believe that the variation between these scopes is not significant enough to warrant maintaining these distinctions, and we believe that creating and pricing a single scope equipment code for each category would help provide additional clarity. We are seeking public comment on the merits of this potential scope organization, as well as any pricing information regarding these five new scope categories.

For CY 2018, we are proposing two minor changes to PE inputs related to scopes. We are proposing to add an LED light source into the cost of the scope video system (ES031), which would remove the need for a separate light source in these procedures. If this proposal were to be finalized, we would remove the equipment time for the separate light source from CPT codes that include the scope video system. We are also proposing an increase to the price of the scope video system of $1,000.00 to cover the expense of miscellaneous small equipment associated with the system that falls below the threshold of individual equipment pricing as scope accessories (such as cables, microphones, foot pedals, etc.) We seek comments on the inclusion of the LED light in the scope video system, and the appropriate pricing of the system with the inclusion of these additional equipment items.

We anticipate adopting detailed changes to scope systems at the code level through rulemaking for CY 2019, because we believe that additional feedback from expert stakeholders will improve the details of the proposed changes. We are not proposing any additional pricing changes to scope equipment for CY 2018 due to the proposed reorganization into a single type of scope equipment for each of the five scope categories. However, we would consider updating prices for these equipment items through the public request process for price updates, or based on information submitted as part of RUC recommendations.

(4) Clarivein Kit for Mechanochemical Vein Ablation

In the CY 2017 PFS final rule, we finalized work RVUs and direct PE inputs for two new codes related to mechanochemical vein ablation, CPT codes 36473 and 36474. Following the publication of the final rule, stakeholders contacted CMS and requested that a Clarivein kit supply item (SA122) be added to the direct PE inputs for CPT code 36474, the add-on code for ablation of subsequent veins. They stated that the Clarivein kit was accidentally omitted from the RUC recommendations, and that an additional kit is necessary to perform the service described by the add-on procedure. We are soliciting comment regarding the use of multiple kits during procedures described by the base and add-on codes to determine whether or not this supply should be included as a direct PE input for CPT code 36474 for CY 2018.

(5) Removal of Oxygen From Non-Moderate Sedation Post-Procedure Monitoring

After finalizing the creation of separately billable codes for moderate sedation during the CY 2017 PFS final rule, we received additional recommendations to remove the oxygen gas supply item (SD084) from a series of CPT codes that were previously valued with moderate sedation as an inherent part of the procedure. Because oxygen gas is included in the moderate sedation pack contained within the separately billed moderate sedation codes, we believe that the continued inclusion of the oxygen gas in these codes is a duplicative supply. We are therefore proposing to remove the oxygen gas from the following codes (see Table 4):

TABLE 4—CY 2018 PROPOSED REMOVAL OF OXYGEN (SD084) FROM NON-MODERATE SEDATION POST-PROCEDURE MONITORING

HCPCS	NF/F	Current (liters)	Cost
31622	NF	90	−0.27
31625	NF	105	−0.32
31626	NF	135	−0.41
31627	NF	150	−0.45
31628	NF	120	−0.36
31629	NF	105	−0.32
31632	NF	54	−0.16
31633	NF	60	−0.18
31645	NF	175	−0.53
31652	NF	180	−0.54
31653	NF	225	−0.68
31654	NF	90	−0.27
52647	NF	10	−0.03
52648	NF	10	−0.03
90870	NF	198	−0.59

(6) Technical Corrections to Direct PE Input Database and Supporting Files

Subsequent to the publication of the CY 2017 PFS final rule, stakeholders alerted us to several clerical inconsistencies in the direct PE database. We are proposing to correct these inconsistencies as described in this proposed rule and reflected in the CY 2018 proposed direct PE input database displayed on the CMS Web site under downloads for the CY 2018 PFS proposed rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.*

For CY 2018, we are proposing to address the following inconsistencies:

- For CY 2018, we are proposing to make direct PE changes for CPT code 96416 (Chemotherapy administration, intravenous infusion technique; initiation of prolonged chemotherapy infusion (more than 8 hours), requiring use of a portable or implantable pump) to improve payment accuracy, in response to a stakeholder inquiry regarding the use of the ambulatory IV pump equipment for this service. We are proposing to add 6 additional minutes of RN/OCN clinical labor (L056A), 4 minutes for the ''Review charts by chemo nurse regarding course of treatment & obtain chemotherapy-related medical hx'' task, and 2 minutes for the ''Greet patient and provide gowning'' task. We are proposing to add 1 quantity of the IV infusion set supply (SC018) and proposing to lower the quantity from 2 to 1 of the 20 ml syringe supply (SC053). We are proposing to add 1800 minutes for the new ambulatory IV pump equipment, and we are proposing to increase the equipment time of the medical recliner chair (EF009) from 83 minutes to 89 minutes to match the increase in RN/OCN clinical labor. For CY 2018, these

proposed direct PE changes would be used to calculate the PE RVU for CPT code 96416. We seek comments on these proposed direct PE refinements.

• We propose to correct an anomaly in the postservice work time for CPT code 91200 (Liver elastography, mechanically induced shear wave (*e.g.,* vibration), without imaging, with interpretation and report) by changing it from 5 minutes to 3 minutes, which also results in a refinement in the total work time for the code from 18 minutes to 16 minutes.

• In the process of making updates to our direct PE database, we discovered a series of discrepancies between the finalized direct PE inputs and the values entered into the database from previous calendar years. To reconcile these discrepancies, we are proposing the following direct PE refinements:

TABLE 5—DIRECT PE DATABASE DATA DISCREPANCIES AND PROPOSED CHANGES

HCPCS	Input code	Input code description	NF/F	Old	New	Cost
11307	SF033	scalpel with blade, surgical (#10–20)	NF	1	2	0.69
11311	SG056	gauze, sterile 4in x 4in (10 pack uou)	NF	1	2	0.80
11311	SH046	lidocaine 1% w-epi inj (Xylocaine w-epi)	NF	10	4	−0.38
11719	L037D	Greet patient, provide gowning, ensure appropriate medical records are available.	NF	1	3	0.74
11719	L037D	Provide pre-service education/obtain consent	NF	1	2	0.37
11719	L037D	Prepare room, equipment, supplies	NF	1	2	0.37
11719	L037D	Clean room/equipment by physician staff	NF	1	3	0.74
17312	SL097	OCT Tissue-Tek	NF	8	6	−0.12
17313	SF004	blade, microtome	NF	1	0	−1.72
17313	SF044	blade, surgical, super-sharp	NF	0	1	4.17
17313	SG056	gauze, sterile 4in x 4in (10 pack uou)	NF	3	0	−2.39
17313	SG088	tape, foam, elastic, 2in (Microfoam)	NF	10	8	−0.01
17314	SG056	gauze, sterile 4in x 4in (10 pack uou)	NF	2	0	−1.60
17314	SL097	OCT Tissue-Tek	NF	8	6	−0.12
17315	SL078	histology freezing spray (Freeze-It)	NF	0	0.2	0.29
19283	L043A	Service total costs	NF	55	54	−0.43
19286	L051B	Service total costs	NF	30	31	0.51
19286	EL015	room, ultrasound, general	NF	19	20	1.40
19286	EQ168	light, exam	NF	19	20	0.00
23333	L037D	Post service total costs	F	63	90	9.99
28045	SC029	needle, 18–27g	NF	2	1	−0.09
32405	L041B	Service total costs	NF	52	57	2.05
37765	L037D	Service total costs	NF	91	94	1.11
37766	L037D	Service total costs	NF	121	124	1.11
45171	SJ052	swab, procto 16in	F	2	3	0.12
45172	L037D	Service total costs	F	6	12	2.22
45172	SJ052	swab, procto 16in	F	2	3	0.12
52214	SH047	lidocaine 1%–2% inj (Xylocaine)	NF	1	50	1.72
72120	EL012	room, basic radiology	NF	16	17	0.48
72148	L047A	Service total costs	NF	47	49	0.84
74230	L041B	Technologist QC's images in PACS, checking for all images, reformats, and dose page.	NF	0	2	0.82
91013	EF023	table, exam	NF	0	9	0.03
91013	EF015	mayo stand	NF	0	9	0.01
91013	EQ235	suction machine (Gomco)	NF	0	9	0.02
91013	EQ181	manometry system (computer, transducers, catheter).	NF	0	9	1.15
91013	EQ339	manometry accessory cable	NF	0	9	0.05
91013	ED050	PACS Workstation Proxy	NF	0	9	0.20
91132	EQ019	EGG monitoring system	NF	22	30	0.83
92227	EL006	lane, screening (oph)	NF	12	0	−1.07
92227	EL005	lane, exam (oph)	NF	0	12	1.15
93017	L051A	Preservice total costs	NF	15	5	−5.10
95819	SG079	tape, surgical paper 1in (Micropore)	NF	6	42	0.07

The proposed PE RVUs displayed in Addendum B on our Web site were calculated with the inputs displayed in the CY 2018 proposed direct PE input database.

(7) Updates to Prices for Existing Direct PE Inputs

In the CY 2011 PFS final rule with comment period (75 FR 73205), we finalized a process to act on public requests to update equipment and supply price and equipment useful life inputs through annual rulemaking, beginning with the CY 2012 PFS proposed rule. For CY 2018, we are proposing the following price updates for existing direct PE inputs.

We are proposing to update the price of thirteen supplies and one equipment item in response to the public submission of invoices. For the details of these proposed price updates, please refer to section II.H, of this proposed rule, Table 14: Invoices Received for Existing Direct PE Inputs.

We are not proposing to update the price of the blood warmer (EQ072), the cell separator system (EQ084), or the photopheresor system (EQ206) equipment items. The only pricing information that we received for these three equipment items was an invoice that included a hand-written price over redacted information. We were unable to verify the accuracy of this invoice. We are also not proposing to update the price of the DNA image analyzer (ACIS) (EP001) equipment item, due to the

inclusion of many components on the submitted invoice that are not part of the price of the DNA image analyzer. We were unable to determine which of these components were included in the cost of the DNA image analyzer, and which of these components were unrelated types of equipment. To price these equipment items accurately, we believe that we need additional information. We continue to use the current price for these equipment items pending the submission of additional pricing information. We welcome the submission of updated pricing information regarding these equipment items through valid invoices from commenters and other stakeholders.

We are also proposing to change the name of the ED050 equipment from the ''PACS Workstation Proxy'' to the ''Technologist PACS workstation.'' In the CY 2017 final rule (81 FR 80180–80182), we finalized a policy to add a professional PACS workstation (ED053) to the list of approved equipment items, and we believe that renaming ED050 to the technologist PACS workstation would help to alleviate potential confusion between the two PACS workstations.

We routinely accept public submission of invoices as part of our process for developing payment rates for new, revised, and potentially misvalued codes. Often these invoices are submitted in conjunction with the RUC-recommended values for the codes. For CY 2018, we note that some stakeholders have submitted invoices for new, revised, or potentially misvalued codes after the February 10th deadline established for code valuation recommendations. To be included in a given year's proposed rule, we generally need to receive invoices by the same February 10th deadline. However, we would consider invoices submitted as public comments during the comment period following the publication of the proposed rule, and would consider any invoices received after February or outside of the public comment process as part of our established annual process for requests to update supply and equipment prices.

4. Adjustment to Allocation of Indirect PE for Some Office-Based Services

As we explain in section II.B.2.c.(2) of this proposed rule, we allocate indirect costs for each code on the basis of the direct costs specifically associated with a code and the greater of either the clinical labor costs or the work RVUs. Indirect expenses include administrative labor, office expense, and all other expenses. For PFS services priced in both the facility and non-facility settings, the difference in indirect PE RVUs between the settings is driven by differences in direct PE inputs for those settings since the other allocator of indirect PE, the work RVU, does not differ between settings. For most services, the direct PE input costs are higher in the nonfacility setting than in the facility setting. As a result, indirect PE RVUs allocated to these services are higher in the nonfacility setting than in the facility setting. When direct PE inputs for a service are very low, however, the allocation of indirect PE RVUs is almost exclusively based on work RVUs, which results in a very small (or no) site of service differential between the total PE RVUs in the facility and nonfacility setting.

Some stakeholders have suggested that for codes in which direct PE inputs for a service are very low, this allocation methodology does not allow for a site of service differential that accurately reflects the relative indirect costs involved in furnishing services in nonfacility settings. Among the services most affected by this anomaly are the primary therapy and counseling services available to Medicare beneficiaries for treatment of behavioral health conditions, including substance use disorders. For example, for the most commonly reported psychotherapy service (CPT code 90834), the difference between the nonfacility and facility PE RVUs is only 0.02 RVUs, which seems unlikely to represent the difference in relative resource costs in terms of administrative labor, office expense, and all other expenses incurred by the billing practitioner for 45 minutes of psychotherapy services when furnished in the office setting versus the facility setting.

We agree with these stakeholders that the site of service differential for these services that is produced by our PE methodology seems unlikely to reflect the relative resource costs for the practitioners furnishing these services in nonfacility settings. For example, we believe the 0.02 RVUs, which translates to approximately $0.72, would be unlikely to reflect the relative administrative labor, office rent, and other overhead involved in furnishing the 45 minute psychotherapy service in a nonfacility setting. Consequently, we believe it would be appropriate to modify the existing methodology for allocating indirect PE RVUs in order to better reflect the relative indirect PE resources involved in furnishing these kinds of services in the nonfacility setting.

In examining the range of services furnished in the nonfacility setting that are most affected by this circumstance, we identified HCPCS codes that describe face-to-face services, have work RVUs greater than zero, and are priced in both the facility and nonfacility setting. From among these codes, we further selected those with the lowest ratio between nonfacility PE RVUs and work RVUs. We selected 0.4 as an appropriate threshold based on several factors, including the range of nonfacility PE RVU to work RVU ratios among the codes identified. Based on these criteria, there were fewer than 50 codes that we identified with a ratio of less than 0.4 nonfacility PE RVUs for each work RVU, most of which are primarily furnished by behavioral health professionals, for a potential modification to our indirect PE allocation methodology.

In considering how to address the anomaly and ensure that an appropriate number of indirect PE RVUs are allocated to these services in the nonfacility setting, we looked at the indirect, nonfacility PE RVU for the most commonly billed physician office visit, CPT code 99213, which is billed by a wide range of physicians and non-physician practitioners under the PFS. We believe that the indirect PE costs allocated to services reported with CPT code 99213, including administrative labor and office rent, would be common for a broad range of physicians and non-physician practitioners across the PFS. We recognize that the services we seek to address are primarily furnished by behavioral health professionals who may be unlikely to incur some of the costs incurred by other practitioners furnishing a broader range of medical services. For instance, a practitioner furnishing a broader range of primary care services likely requires separate office and examination room space, and storage for disposable medical supplies and equipment. Some costs, however, such as those for office staff and records maintenance, would be analogous.

We looked at the relationship between indirect PE and work RVUs for CPT code 99213 as a marker because that is the most commonly and broadly reported PFS code that describes face-to-face office-based services. We compared the relationship between indirect PE and work RVUs for the set of HCPCS codes that we identified using the criteria discussed above and found that for the significant majority of codes, that ratio was at least 0.4 nonfacility PE RVUs for each work RVU. We believe the 0.4 nonfacility PE RVUs can serve as an appropriate marker that appropriately reflects the relative resources involved in furnishing these services.

For the fewer than 50 outlier codes identified using the criteria above, we believe it would be appropriate to establish a minimum nonfacility indirect PE RVU that would be a better reflection the resources involved in furnishing these services. We propose to set the nonfacility indirect PE RVUs for these codes using the indirect PE RVU to work RVU ratio for the most commonly furnished office-based, face-to-face service (CPT 99213) as a marker. Specifically, for each of these outlier codes, we propose to compare the ratio between indirect PE RVUs and work RVUs that result from the preliminary application of the standard methodology to the ratio for the marker code, CPT code 99213. Our proposed change in the methodology would then increase the allocation of indirect PE RVUs to the outlier codes to at least one quarter of the difference between the two ratios. We believe this approach reflects a reasonable minimum allocation of indirect PE RVUs, but we do not currently have empirical data that would be useful in establishing a more precise number.

In developing the proposed PE RVUs for CY 2018, we propose to implement only one quarter of this proposed minimum value for nonfacility indirect PE for the outlier codes. We recognize that this change in the PE methodology could have a significant impact on the allocation of indirect PE RVUs across all PFS services. In making significant changes to the PE methodology in previous years, we have implemented such changes using 4 year transitions, based largely on concerns that some specialties experience significant payment reductions with changes in PE relativity, and a transition period allows for a more gradual adjustment for affected practitioners. Under the approach we are proposing, we estimate that approximately $40 million, or approximately 0.04 percent of total PFS allowed charges, would shift within the PE methodology for each year of the proposed 4-year transition, including for CY 2018. We also note that we are proposing to exclude the codes directly subject to this proposed change from the misvalued code target calculation because the proposed change is a methodological change to address an anomaly produced by our indirect PE allocation process as opposed to a change to address misvalued codes. The PE RVUs displayed in Addendum B on our Web site were calculated with the one quarter of the indirect PE adjustment factor implemented.

C. Determination of Malpractice Relative Value Units (RVUs)

1. Overview

Section 1848(c) of the Act requires that each service paid under the PFS be composed of three components: work, PE, and malpractice (MP) expense. As required by section 1848(c)(2)(C)(iii) of the Act, beginning in CY 2000, MP RVUs are resource based. Section 1848(c)(2)(B)(i) of the Act also requires that we review, and if necessary adjust, RVUs no less often than every 5 years. In the CY 2015 PFS final rule with comment period, we implemented the third review and update of MP RVUs. For a comprehensive discussion of the third review and update of MP RVUs see the CY 2015 proposed rule (79 FR 40349 through 40355) and final rule with comment period (79 FR 67591 through 67596).

To determine MP RVUs for individual PFS services, our MP methodology is composed of three factors: (1) Specialty-level risk factors derived from data on specialty-specific MP premiums incurred by practitioners, (2) service level risk factors derived from Medicare claims data of the weighted average risk factors of the specialties that furnish each service, and (3) an intensity/complexity of service adjustment to the service level risk factor based on either the higher of the work RVU or clinical labor RVU. Prior to CY 2016, MP RVUs were only updated once every 5 years, except in the case of new and revised codes.

As explained in the CY 2011 PFS final rule with comment period (75 FR 73208), MP RVUs for new and revised codes effective before the next 5-year review of MP RVUs were determined either by a direct crosswalk from a similar source code or by a modified crosswalk to account for differences in work RVUs between the new/revised code and the source code. For the modified crosswalk approach, we adjusted (or scaled) the MP RVU for the new/revised code to reflect the difference in work RVU between the source code and the new/revised work RVU (or, if greater, the difference in the clinical labor portion of the fully implemented PE RVU) for the new code. For example, if the proposed work RVU for a revised code were 10 percent higher than the work RVU for its source code, the MP RVU for the revised code would be increased by 10 percent over the source code MP RVU. Under this approach, the same risk factor was applied for the new/revised code and source code, but the work RVU for the new/revised code was used to adjust the MP RVUs for risk.

In the CY 2016 PFS final rule with comment period (80 FR 70906 through 70910), we finalized a policy to begin conducting annual MP RVU updates to reflect changes in the mix of practitioners providing services (using Medicare claims data), and to adjust MP RVUs for risk, intensity and complexity (using the work RVU or clinical labor RVU). We also finalized a policy to modify the specialty mix assignment methodology (for both MP and PE RVU calculations) to use an average of the 3 most recent years of data instead of a single year of data. Under this approach, for new and revised codes, we generally assign a specialty risk factor to individual codes based on the same utilization assumptions we make regarding specialty mix we use for calculating PE RVUs and for PFS budget neutrality. We continue to use the work RVU or clinical labor RVU to adjust the MP RVU for each code for intensity and complexity. In finalizing this policy, we stated that the specialty-specific risk factors would continue to be updated through notice and comment rulemaking every 5 years using updated premium data, but would remain unchanged between the 5-year reviews.

In CY 2017, we finalized the eighth GPCI update, which reflected updated MP premium data. We did not propose to use the updated MP premium data to propose updates for CY 2017 to the specialty risk factors used in the calculation of MP RVUs because it was inconsistent with the policy we previously finalized in the CY 2016 PFS final rule with comment period, whereby we indicated that the specialty-specific risk factors would continue to be updated through notice and comment rulemaking every 5 years using updated premium data, but would remain unchanged between the 5-year reviews. However, we solicited comment on whether we should consider doing so, perhaps as early as for CY 2018, prior to the fourth review and update of MP RVUs that must occur no later than CY 2020. After consideration of the comments received, we stated that we would consider the possibility of using the updated MP data to update the specialty risk factors used in the calculation of the MP RVUs prior to the next 5-year update in future rulemaking (81 FR 80191 through 80192). Since MP premium data are used to update both the MP GPCIs and the MP RVUs, going forward we believe it would be logical to align the update of MP premium data used to determine the MP RVUs with the update of the MP GPCI. Section 1848(e)(1)(C) of the Act requires us to review and, if necessary, adjust the

GPCIs at least every 3 years. The next review of the GPCIs must occur by CY 2020.

We propose to use the most recent data for the proposed MP RVUs for CY 2018 and to align the update of MP premium data and MP GPCIs to once every 3 years. We are seeking comment on these proposals, and we are also seeking comment on methodologies and sources that we might use to improve the next update of MP premium data.

2. Methodology for the Proposed Revision of Resource Based Malpractice RVUs

a. General Discussion

The proposed MP RVUs were calculated based on updated malpractice premium data obtained from state insurance rate filings by a CMS contractor. The methodology used in calculating the proposed CY 2018 review and update of resource based MP RVUs largely parallels the process used in the CY 2015 update. The calculation requires using information on specialty-specific malpractice premiums linked to specific services based upon the relative risk factors of the various specialties that furnish a particular service. Because malpractice premiums vary by state and specialty, the malpractice premium information must be weighted geographically and by specialty. Accordingly, the proposed MP RVUs are based upon four data sources: CY 2014 and CY 2015 malpractice premium data; CY 2016 and 2017 Medicare payment and utilization data; CY 2017 geographic practice cost indices (GPCIs), and CY 2018 proposed work and clinical labor RVUs.

Similar to the previous update, we calculated the proposed MP RVUs using specialty-specific malpractice premium data because they represent the actual expense incurred by practitioners to obtain malpractice insurance. We obtained malpractice premium data exclusively from the most recently available data published in the 2014 and 2015 Market Share Reports accessed from the National Association of Insurance Commissioners (NAIC) Web site. We used information obtained from malpractice insurance rate filings with effective dates in 2014 and 2015. These were the most current data available during our data collection process. We collected malpractice insurance premium data from all 50 States, and the District of Columbia, and Puerto Rico. Rate filings were not available in American Samoa, Guam or the Virgin Islands. Premiums were for $1 million/$3 million, mature, claims-made policies (policies covering claims made, rather than those covering services furnished, during the policy term). A $1 million/$3 million liability limit policy means that the most that would be paid on any claim is $1 million and the most that the policy would pay for claims over the timeframe of the policy is $3 million. We made adjustments to the premium data to reflect mandatory surcharges for patient compensation funds (funds to pay for any claim beyond the statutory amount, thereby limiting an individual physician's liability in cases of a large suit) in states where participation in such funds is mandatory.

We included premium information for all physician and NPP specialties, and all risk classifications available in the collected rate filings. Although we collected premium data from all states, the District of Columbia, and Puerto Rico, not all specialties had distinct premium data in the rate filings from all states. Additionally, for some specialties, MP premiums were not available from the rate filings in any state. Therefore, for specialties for which there were not premium data for at least 35 states, and specialties for which there were not distinct premium data in the rate filings, we crosswalked the specialty to a similar specialty, either conceptually or by available premium data, for which we did have sufficient and reliable data. These specialties and the specialty data that we propose to use are shown in Table 6.

For example, for radiation oncology, data were only available from 23 states, and therefore this specialty does not meet our 35-state threshold, which determines whether or not a specialty is deemed to have premium data sufficient to construct a unique risk factor. However, based on the 23 states' worth of rate filings for radiation oncology, the resource costs for the premiums suggests a similar, though slightly lesser average than that of the premiums for diagnostic radiology. We developed the proposed MP RVUs for radiation oncology by crosswalking the risk factor for diagnostic radiology as a similar specialty with similar premium data. We are seeking comment as to the appropriateness of this and the other crosswalks used in developing MP RVUs.

For the proposed CY 2018 MP RVU update, sufficient and reliable premium data were available for 43 specialty types, representing over 76 percent of allowed Medicare PFS services, which we used to develop specialty specific malpractice risk factors. (See Table 8 for a list of these specialties.)

TABLE 6—PROPOSED CROSSWALK OF SPECIALTIES TO SIMILAR SPECIALTIES

Specialty code	Medicare specialty name	Crosswalk specialty code	Crosswalk specialty
12	Osteopathic Manipulative Medicine	03	Allergy/Immunology.
15	Speech Language Pathology	03	Allergy/Immunology.
17	Hospice and Palliative Care	03	Allergy/Immunology.
19	Oral Surgery (Dentist only)	24	Plastic and Reconstructive Surgery.
23	Sports Medicine	01	General Practice.
27	Geriatric Psychiatry	26	Psychiatry.
32	Anesthesiology Assistant	05	Anesthesiology.
35	Chiropractic	03	Allergy/Immunology.
36	Nuclear Medicine	30	Diagnostic Radiology.
40	Hand Surgery	20	Orthopedic Surgery.
41	Optometry	03	Allergy/Immunology.
42	Certified Nurse Midwife	16	Obstetrics & Gynecology.
43	Certified Registered Nurse Anesthetist (CRNA)	05	Anesthesiology.
48	Podiatry	07	Dermatology.
62	Psychologist	03	Allergy/Immunology.
64	Audiologist	03	Allergy/Immunology.
65	Physical Therapist in Private Practice	03	Allergy/Immunology.
67	Occupational Therapist in Private Practice	03	Allergy/Immunology.
68	Psychologist, Clinical	03	Allergy/Immunology.

TABLE 6—PROPOSED CROSSWALK OF SPECIALTIES TO SIMILAR SPECIALTIES—Continued

Specialty code	Medicare specialty name	Crosswalk specialty code	Crosswalk specialty
76	Peripheral Vascular Disease	77	Vascular Surgery.
79	Addiction Medicine	03	Allergy/Immunology.
80	Licensed Clinical Social Worker	03	Allergy/Immunology.
81	Critical Care (Intensivists)	29	Pulmonary Disease.
85	Maxillofacial Surgery	24	Plastic and Reconstructive Surgery.
86	Neuropsychiatry	26	Psychiatry.
89	Certified Clinical Nurse Specialist	01	General Practice.
92	Radiation Oncology	30	Diagnostic Radiology.
94	Interventional Radiology	30	Diagnostic Radiology.
97	Physician Assistant	03	Allergy/Immunology.
98	Gynecological Oncology	02	General Surgery.
C0	Sleep Medicine	01	General Practice.

b. Steps for Calculating Malpractice RVUs

Calculation of the proposed MP RVUs conceptually follows the specialty-weighted approach used in the CY 2015 final rule with comment period (79 FR 67591). The specialty-weighted approach bases the MP RVUs for a given service upon a weighted average of the risk factors of all specialties furnishing the service. This approach ensures that all specialties furnishing a given service are accounted for in the calculation of the MP RVUs. The steps for calculating the proposed MP RVUs are described below.

Step (1): Compute a preliminary national average premium for each specialty.

Insurance rating area malpractice premiums for each specialty are mapped to the county level. The specialty premium for each county is then multiplied by its share of the total U.S. population (from the U.S. Census Bureau's 2014 American Community (ACS) estimates). This is in contrast to the method used for creating national average premiums for each specialty in the 2015 update; in that update, specialty premiums were weighted by the total RVU per county, rather than by the county share of the total U.S. population. We refer readers to the PFS 2016 Final Rule with comment period (80 FR 70909) for a discussion of why we have adopted a weighting method based on share of total U.S. population. This calculation is then divided by the average MP GPCI across all counties for each specialty to yield a normalized national average premium for each specialty. The specialty premiums are normalized for geographic variation so that the locality cost differences (as reflected by the GPCIs) would not be counted twice. Without the geographic variation adjustment, the cost differences among fee schedule areas would be reflected once under the methodology used to calculate the MP RVUs and again when computing the service specific payment amount for a given fee schedule area.

Step (2): Determine which premium class(es) to use within each specialty.

Some specialties had premium rates that differed for surgery, surgery with obstetrics, and non-surgery. These premium classes are designed to reflect differences in risk of professional liability and the cost of malpractice claims if they occur. To account for the presence of different classes in the malpractice premium data and the task of mapping these premiums to procedures, we calculated distinct risk factors for surgical, surgical with obstetrics, and nonsurgical procedures. However, the availability of data by surgery and non-surgery varied across specialties. Consistent with the CY 2015 MP RVU update, because no single approach accurately addressed the variability in premium class among specialties, we employed several methods for calculating average premiums by specialty. These methods are discussed below.

(a) *Substantial Data for Each Class:* For 10 out of 86 specialties, we determined that there were sufficient data for surgery and non-surgery premiums, as well as sufficient differences in rates between classes. These specialties are listed in Table 7. Therefore, we calculated a national average surgical premium and non-surgical premium. We note that, unlike in the CY 2015 MP RVU update, for CY 2018, there were no specialties that fell under the ''unspecified dominates'' specialty/surgery class scenario, therefore we have omitted that surgical class category.

(b) *Major Surgery Dominates:* For 9 surgical specialties, rate filings that included non-surgical premiums were relatively rare. For most of these surgical specialties, the rate filings did not include an ''unspecified'' premium. When it did, the unspecified premium was lower than the major surgery rate. For these surgical specialties, we calculated only a surgical premium and used the premium for major surgery for all procedures furnished by this specialty.

(c) *Blend All Available:* For the remaining specialties, there was wide variation across the rate filings in terms of whether or not premium classes were reported and which categories were reported. Because there was no clear strategy for these remaining specialties, we blended the available rate information into one general premium rate. For these specialties, we developed a weighted average ''blended'' premium at the national level, according to the percentage of work RVUs correlated with the premium classes within each specialty. For example, the surgical premiums for a given specialty were weighted by that specialty's work RVUs for surgical services; the nonsurgical premiums were weighted by the work RVUs for non-surgical services and the unspecified premiums were weighted by all work RVUs for the specialty type.

The three methods for calculating premiums by specialty type are summarized in Table 7. (See Table 8: ''Proposed Risk Factors by Specialty Type'' for the specialty names associated with the specialty codes listed in Table 7.)

TABLE 7—PROPOSED PREMIUM CALCULATION APPROACH BY SPECIALTY TYPE

Method	Medicare specialty codes
(a) Substantial Data for Each Class (10).	01, 04, 08, 09, 13, 16, 18, 34, 72, 93.
(b) Major Surgery Dominates (9).	02, 14, 20, 24, 28, 33, 77, 78, 91.

TABLE 7—PROPOSED PREMIUM CALCULATION APPROACH BY SPECIALTY TYPE—Continued

Method	Medicare specialty codes
(c) Blend all Available (24).	03, 05, 06, 07, 10, 11, 22, 25, 26, 29, 30, 37, 38, 39, 44, 46, 50, 66, 71, 82, 83, 84, 90, 99.

Step (3): Calculate a risk factor for each specialty.

The relative differences in national average premiums between specialties are expressed in our methodology as a specialty risk factor. These risk factors are an index calculated by dividing the national average premium for each specialty by the national average premium for the specialty with the lowest premiums for which we had sufficient and reliable data, allergy and immunology. For specialties with sufficient surgical and non-surgical premium data, we calculated both a surgical and non-surgical risk factor. For specialties with rate filings that distinguished surgical premiums with obstetrics, we calculated a separate surgical with obstetrics risk factor. For all other specialties we calculated a single risk factor and applied the specialty risk factor to both surgery and non-surgery services.

We note that for determining the risk factor for suppliers of TC-only services in the CY 2015 update, we updated the premium data for independent diagnostic testing facilities (IDTFs) that we used in the CY 2010 update. These data were obtained from a survey conducted by the Radiology Business Management Association (RBMA) in 2009; we ultimately used these data to calculate an updated TC specialty risk factor. We applied the updated TC specialty risk factor to suppliers of TC-only services. In the CY 2015 final rule with comment period (79 FR 67595), RBMA voluntarily submitted updated MP premium information collected from independent diagnostic testing facilities (IDTFs) in 2014, and requested that we use the data for calculating the CY 2015 MP RVUs for TC services. We declined to utilize the data and stated that we believe further study is necessary and we would consider this matter and propose any changes through future rulemaking. We believe that data for a broader set of technical component services are needed, and seek comment on appropriate, comparable data sources for such information. We also seek comment on whether the data for IDTFs are comparable and appropriate as a proxy for the broader set of TC services. We endeavor to, in the next update of specialty risk factors, collect more data across a broader set of the technical component services, not just for radiology (as is currently reflected in the RBMA data), but data for services performed by other non-physician practitioners including cytotechnologists, and cardiovascular technologists. In the interim, for CY 2018, we propose to assign a TC risk factor of 1.0, which corresponds to the lowest physician specialty risk factor.

We assigned the risk factor of 1.0 to the TC services because we do not have comparable professional liability premium data for the full range of clinicians that furnish these services. In lieu of comprehensive, comparable data, we used 1.0 as the default minimum risk factor, though we seek information on the best available data sources for use in the next update, as well as empirical information that would support assignment of an alternative risk factor for these services. Table 8 shows the proposed risk factors by specialty type.

TABLE 8—PROPOSED RISK FACTORS BY SPECIALTY TYPE

Specialty code	Medicare specialty name	Non-surgical risk factor	Surgical risk factor
01	General Practice	1.80	3.72
01	General Practice w/OB		4.30
02	General Surgery		6.75
03	Allergy/Immunology	1.00	1.00
04	Otolaryngology	1.53	4.08
05	Anesthesiology	2.58	2.58
06	Cardiovascular Disease (Cardiology)	1.90	1.90
07	Dermatology	2.77	2.77
08	Family Practice	1.67	3.74
08	Family Practice w/OB		4.31
09	Interventional Pain Management	2.08	2.97
10	Gastroenterology	2.40	2.40
11	Internal Medicine	2.70	2.70
12	Osteopathic Manipulative Medicine	1.00	1.00
13	Neurology	2.46	13.02
14	Neurosurgery		10.66
15	Speech Language Pathology	1.00	1.00
16	Obstetrics & Gynecology	1.59	4.52
16	Obstetrics & Gynecology w/OB		8.67
17	Hospice and Palliative Care	1.00	1.00
18	Ophthalmology	1.03	2.16
19	Oral Surgery (Dentist only)		4.93
20	Orthopedic Surgery		6.22
22	Pathology	1.60	1.60
23	Sports Medicine	1.80	3.72
24	Plastic and Reconstructive Surgery		4.93
25	Physical Medicine and Rehabilitation	1.49	1.49
26	Psychiatry	1.27	1.27
27	Geriatric Psychiatry	1.27	1.27
28	Colorectal Surgery (Proctology)		4.19
29	Pulmonary Disease	1.82	1.82
30	Diagnostic Radiology	2.82	2.82
32	Anesthesiology Assistant	2.58	2.58
33	Thoracic Surgery		6.06
34	Urology	1.66	2.97

TABLE 8—PROPOSED RISK FACTORS BY SPECIALTY TYPE—Continued

Specialty code	Medicare specialty name	Non-surgical risk factor	Surgical risk factor
35	Chiropractic	1.00	1.00
36	Nuclear Medicine	2.82	2.82
37	Pediatric Medicine	1.82	1.82
38	Geriatric Medicine	1.52	1.52
39	Nephrology	1.56	1.56
40	Hand Surgery		6.22
41	Optometry	1.00	1.00
42	Certified Nurse Midwife	1.59	4.52
42	Certified Nurse Midwife w/OB		8.67
43	Certified Registered Nurse Anesthetist (CRNA)	2.58	2.58
44	Infectious Disease	2.03	2.03
46	Endocrinology	1.75	1.75
48	Podiatry	2.77	2.77
50	Nurse Practitioner	1.95	1.95
62	Psychologist	1.00	1.00
64	Audiologist	1.00	1.00
65	Physical Therapist in Private Practice	1.00	1.00
66	Rheumatology	1.58	1.58
67	Occupational Therapist in Private Practice	1.00	1.00
68	Psychologist, Clinical	1.00	1.00
71	Registered Dietitian or Nutrition Professional	1.37	1.37
72	Pain Management	2.65	3.65
76	Peripheral Vascular Disease		6.67
77	Vascular Surgery		6.67
78	Cardiac Surgery		6.87
79	Addiction Medicine	1.00	1.00
80	Licensed Clinical Social Worker	1.00	1.00
81	Critical Care (Intensivists)	1.82	1.82
82	Hematology	1.77	1.77
83	Hematology-Oncology	1.85	1.85
84	Preventive Medicine	1.15	1.15
85	Maxillofacial Surgery		4.93
86	Neuropsychiatry	1.27	1.27
89	Certified Clinical Nurse Specialist	1.80	3.72
90	Medical Oncology	1.82	1.82
91	Surgical Oncology		4.32
92	Radiation Oncology	2.82	2.82
93	Emergency Medicine	2.29	5.03
94	Interventional Radiology	2.82	2.82
97	Physician Assistant	1.95	1.95
98	Gynecological Oncology		6.75
99	Undefined Physician type	1.95	1.95
C0	Sleep Medicine	1.80	3.72

Step (4): Calculate malpractice RVUs for each HCPCS code.

Resource-based MP RVUs were calculated for each HCPCS code that has work or PE RVUs. The first step was to identify the percentage of services furnished by each specialty for each respective HCPCS code. This percentage was then multiplied by each respective specialty's risk factor as calculated in Step 3. The products for all specialties for the HCPCS code were then added together, yielding a specialty-weighted service specific risk factor reflecting the weighted malpractice costs across all specialties furnishing that procedure. The service specific risk factor was multiplied by the greater of the work RVU or PE clinical labor index for that service to reflect differences in the complexity and risk-of-service between services.

Low volume service codes: As we discussed in section II.B. of this proposed rule, we are proposing to use a list of expected specialties instead of the claims-based specialty mix for low volume services in order to address stakeholder concerns about the year to year variability in PE and MP RVUs for low volume services. We are soliciting comments on the proposal to use these service-level overrides to determine the specialty for low volume procedures, as well as on the list of overrides itself. The proposed list of codes and expected specialties is available on our Web site under downloads for the CY 2018 PFS proposed rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.* In previous MP RVU updates, as discussed in the CY 2015 final rule with comment period (79 FR 40354), we assigned specialty for low volume services based on dominant specialty. As discussed in the CY 2012 final rule with comment period (76 FR 73187 through 73189), we applied an additional list of service-level overrides for purposes of calculating MP RVUs for a number of cardiothoracic surgery codes. Therefore, we note that there are certain codes for which we have previously applied expected specialty overrides for purposes of calculating MP RVUs based on assumptions regarding low Medicare volume. Because we are consolidating policies for low volume service expected specialty overrides into a single list for PE and MP, and because we do not believe that there is a reason to assume different specialties for purposes of calculating PE RVUs than for MP RVUs for any particular code, we

are also proposing to assign the specialty mix solely based on the claims data for any code that does not meet the low volume threshold of 99 allowed services or fewer in the previous year, for the purposes of calculating MP RVUs.

Given that we now annually recalibrate MP RVUs based on claims data, and in light of our proposed introduction of the service-level specialty override for low volume services, we believe that there would no longer be a need to apply service-level MP crosswalks in order to assign a specialty-mix risk factor. Contingent on finalizing this proposal, we are also proposing to eliminate general use of an MP-specific specialty-mix crosswalk for new and revised codes. However, we would continue to consider, in conjunction with annual recommendations, specific recommendations from the public and the RUC regarding specialty mix assignments for new and revised codes, particularly in cases where coding changes are expected to result in differential reporting of services by specialty, or where the new or revised code is expected to be low-volume. Absent such information, we would derive the specialty mix assumption for the first year for a new or revised code from the specialty mix used for purposes of ratesetting. In subsequent years when claims data are available, we would assign the specialty based on claims data unless the service does not exceed the low volume threshold (99 or fewer allowed services). If the service is low volume, we would assign the expected specialty, establishing a new expected specialty through rulemaking as needed, which is consistent with our approach for developing PE RVUs.

Step (5): Rescale for budget neutrality.

The statute requires that changes to fee schedule RVUs must be budget neutral. Thus, the last step is to adjust for relativity by rescaling the proposed MP RVUs so that the total proposed resource based MP RVUs are equal to the total current resource based MP RVUs scaled by the ratio of current aggregate MP and work RVUs. This scaling is necessary in order to maintain the work RVUs for individual services from year to year while also maintaining the overall relationship among work, PE, and MP RVUs.

The proposed resource based MP RVUs are shown in Addendum B, which is available on the CMS Web site under the downloads section of the CY 2018 PFS proposed rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html.*

Because a different share of the resources involved in furnishing PFS services is reflected in each of the three fee schedule components, implementation of the resource based MP RVU update will have much smaller payment effects than implementing updates of resource based work RVUs and resource based PE RVUs. On average, work represents about 50.9 percent of payment for a service under the fee schedule, PE about 44.8 percent, and MP about 4.3 percent. Therefore, a 25 percent change in PE RVUs or work RVUs for a service would result in a change in payment of about 11 to 13 percent. In contrast, a corresponding 25 percent change in MP values for a service would yield a change in payment of only about one percent. Estimates of the effects on payment by specialty type can be found in section VI. of this proposed rule.

Additional information on our proposed methodology for updating the MP RVUs may be found in our contractor's report, ''*Interim Report on Malpractice RVUs for the CY 2018 PFS Proposed Rule,*'' which is available on the CMS Web site under the downloads section of the CY 2018 PFS proposed rule located at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html.*

We are seeking comments on these proposals for calculating the MP RVUs for CY 2018.

C. Medicare Telehealth Services

1. Billing and Payment for Telehealth Services

Several conditions must be met for Medicare to make payments for telehealth services under the PFS. The service must be on the list of Medicare telehealth services and meet all of the following additional requirements:

- The service must be furnished via an interactive telecommunications system.
- The service must be furnished by a physician or other authorized practitioner.
- The service must be furnished to an eligible telehealth individual.
- The individual receiving the service must be located in a telehealth originating site.

When all of these conditions are met, Medicare pays a facility fee to the originating site and makes a separate payment to the distant site practitioner furnishing the service.

Section 1834(m)(4)(F)(i) of the Act defines Medicare telehealth services to include professional consultations, office visits, office psychiatry services, and any additional service specified by the Secretary, when furnished via a telecommunications system. We first implemented this statutory provision, which was effective October 1, 2001, in the CY 2002 PFS final rule with comment period (66 FR 55246). We established a process for annual updates to the list of Medicare telehealth services as required by section 1834(m)(4)(F)(ii) of the Act in the CY 2003 PFS final rule with comment period (67 FR 79988).

As specified at § 410.78(b), we generally require that a telehealth service be furnished via an interactive telecommunications system. Under § 410.78(a)(3), an interactive telecommunications system is defined as multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and distant site physician or practitioner.

Telephones, facsimile machines, and stand-alone electronic mail systems do not meet the definition of an interactive telecommunications system. An interactive telecommunications system is generally required as a condition of payment; however, section 1834(m)(1) of the Act allows the use of asynchronous ''store-and-forward'' technology when the originating site is part of a federal telemedicine demonstration program in Alaska or Hawaii. As specified in § 410.78(a)(1), asynchronous store-and-forward is the transmission of medical information from an originating site for review by the distant site physician or practitioner at a later time.

Medicare telehealth services may be furnished to an eligible telehealth individual notwithstanding the fact that the practitioner furnishing the telehealth service is not at the same location as the beneficiary. An eligible telehealth individual is an individual enrolled under Part B who receives a telehealth service furnished at a telehealth originating site.

Practitioners furnishing Medicare telehealth services are reminded that these services are subject to the same non-discrimination laws as other services, including the effective communication requirements for persons with disabilities of section 504 of the Rehabilitation Act and language access for persons with limited English proficiency, as required under Title VI of the Civil Rights Act of 1964. For more information, see *http://www.hhs.gov/ocr/civilrights/resources/specialtopics/hospitalcommunication.*

Practitioners furnishing Medicare telehealth services submit claims for

telehealth services to the Medicare Administrative Contractors (MACs) that process claims for the service area where their distant site is located. Section 1834(m)(2)(A) of the Act requires that a practitioner who furnishes a telehealth service to an eligible telehealth individual be paid an amount equal to the amount that the practitioner would have been paid if the service had been furnished without the use of a telecommunications system.

Originating sites, which can be one of several types of sites specified in the statute where an eligible telehealth individual is located at the time the service is being furnished via a telecommunications system, are paid a facility fee under the PFS for each Medicare telehealth service. The statute specifies both the types of entities that can serve as originating sites and the geographic qualifications for originating sites. For geographic qualifications, our regulation at § 410.78(b)(4) limits originating sites to those located in rural health professional shortage areas (HPSAs) or in a county that is not included in a metropolitan statistical area (MSA).

Historically, we have defined rural HPSAs to be those located outside of MSAs. Effective January 1, 2014, we modified the regulations regarding originating sites to define rural HPSAs as those located in rural census tracts as determined by the Federal Office of Rural Health Policy of the Health Resources and Services Administration (HRSA) (78 FR 74811). Defining ''rural'' to include geographic areas located in rural census tracts within MSAs allows for broader inclusion of sites within HPSAs as telehealth originating sites. Adopting the more precise definition of ''rural'' for this purpose expands access to health care services for Medicare beneficiaries located in rural areas. HRSA has developed a Web site tool to provide assistance to potential originating sites to determine their geographic status. To access this tool, see our Web site at *https://www.cms.gov/MedicareMedicare-General-Information/Telehealth/index.html.*

An entity participating in a federal telemedicine demonstration project that has been approved by, or received funding from, the Secretary as of December 31, 2000 is eligible to be an originating site regardless of its geographic location.

Effective January 1, 2014, we also changed our policy so that geographic status for an originating site would be established and maintained on an annual basis, consistent with other telehealth payment policies (78 FR 74400). Geographic status for Medicare telehealth originating sites for each calendar year is now based upon the status of the area as of December 31 of the prior calendar year.

For a detailed history of telehealth payment policy, see 78 FR 74399.

2. Adding Services to the List of Medicare Telehealth Services

As noted previously, in the CY 2003 PFS final rule with comment period (67 FR 79988), we established a process for adding services to or deleting services from the list of Medicare telehealth services. This process provides the public with an ongoing opportunity to submit requests for adding services. Under this process, we assign any qualifying request to make additions to the list of telehealth services to one of two categories. Revisions to criteria that we use to review requests in the second category were finalized in the CY 2012 PFS final rule with comment period (76 FR 73102). The two categories are:

- *Category 1:* Services that are similar to professional consultations, office visits, and office psychiatry services that are currently on the list of telehealth services. In reviewing these requests, we look for similarities between the requested and existing telehealth services for the roles of, and interactions among, the beneficiary, the physician (or other practitioner) at the distant site and, if necessary, the telepresenter, a practitioner who is present with the beneficiary in the originating site. We also look for similarities in the telecommunications system used to deliver the service; for example, the use of interactive audio and video equipment.
- *Category 2:* Services that are not similar to the current list of telehealth services. Our review of these requests includes an assessment of whether the service is accurately described by the corresponding code when furnished via telehealth and whether the use of a telecommunications system to furnish the service produces demonstrated clinical benefit to the patient. Submitted evidence should include both a description of relevant clinical studies that demonstrate the service furnished by telehealth to a Medicare beneficiary improves the diagnosis or treatment of an illness or injury or improves the functioning of a malformed body part, including dates and findings, and a list and copies of published peer reviewed articles relevant to the service when furnished via telehealth. Our evidentiary standard of clinical benefit does not include minor or incidental benefits.

Some examples of clinical benefit include the following:

- Ability to diagnose a medical condition in a patient population without access to clinically appropriate in-person diagnostic services.
- Treatment option for a patient population without access to clinically appropriate in-person treatment options.
- Reduced rate of complications.
- Decreased rate of subsequent diagnostic or therapeutic interventions (for example, due to reduced rate of recurrence of the disease process).
- Decreased number of future hospitalizations or physician visits.
- More rapid beneficial resolution of the disease process treatment.
- Decreased pain, bleeding, or other quantifiable symptom.
- Reduced recovery time.

The list of telehealth services, including the proposed additions described below, is included in the Downloads section to this proposed rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.*

Requests to add services to the list of Medicare telehealth services must be submitted and received no later than December 31 of each calendar year to be considered for the next rulemaking cycle. For example, qualifying requests submitted before the end of CY 2017 will be considered for the CY 2019 proposed rule. Each request to add a service to the list of Medicare telehealth services must include any supporting documentation the requester wishes us to consider as we review the request. Because we use the annual PFS rulemaking process as a vehicle for making changes to the list of Medicare telehealth services, requesters should be advised that any information submitted is subject to public disclosure for this purpose. For more information on submitting a request for an addition to the list of Medicare telehealth services, including where to mail these requests, see our Web site at *https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/index.html.*

3. Submitted Requests To Add Services to the List of Telehealth Services for CY 2018

Under our existing policy, we add services to the telehealth list on a category 1 basis when we determine that they are similar to services on the existing telehealth list for the roles of, and interactions among, the beneficiary, physician (or other practitioner) at the distant site and, if necessary, the telepresenter. As we stated in the CY

2012 final rule with comment period (76 FR 73098), we believe that the category 1 criteria not only streamline our review process for publicly requested services that fall into this category, but also expedite our ability to identify codes for the telehealth list that resemble those services already on this list.

We received several requests in CY 2016 to add various services as Medicare telehealth services effective for CY 2018. The following presents a discussion of these requests, and our proposals for additions to the CY 2018 telehealth list. Of the requests received, we found that three services were sufficiently similar to services currently on the telehealth list to qualify on a category 1 basis. Therefore, we are proposing to add the following services to the telehealth list on a category 1 basis for CY 2018:

- HCPCS code G0296 (Counseling visit to discuss need for lung cancer screening using low dose ct scan (ldct) (service is for eligibility determination and shared decision making))

We found that the service described by HCPCS code G0296 is sufficiently similar to office visits currently on the telehealth list. We believe that all the components of this service, which include assessment of the patient's risk for lung cancer, shared decision making, and counseling on the risks and benefits of LDCT, can be furnished via interactive telecommunications technology.

- CPT codes 90839 and 90840 (Psychotherapy for crisis; first 60 minutes) and (Psychotherapy for crisis; each additional 30 minutes (List separately in addition to code for primary service))

We are proposing to add CPT codes 90839 and 90840 on a Category 1 basis. We found that these services are sufficiently similar to the psychotherapy services currently on the telehealth list, even though these codes describe patients requiring more urgent care and psychotherapeutic interventions to minimize the potential for psychological trauma. However, we did identify one specific element of the services as described in the CPT prefatory language that we concluded may or may not be able to be furnished via telehealth, depending on the circumstances of the particular service. The CPT prefatory language specifies that the treatment described by these codes requires, ''mobilization of resources to defuse the crisis and restore safety.'' In many cases, we believe that a distant site practitioner would have access (via telecommunication technology, presumably) to the resources at the originating site that would allow for the kind of mobilization required to restore safety. However, we also believe that it would be possible that a distant site practitioner would not have access to such resources. Therefore we are proposing to add the codes to the telehealth list with the explicit condition of payment that the distant site practitioner be able to mobilize resources at the originating site to defuse the crisis and restore safety, when applicable, when the codes are furnished via telehealth. ''Mobilization of resources'' is a description used in the CPT prefatory language. We believe the critical element of ''mobilizing resources'' is the ability to communicate with and inform staff at the originating site to the extent necessary to restore safety. We solicit comment on whether our assumption that the remote practitioner is able to mobilize resources at the originating site to defuse the crisis and restore safety is valid.

Although we did not receive specific requests, we are also proposing to add four additional services to the telehealth list based on our review of services. All four of these codes are add-on codes that describe additional elements of services currently on the telehealth list and would only be considered telehealth services when billed as an add-on to codes already on the telehealth list. The four codes are:

- CPT code 90785 (Interactive complexity (List separately in addition to the code for primary procedure))
- CPT codes 96160 and 96161 (Administration of patient-focused health risk assessment instrument (*e.g.*, health hazard appraisal) with scoring and documentation, per standardized instrument) and (Administration of caregiver-focused health risk assessment instrument (*e.g.*, depression inventory) for the benefit of the patient, with scoring and documentation, per standardized instrument))
- HCPCS code G0506 (Comprehensive assessment of and care planning for patients requiring chronic care management services (list separately in addition to primary monthly care management service))

In the case of CPT codes 96160 and 96161, and HCPCS code G0506, we recognize that these services may not necessarily be ordinarily furnished in-person with a physician or billing practitioner. Ordinarily, services that are typically not considered to be face-to-face services do not need to be on the list of Medicare telehealth services; however, these services would only be considered Medicare telehealth services when billed with a base code that is also on the telehealth list and would not be considered Medicare telehealth services when billed with codes not on the Medicare telehealth list. We believe that by adding these services to the telehealth list it will be administratively easier for practitioners who report these services in association with a visit code that is furnished via telehealth as both the base code and the add-on code would be reported with the telehealth place of service.

We also received requests to add services to the telehealth list that do not meet our criteria for Medicare telehealth services. We are not proposing to add the following procedures for physical, occupational, and speech therapy, initial hospital care, and online E/M by physician/qualified healthcare professional to the telehealth list, or changing the requirements for ESRD procedure codes furnished via telehealth, for the reasons noted in the paragraphs that follow.

a. Physical and Occupational Therapy and Speech-Language Pathology Services: CPT Codes—

- CPT code 97001: Now deleted and reported as CPT code 97161 (Physical therapy evaluation: low complexity, requiring these components: A history with no personal factors and/or comorbidities that impact the plan of care; An examination of body system(s) using standardized tests and measures addressing 1–2 elements from any of the following: Body structures and functions, activity limitations, and/or participation restrictions; A clinical presentation with stable and/or uncomplicated characteristics; and Clinical decision making of low complexity using standardized patient assessment instrument and/or measurable assessment of functional outcome.)
- CPT code 97002: Now deleted and reported as CPT code 97162 (Physical therapy evaluation: moderate complexity, requiring these components: A history of present problem with 1–2 personal factors and/or comorbidities that impact the plan of care; An examination of body systems using standardized tests and measures in addressing a total of 3 or more elements from any of the following: Body structures and functions, activity limitations, and/or participation restrictions; An evolving clinical presentation with changing characteristics; and Clinical decision making of moderate complexity using standardized patient assessment instrument and/or measurable assessment of functional outcome)
- CPT code 97003: Now deleted and reported as CPT code 97165 (Occupational therapy evaluation, low

complexity, requiring these components: An occupational profile and medical and therapy history, which includes a brief history including review of medical and/or therapy records relating to the presenting problem; An assessment(s) that identifies 1–3 performance deficits (*i.e.*, relating to physical, cognitive, or psychosocial skills) that result in activity limitations and/or participation restrictions; and Clinical decision making of low complexity, which includes an analysis of the occupational profile, analysis of data from problem-focused assessment(s), and consideration of a limited number of treatment options. Patient presents with no comorbidities that affect occupational performance. Modification of tasks or assistance (*e.g.*, physical or verbal) with assessment(s) is not necessary to enable completion of evaluation component)

- CPT code 97004: Now deleted and reported as CPT code 97166 (Occupational therapy evaluation, moderate complexity, requiring these components: An occupational profile and medical and therapy history, which includes an expanded review of medical and/or therapy records and additional review of physical, cognitive, or psychosocial history related to current functional performance; An assessment(s) that identifies 3–5 performance deficits (*i.e.*, relating to physical, cognitive, or psychosocial skills) that result in activity limitations and/or participation restrictions; and Clinical decision making of moderate analytic complexity, which includes an analysis of the occupational profile, analysis of data from detailed assessment(s), and consideration of several treatment options. Patient may present with comorbidities that affect occupational performance. Minimal to moderate modification of tasks or assistance (*e.g.*, physical or verbal) with assessment(s) is necessary to enable patient to complete evaluation component))
- CPT code 97110 (Therapeutic procedure, 1 or more areas, each 15 minutes; therapeutic exercises to develop strength and endurance, range of motion and flexibility)
- CPT code 97112 (Therapeutic procedure, 1 or more areas, each 15 minutes; neuromuscular reeducation of movement, balance, coordination, kinesthetic sense, posture, and/or proprioception for sitting and/or standing activities)
- CPT code 97116 (Therapeutic procedure, 1 or more areas, each 15 minutes; gait training (includes stair climbing))
- CPT code 97535 (Self-care/home management training (*e.g.*, activities of daily living (ADL) and compensatory training, meal preparation, safety procedures, and instructions in use of assistive technology devices/adaptive equipment) direct one-on-one contact, each 15 minutes)
- CPT code 97750 (Physical performance test or measurement (*e.g.*, musculoskeletal, functional capacity), with written report, each 15 minutes)
- CPT code 97755 (Assistive technology assessment (*e.g.*, to restore, augment or compensate for existing function, optimize functional tasks and/or maximize environmental accessibility), direct one-on-one contact, with written report, each 15 minutes).
- CPT code 97760 (Orthotic(s) management and training (including assessment and fitting when not otherwise reported), upper extremity(s), lower extremity(s) and/or trunk, each 15 minutes).
- CPT code 97761 (Prosthetic training, upper and/or lower extremity(s), each 15 minutes).
- CPT code 97762 (Checkout for orthotic/prosthetic use, established patient, each 15 minutes).

In section 1834(m)(4)(E) of the Act, the statute specifies the types of practitioners who may furnish and bill for Medicare telehealth services as those practioners under section 1842(b)(18)(C) of the Act. Physical therapists, occupational therapists and speech-language pathologists are not among the practitioners identified in section 1842(b)(18)(C) of the Act. We stated in the CY 2017 PFS final rule (81 FR 80198) that because these services are predominantly furnished by physical therapists, occupational therapists and speech-language pathologists, we did not believe it would be appropriate to add them to the list of telehealth services at this time. In an ensuing submission for 2018, the original requester suggested that we might propose these services to be added to the list so that they can be furnished via telehealth when furnished by eligible distant site practitioners. We considered that possibility; however, since the majority of the codes are furnished by therapy professionals over 90 percent of the time, we believe that adding therapy services to the telehealth list that explicitly describe the services of the kinds of professionals not included on the statutory list of distant site practitioners could result in confusion about who is authorized to furnish and bill for these services when furnished via telehealth. We also note that several of these services, such as CPT code 97761, require directly physically manipulating the beneficiary, which is not possible to do through telecommunications technology. Therefore, we are not proposing to add these codes to the list of Medicare telehealth services.

b. Initial Hospital Care Services: CPT Codes—

- CPT code 99221 (Initial hospital care, per day, for the evaluation and management of a patient, which requires these 3 key components: A detailed or comprehensive history; A detailed or comprehensive examination; and Medical decision making that is straightforward or of low complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the problem(s) requiring admission are of low severity.)
- CPT code 99222 (Initial hospital care, per day, for the evaluation and management of a patient, which requires these 3 key components: A comprehensive history; A comprehensive examination; and Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the problem(s) requiring admission are of moderate severity.)
- CPT code 99223 (Initial hospital care, per day, for the evaluation and management of a patient, which requires these 3 key components: A comprehensive history; A comprehensive examination; and Medical decision making of high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the problem(s) requiring admission are of high severity.)

We previously considered a request to add these codes to the telehealth list. As we stated in the CY 2011 PFS final rule with comment period (75 FR 73315), while initial inpatient consultation services are currently on the list of approved telehealth services, there are no services on the current list of telehealth services that resemble initial hospital care for an acutely ill patient by the admitting practitioner who has ongoing responsibility for the patient's

treatment during the hospital course. Therefore, consistent with prior rulemaking, we are not proposing initial hospital care services be added to the Medicare telehealth services list on a category 1 basis.

The initial hospital care codes describe the first visit of the hospitalized patient by the admitting practitioner who may or may not have seen the patient in the decision-making phase regarding hospitalization. Based on the description of the services for these codes, we believe it is critical that the initial hospital visit by the admitting practitioner be conducted in person to ensure that the practitioner with ongoing treatment responsibility comprehensively assesses the patient's condition upon admission to the hospital through a thorough in-person examination. Additionally, the requester submitted no additional research or evidence that the use of a telecommunications system to furnish the service produces demonstrated clinical benefit to the patient; therefore, we also are not proposing to add initial hospital care services to the Medicare telehealth services list on a category 2 basis.

We note that Medicare beneficiaries who are being treated in the hospital setting can receive reasonable and necessary E/M services using other HCPCS codes that are currently on the Medicare telehealth list including those for subsequent hospital care, initial and followup telehealth inpatient and emergency department consultations, as well as initial and followup critical care telehealth consultations.

Therefore, we do not propose to add the initial hospital care services to the list of Medicare telehealth services for CY 2018.

c. Online E/M by physician/QHP: CPT Code—

- CPT code 99444 (Online evaluation and management service provided by a physician or other qualified health care professional who may report evaluation and management services provided to an established patient or guardian, not originating from a related E/M service provided within the previous 7 days, using the Internet or similar electronic communications network)

As we indicated in the CY 2016 final rule with comment period (80 FR 71061), CPT code 99444 is assigned a status indicator of ''N'' (Non-covered service). Under section 1834(m)(2)(A) of the Act, Medicare pays the physician or practitioner furnishing a telehealth service an amount equal to the amount that would have been paid if the service was furnished without the use of a telecommunications system. Because CPT code 99444 is currently non-covered, there would be no Medicare payment if this service were furnished without the use of a telecommunications system. Because this code is a non-covered service for which no Medicare payment may be made under the PFS, we do not propose to add online E/M services to the list of Medicare telehealth services for CY 2018.

d. Monthly Capitation Payment (MCP) for ESRD-Related Services for Home Dialysis, by Age: CPT Codes—

- CPT codes 90963 (End-stage renal disease (ESRD) related services for home dialysis per full month, for patients younger than 2 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents); 90964 (End-stage renal disease (ESRD) related services for home dialysis per full month, for patients 2–11 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents); 90965 (End-stage renal disease (ESRD) related services for home dialysis per full month, for patients 12–19 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents); and 90966 (End-stage renal disease (ESRD) related services for home dialysis per full month, for patients 20 years of age and older)
- 90967 (End-stage renal disease (ESRD) related services for dialysis less than a full month of service, per day; for patients younger than 2 years of age); 90968 (End-stage renal disease (ESRD) related services for dialysis less than a full month of service, per day; for patients 2–11 years of age); and 90969 (End-stage renal disease (ESRD) related services for dialysis less than a full month of service, per day; for patients 12–19 years of age); and 90970 (End-stage renal disease (ESRD) related services for dialysis less than a full month of service, per day; for patients 20 years of age and older).

In the CY 2004 PFS final rule (68 FR 63216), we established G-codes for ESRD monthly capitation payments (MCPs), which were replaced by CPT codes in CY 2009 (73 FR 69898). The services described by CPT codes 90963 through 90966 were added to the Medicare telehealth list in CY 2005 (69 FR 66276) and CPT codes 90967 through 90970 were added to the Medicare telehealth list in the CY 2017 PFS final rule (81 FR 80194); however, we specified that the required clinical examination of the vascular access site must be furnished face-to-face ''hands on'' (without the use of an interactive telecommunications system) by a physician, clinical nurse specialist (CNS), nurse practitioner (NP), or physician assistant (PA). The American Telemedicine Association (ATA) submitted a new request for CY 2018 requesting that we allow telehealth coverage of ESRD procedure codes without in-person exam of the catheter access site monthly. Our current policy reflects our understanding that evaluation of the integrity and functionality of the access site is a critical element of the services described by the codes and that this element cannot be performed via telecommunications technology. The requester did not submit evidence to support the assertion that effective examination of the access site can be executed via telecommunications technology. Therefore, for CY 2018, we are not proposing any changes to the policy requiring that the MCP practitioner must furnish at least one face-to-face encounter with the home dialysis patient per month for clinical examination of the catheter access site. However, we are interested in more information about current clinically accepted care practices and to what extent telecommunications technology can be used to examine the access site. We are also interested in information about the clinical standards of care regarding the frequency of the evaluation of the access site.

In summary, we are proposing to add the following codes to the list of Medicare telehealth services beginning in CY 2018 on a category 1 basis:

- HCPCS code G0296 (Counseling visit to discuss need for lung cancer screening using low dose CT scan (ldct) (service is for eligibility determination and shared decision making)).
- HCPCS code G0506 (Comprehensive assessment of and care planning for patients requiring chronic care management services (list separately in addition to primary monthly care management service)).
- CPT code 90785 (Interactive complexity (List separately in addision to the code for primary procedure)).
- CPT codes 90839 and 90840 (Psychotherapy for crisis; first 60 minutes) and (Psychotherapy for crisis; each additional 30 minutes (List separately in addition to code for primary procedure)).
- CPT codes 96160 and 96161 (Administration of patient-focused health risk assessment instrument (*e.g.,* health hazard appraisal) with scoring and documentation, per standardized

instrument) and (Administration of caregiver-focused health risk assessment instrument (*e.g.,* depression inventory) for the benefit of the patient, with scoring and documentation, per standardized instrument).

4. Elimination of the Required Use of the GT Modifier on Professional Claims

Medicare has required distant site practitioners to report one of two longstanding HCPCS modifiers when reporting telehealth services. Current guidance instructs practitioners to submit claims for telehealth services using the appropriate CPT or HCPCS code for the professional service along with the telehealth modifier GT (via interactive audio and video telecommunications systems). For federal telemedicine demonstration programs in Alaska or Hawaii, practitioners are instructed to submit claims using the appropriate CPT or HCPCS code for the professional service along with the telehealth modifier GQ if telehealth services are performed ''via an asynchronous telecommunications system.'' By coding and billing these modifiers with a service code, practitioners are certifying that both the broad and code-specific telehealth requirements have been met.

In the CY 2017 PFS final rule (81 FR 80201), we finalized payment policies regarding Medicare's use of a new Place of Service (POS) Code describing services furnished via telehealth. The new POS code became effective January 1, 2017, and we believe its use is redundant with the requirements to apply the GT modifier for telehealth services. We did not propose to implement a change to the modifier requirements during CY 2017 rulemaking because at the time of the CY 2017 PFS proposed rule, we did not know whether the telehealth POS code would be made effective for January 1, 2017. However, we noted in the CY 2017 PFS final rule that, like the modifiers, use of the telehealth POS code certifies that the service meets the telehealth requirements.

Because a valid POS code is required on professional claims for all services, and the appropriate reporting of the telehealth POS code serves to indicate both the provision of the service via telehealth and certification that the requirements have been met, we believe that it is unnecessary to also require the distant site practitioner report the GT modifier on the claim. Therefore, we are proposing to eliminate the required use of the GT modifier on professional claims. Because institutional claims do not use a POS code, we propose for distant site practitioners billing under CAH Method II to continue to use the GT modifier on institutional claims. For purposes of the federal telemedicine demonstration programs in Alaska or Hawaii, we propose to retain the GQ modifier to maintain the distinction between synchronous and asynchronous telehealth services, as reflected in statute.

5. Comment Solicitation on Medicare Telehealth Services

We have received numerous requests from stakeholders to expand access to telehealth services. As noted above, Medicare payment for telehealth services is restricted by statute, which establishes the services initially eligible for Medicare telehealth and limits the use of telehealth by defining both eligible originating sites (the location of the beneficiary) and the distant site practitioners who may furnish and bill for telehealth services. Originating sites are limited both by geography and provider setting. We have the authority to add to the list of eligible services based on our annual process, but cannot change the limitations relating to geography, patient setting, or type of furnishing practitioner because these requirements are specified in statute. For CY 2018, we are seeking information regarding ways that we might further expand access to telehealth services within the current statutory authority and pay appropriately for services that take full advantage of communication technologies.

6. Comment Solicitation on Remote Patient Monitoring

In addition to the broad comment solicitation regarding Medicare telehealth services, we are also specifically seeking comment on whether to make separate payment for CPT codes that describe remote patient monitoring. We note that remote patient monitoring services would generally not be considered Medicare telehealth services as defined under section 1834(m) of the Act. Rather, like the interpretation by a physician of an actual electrocardiogram or electroencephalogram tracing that has been transmitted electronically, these services involve the interpretation of medical information without a direct interaction between the practitioner and beneficiary. As such, they are paid under the same conditions as in-person physicians' services with no additional requirements regarding permissible originating sites or use of the telehealth place of service code.

We are particularly interested in comments regarding CPT code 99091 (Collection and interpretation of physiologic data (*e.g.,* ECG, blood pressure, glucose monitoring) digitally stored and/or transmitted by the patient and/or caregiver to the physician or other qualified health care professional, qualified by education, training, licensure/regulation (when applicable) requiring a minimum of 30 minutes of time). This code is currently assigned a procedure status of B (bundled). As with many other bundled codes, we currently assign RVUs for this code based on existing RUC recommendations, even though we have considered the services described by the code to be bundled with other services. In addition to comments on the payment status and valuation for this code (the RUC-recommended value, specifically) we are seeking information about the circumstances under which this code might be reported for separate payment, including how to differentiate the time related to these services from other services, including care management services. For example, PFS payment for analysis of patient-generated health data is considered included in chronic care management (CCM) services (CPT codes 99487, 99489, and 99490) to the extent that this activity is medically necessary and performed as part of CCM (see the CY 2015 PFS final rule (79 FR 67727), CY 2016 PFS final rule (81 FR 80244), and the CMS FAQ available at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Downloads/Payment_for_CCM_Services_FAQ.pdf.*). We also seek comment from beneficiaries and beneficiary advocacy organizations on the value of such services and what protections might be necessary to assure that beneficiaries are properly informed that they are receiving a remote monitoring service, since beneficiaries would be required to pay standard cost sharing for such services. Finally, regarding CPT code 99091, we are seeking available information regarding potential utilization assumptions we might make for the service for purposes of PFS ratesetting, were we to make it payable for CY 2018 or in the future; since making such asumptions would be necessary to implement separate payment. We note that since the PFS is a budget neutral system, any increase in payment made for particular services would result in decreases in payment for other services, and the degree of that decrease would depend, in large part, on the utilization assumptions.

We are also seeking comment on other existing codes that describe extensive use of communications technology for

consideration for future rulemaking, including CPT code 99090 (Analysis of clinical data stored in computers (*e.g.,* ECGs, blood pressures, hematologic data)). CPT code 99090 is also assigned a procedure status of B (bundled). However, we do not have RUC recommended values for this service, and therefore, currently do not assign RVUs.

E. Proposed Potentially Misvalued Services Under the Physician Fee Schedule

1. Background

Section 1848(c)(2)(B) of the Act directs the Secretary to conduct a periodic review, not less often than every 5 years, of the RVUs established under the PFS. Section 1848(c)(2)(K) of the Act requires the Secretary to periodically identify potentially misvalued services using certain criteria and to review and make appropriate adjustments to the relative values for those services. Section 1848(c)(2)(L) to the Act also requires the Secretary to develop a process to validate the RVUs of certain potentially misvalued codes under the PFS, using the same criteria used to identify potentially misvalued codes, and to make appropriate adjustments.

As discussed in section II.H. of this proposed rule, each year we develop appropriate adjustments to the RVUs taking into account recommendations provided by the American Medical Association/Specialty Society Relative Value Scale Update Committee (RUC), the Medicare Payment Advisory Commission (MedPAC), and others. For many years, the RUC has provided us with recommendations on the appropriate relative values for new, revised, and potentially misvalued PFS services. We review these recommendations on a code-by-code basis and consider these recommendations in conjunction with analyses of other data, such as claims data, to inform the decision-making process as authorized by law. We may also consider analyses of work time, work RVUs, or direct PE inputs using other data sources, such as Department of Veteran Affairs (VA), National Surgical Quality Improvement Program (NSQIP), the Society for Thoracic Surgeons (STS), and the Physician Quality Reporting System (PQRS) databases. In addition to considering the most recently available data, we assess the results of physician surveys and specialty recommendations submitted to us by the RUC for our review. We also consider information provided by other stakeholders. We conduct a review to assess the appropriate RVUs in the context of contemporary medical practice. We note that section 1848(c)(2)(A)(ii) of the Act authorizes the use of extrapolation and other techniques to determine the RVUs for physicians' services for which specific data are not available and requires us to take into account the results of consultations with organizations representing physicians who provide the services. In accordance with section 1848(c) of the Act, we determine and make appropriate adjustments to the RVUs.

In its March 2006 Report to the Congress (*http://www.medpac.gov/documents/reports/Mar06_EntireReport.pdf?sfvrsn=0*), MedPAC discussed the importance of appropriately valuing physicians' services, noting that misvalued services can distort the market for physicians' services, as well as for other health care services that physicians order, such as hospital services. In that same report MedPAC postulated that physicians' services under the PFS can become misvalued over time. MedPAC stated, ''When a new service is added to the physician fee schedule, it may be assigned a relatively high 0l value because of the time, technical skill, and psychological stress that are often required to furnish that service. Over time, the work required for certain services would be expected to decline as physicians become more familiar with the service and more efficient in furnishing it.'' We believe services can also become overvalued when PE declines. This can happen when the costs of equipment and supplies fall, or when equipment is used more frequently than is estimated in the PE methodology, reducing its cost per use. Likewise, services can become undervalued when physician work increases or PE rises.

As MedPAC noted in its March 2009 Report to Congress (*http://www.medpac.gov/documents/reports/march-2009-report-to-congress-medicare-payment-policy.pdf?sfvrsn=0*), in the intervening years since MedPAC made the initial recommendations, CMS and the RUC have taken several steps to improve the review process. Also, section 1848(c)(2)(K)(ii) of the Act augments our efforts by directing the Secretary to specifically examine, as determined appropriate, potentially misvalued services in the following categories:

- Codes that have experienced the fastest growth.
- Codes that have experienced substantial changes in practice expenses.
- Codes that describe new technologies or services within an appropriate time period (such as 3 years) after the relative values are initially established for such codes.
- Codes which are multiple codes that are frequently billed in conjunction with furnishing a single service.
- Codes with low relative values, particularly those that are often billed multiple times for a single treatment.
- Codes that have not been subject to review since implementation of the fee schedule.
- Codes that account for the majority of spending under the physician fee schedule.
- Codes for services that have experienced a substantial change in the hospital length of stay or procedure time.
- Codes for which there may be a change in the typical site of service since the code was last valued.
- Codes for which there is a significant difference in payment for the same service between different sites of service.
- Codes for which there may be anomalies in relative values within a family of codes.
- Codes for services where there may be efficiencies when a service is furnished at the same time as other services.
- Codes with high intra-service work per unit of time.
- Codes with high practice expense relative value units.
- Codes with high cost supplies.
- Codes as determined appropriate by the Secretary.

Section 1848(c)(2)(K)(iii) of the Act also specifies that the Secretary may use existing processes to receive recommendations on the review and appropriate adjustment of potentially misvalued services. In addition, the Secretary may conduct surveys, other data collection activities, studies, or other analyses, as the Secretary determines to be appropriate, to facilitate the review and appropriate adjustment of potentially misvalued services. This section also authorizes the use of analytic contractors to identify and analyze potentially misvalued codes, conduct surveys or collect data, and make recommendations on the review and appropriate adjustment of potentially misvalued services. Additionally, this section provides that the Secretary may coordinate the review and adjustment of any RVU with the periodic review described in section 1848(c)(2)(B) of the Act. Section 1848(c)(2)(K)(iii)(V) of the Act specifies that the Secretary may make appropriate coding revisions

(including using existing processes for consideration of coding changes) that may include consolidation of individual services into bundled codes for payment under the physician fee schedule.

2. Progress in Identifying and Reviewing Potentially Misvalued Codes

To fulfill our statutory mandate, we have identified and reviewed numerous potentially misvalued codes as specified in section 1848(c)(2)(K)(ii) of the Act, and we plan to continue our work examining potentially misvalued codes in these areas over the upcoming years. As part of our current process, we identify potentially misvalued codes for review, and request recommendations from the RUC and other public commenters on revised work RVUs and direct PE inputs for those codes. The RUC, through its own processes, also identifies potentially misvalued codes for review. Through our public nomination process for potentially misvalued codes established in the CY 2012 PFS final rule with comment period, other individuals and stakeholder groups submit nominations for review of potentially misvalued codes as well.

Since CY 2009, as a part of the annual potentially misvalued code review and Five-Year Review process, we have reviewed approximately 1,700 potentially misvalued codes to refine work RVUs and direct PE inputs. We have assigned appropriate work RVUs and direct PE inputs for these services as a result of these reviews. A more detailed discussion of the extensive prior reviews of potentially misvalued codes is included in the CY 2012 PFS final rule with comment period (76 FR 73052 through 73055). In the CY 2012 PFS final rule with comment period (76 FR 73055 through 73958), we finalized our policy to consolidate the review of physician work and PE at the same time, and established a process for the annual public nomination of potentially misvalued services.

In the CY 2013 PFS final rule with comment period, we built upon the work we began in CY 2009 to review potentially misvalued codes that have not been reviewed since the implementation of the PFS (so-called ''Harvard-valued codes''). In CY 2009 (73 FR 38589), we requested recommendations from the RUC to aid in our review of Harvard-valued codes that had not yet been reviewed, focusing first on high-volume, low intensity codes. In the fourth Five-Year Review (76 FR 32410), we requested recommendations from the RUC to aid in our review of Harvard-valued codes with annual utilization of greater than 30,000. In the CY 2013 PFS final rule with comment period, we identified specific Harvard-valued services with annual allowed charges that total at least $10,000,000 as potentially misvalued. In addition to the Harvard-valued codes, in the CY 2013 PFS final rule with comment period we finalized for review a list of potentially misvalued codes that have stand-alone PE (codes with physician work and no listed work time and codes with no physician work that have listed work time).

In the CY 2016 PFS final rule with comment period, we finalized for review a list of potentially misvalued services, which included eight codes in the neurostimulators analysis-programming family (CPT 95970–95982). We also finalized as potentially misvalued 103 codes identified through our screen of high expenditure services across specialties.

In the CY 2017 PFS final rule, we finalized for review a list of potentially misvalued services, which included eight codes in the end-stage renal disease home dialysis family (CPT codes 90963–90970). We also finalized as potentially misvalued 19 codes identified through our screen for 0-day global services that are typically billed with an evaluation and management (E/M) service with modifier 25.

3. CY 2018 Identification and Review of Potentially Misvalued Services

In the CY 2012 PFS final rule with comment period (76 FR 73058), we finalized a process for the public to nominate potentially misvalued codes. The public and stakeholders may nominate potentially misvalued codes for review by submitting the code with supporting documentation by February 10 of each year. Supporting documentation for codes nominated for the annual review of potentially misvalued codes may include the following:

- Documentation in peer reviewed medical literature or other reliable data that there have been changes in physician work due to one or more of the following: technique, knowledge and technology, patient population, site-of-service, length of hospital stay, and work time.
- An anomalous relationship between the code being proposed for review and other codes.
- Evidence that technology has changed physician work.
- Analysis of other data on time and effort measures, such as operating room logs or national and other representative databases.
- Evidence that incorrect assumptions were made in the previous valuation of the service, such as a misleading vignette, survey, or flawed crosswalk assumptions in a previous evaluation.
- Prices for certain high cost supplies or other direct PE inputs that are used to determine PE RVUs are inaccurate and do not reflect current information.
- Analyses of work time, work RVU, or direct PE inputs using other data sources (for example: Department of Veteran Affairs (VA) National Surgical Quality Improvement Program (NSQIP), the Society for Thoracic Surgeons (STS) National Database, and the Physician Quality Reporting System (PQRS) databases).
- National surveys of work time and intensity from professional and management societies and organizations, such as hospital associations.

We evaluate the supporting documentation submitted with the nominated codes and assess whether the nominated codes appear to be potentially misvalued codes appropriate for review under the annual process. In the following year's PFS proposed rule, we publish the list of nominated codes and indicate whether we are proposing each nominated code as a potentially misvalued code. The public has the opportunity to comment on these and all other proposed potentially misvalued codes. In that year's final rule, we finalize our list of potentially misvalued codes.

After we issued the CY 2017 PFS final rule, we received a nomination and supporting documentation for one code to be considered as potentially misvalued. We evaluated the supporting documentation for this nominated code to ascertain whether the submitted information demonstrated that the code should be proposed as potentially misvalued.

CPT code 27279 (Arthrodesis, sacroiliac joint, percutaneous or minimally invasive (indirect visualization), with image guidance, includes obtaining bone graft when performed, and placement of transfixing device) was nominated for review as a potentially misvalued code because the current work RVU is potentially undervalued and stakeholders recommend that it should be increased to 14.23. We are proposing this code as a potentially misvalued code. In the CY 2017 PFS final rule, we noted that some assertions regarding appropriate values for the dialysis vascular access codes newly created in CY 2017 (CPT codes 36901 through 36909) did not include data that would warrant increases to the work RVUs. However, we urged interested stakeholders to consider

submitting robust data regarding costs for these and other services (81 FR 80294). We have continued to receive feedback from stakeholders regarding the work valuation of these codes. Stakeholders have expressed concerns regarding the typical patient for these procedures as reflected in the information included in the RUC recommendations for CY 2017 and the importance of appropriate payment for ensuring access to care for Medicare beneficiaries. Therefore, we are seeking additional comment and continuing to request robust data regarding the potentially misvalued work RVUs for CPT codes 36901 through 36909 and considering alternate work valuations for CY 2018, such as the RUC-recommended work RVUs from CY 2017, or other potential values based on submission of data through the public comment process. We note that the RUC recommended work RVUs for these services are displayed in the CY 2017 PFS final rule (81 FR 80290 through 80296). We have received conflicting information about the direct PE inputs for CPT codes 88184 (Flow cytometry, cell surface, cytoplasmic, or nuclear marker, technical component only; first marker) and 88185 (Flow cytometry, cell surface, cytoplasmic, or nuclear marker, technical component only; each additional marker (List separately in addition to code for first marker)), and we are proposing these codes as potentially misvalued so that they can be reviewed again because some stakeholders have suggested the clinical labor and supplies that were previously finalized are no longer accurate.

We have received information suggesting that the work RVUs for emergency department visits may not appropriately reflect the full resources involved in furnishing these services. Specifically, stakeholders have expressed concerns that the work RVUs for these services have been undervalued given the increased acuity of the patient population and the heterogeneity of the sites, such as freestanding and off-campus emergency departments, where emergency department visits are furnished. We are, therefore, seeking comment on whether CPT codes 99281–99385 (Emergency department visits for the evaluation and management of a patient) should be reviewed under the misvalued code initiative.

For over a decade, CMS has collaborated with the RUC to regularly prioritize codes for review by using the categories specified in the statute or as determined appropriate. We generally have referred to these categories as ''misvalued code screens.'' To supplement ongoing RUC identification of potentially misvalued codes through established screens, CMS regularly uses PFS rulemaking to identify other screens for use in identifying potentially misvalued codes. For example, in recent years, CMS has prioritized the following screens:

- Codes with low work RVUs commonly billed in multiple units per single encounter.
- Codes with high volume and low work RVUs.
- Codes with site-of-service-anomalies.
- E/M codes.
- PFS high expenditure services.
- Services with standalone PE procedure time.
- Services with anomalous time.
- Contractor Medical Director identified potentially misvalued codes.
- Codes with higher total Medicare payments in office than in hospital or ASC.
- Publicly nominated potentially misvalued codes.
- 0-day global services that are typically billed with an evaluation and management (E/M) service with modifier 25.

Although we are not proposing a new screen for CY 2018, we continue to believe that it is important to prioritize codes for review under the misvalued code initiative. As a result, we are seeking public comment on the best approach for developing screens, as well as what particular new screens we might consider. We will consider these comments for future rulemaking.

F. Payment Incentive for the Transition From Traditional X-Ray Imaging to Digital Radiography and Other Imaging Services

Section 502(a)(1) of Division O, Title V of the Consolidated Appropriations Act of 2016 (Pub. L. 114–113) amended section 1848(b) of the Act by establishing a new paragraph (9) of subsection (b). Section 1848(b)(9)(B) of the Act provides for a 7 percent reduction in payments for the technical component (TC) for imaging services made under the PFS that are X-rays (including the technical component portion of a global service) taken using computed radiography technology furnished during CYs 2018, 2019, 2020, 2021, or 2022, and for a 10 percent reduction for the technical component of such imaging services furnished during CY 2023 or a subsequent year. Computed radiography technology is defined for purposes of this paragraph as cassette-based imaging that utilizes an imaging plate to create the image involved. Section 1848(b)(9) of the Act also requires implementation of the reduction in payments through appropriate mechanisms, which can include the use of modifiers. In accordance with section 1848(c)(2)(B)(v)(X) of the Act, the adjustments under section 1848(b)(9)(A) of the Act are exempt from the budget neutrality requirement.

We stated in the CY 2017 PFS proposed rule that because the required reductions in PFS payment for the TC of imaging services (including the TC portion of a global service) that are X-rays taken using computed radiography technology did not apply for CY 2017, we would address implementation of section 1848(b)(9)(B) of the Act in future rulemaking. Therefore, to implement the provisions of section 1848(b)(9)(B) of the Act relating to the payment reduction for the TC (including the TC portion of a global service) of X-rays taken using computed radiography technology during CY 2018 or subsequent years, we are proposing to establish a new modifier to be used on claims for these services.

We are proposing that beginning January 1, 2018, this modifier would be required to be used when reporting imaging services for which payment is made under the PFS that are X-rays (including the X-ray component of a packaged service) taken using computed radiography technology. The modifier would be required on claims for the technical component of the X-ray service, including when the service is billed globally because the PFS payment adjustment is made to the technical component regardless of whether it is billed globally, or billed separately using the TC modifier. The modifier must be used to report the specific services that are subject to the payment reduction and accurate use is subject to audit. The use of this proposed modifier to indicate an X-ray taken using computed radiography would result in a 7 percent reduction for CYs 2018 through 2022 and a 10 percent reduction for CY 2023 or a subsequent calendar year to the payments for the TC for such imaging services furnished as specified under section 1848(b)(9)(B) of the Act.

G. Proposed Payment Rates Under the Medicare Physician Fee Schedule for Nonexcepted Items and Services Furnished by Nonexcepted Off-Campus Provider-Based Departments of a Hospital

1. Background

Sections 1833(t)(1)(B)(v) and (t)(21) of the Act require that certain items and services furnished by certain off-campus

provider-based departments (PBDs) (collectively referenced here as nonexcepted items and services furnished by nonexcepted off-campus PBDs) shall not be considered covered OPD services for purposes of payment under the OPPS, and payment for those nonexcepted items and services furnished on or after January 1, 2017 shall be made under the applicable payment system. In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79713), we finalized the PFS as the ''applicable payment system'' for most nonexcepted items and services furnished by off-campus PBDs.

As part of that discussion, we indicated that, in response to public comments received on the proposed payment policies for nonexcepted items and services, we would issue an interim final rule with comment period (the CY 2017 interim final rule, 81 FR 79720 through 79729) to establish payment policies under the PFS for nonexcepted items and services furnished on or after January 1, 2017. In the following paragraphs, we propose the payment policies under the PFS for nonexcepted items and services furnished during CY 2018. The CY 2017 interim final rule can be found on the Internet at *https://www.gpo.gov/fdsys/pkg/FR-2016-11-14/pdf/2016-26515.pdf.* We anticipate responding to public comments and finalizing the CY 2017 interim final rule in future PFS rulemaking.

2. Payment Mechanism

Coding and payment policies under the PFS have long recognized the differences between the portions of services for which direct costs generally are incurred by practitioners and the portions of services for which direct costs generally are incurred by facilities. At present, the coding and RVUs established for particular groups of services under the PFS generally reflect such direct cost differences. As described in section II.B of this proposed rule, we establish separate nonfacility and facility RVUs for many HCPCS codes describing particular services paid under the PFS. For many other services, we establish separate RVUs for the professional component and the technical component of the service described by the same HCPCS code. For other services, we establish RVUs for the different HCPCS codes that segregate and describe the discrete professional and technical aspects of particular services.

Because hospitals with nonexcepted off-campus PBDs that furnish nonexcepted items and services are likely to furnish a broader range of services than other provider or supplier types for which there is a separately valued technical component under the PFS, for CY 2017, we established a new set of payment rates under the PFS that reflected the relative resource costs of furnishing the technical component of a broad range of services to be paid under the PFS specific to the off-campus PBD of a hospital with packaging (bundling) rules that are unique to the hospital outpatient setting under the OPPS.

In principle, the coding and billing mechanisms required to make appropriate payment to hospitals for nonexcepted items and services furnished by nonexcepted off-campus PBDs are parallel to those used to make payment for the technical component services for a range of supplier types paid under the PFS. That is, payments to hospitals are made for the technical aspect of services, while physicians and other practitioners report the professional aspect of these same services. In some cases, the entities reporting the technical aspect of services use the same coding that is used by the individuals reporting the professional services. In other cases, different coding applies. We are proposing to maintain this mechanism for CY 2018.

3. Establishment of Payment Rates

Using the relativity among OPPS payments to establish rates for the nonexcepted items and services furnished by nonexcepted off-campus PBDs and billed by hospitals under the PFS was only one aspect of establishing the necessary relativity of these services under the PFS more broadly. It was necessary to estimate the relativity of these services compared to PFS services furnished in other settings. For CY 2017, we used our best estimate of the more general relativity between the technical component of PFS services furnished in nonexcepted off-campus PBDs and all other PFS services furnished in other settings using the limited information available to us at that time. As described in the CY 2017 interim final rule (81 FR 79722 through 79726), we estimated that for CY 2017, scaling the OPPS payment rates by 50 percent would strike an appropriate balance that avoided potentially underestimating the relative resources involved in furnishing services in nonexcepted off-campus PBDs as compared to the services furnished in other settings for which payment was made under the PFS. Specifically, we established site-specific rates under the PFS for the technical component of the broad range of nonexcepted items and services furnished by nonexcepted off-campus PBDs to be paid under the PFS that was based on the OPPS payment amount for the same items and services, scaled downward by 50 percent. We called this adjustment the ''PFS Relativity Adjuster.'' The PFS Relativity Adjuster refers to the percentage of the OPPS payment amount paid under the PFS for a nonexcepted item or service to the non-excepted off-campus PBD under this policy.

a. Methodology for Establishing CY 2017 PFS Relativity Adjuster

In developing the CY 2017 interim final rule, we began by analyzing hospital outpatient claims data from January 1 through August 26, 2016, that contained the ''PO'' modifier signifying that they were billed by an off-campus department of a hospital paid under the OPPS other than a remote location, a satellite facility, or a dedicated emergency department (ED). We noted that the use of the ''PO'' modifier was a new mandatory reporting requirement for CY 2016. We limited our analysis to those claims billed on the 13X Type of Bill because those claims were used for Medicare Part B billing under the OPPS. We then identified the top (most frequently billed) 25 major codes that were billed by claim line; that is, items and services that were separately payable or conditionally packaged. Specifically, we restricted our analysis to codes with OPPS status indicators ''J1'', ''J2'', ''Q1'', ''Q2'', ''Q3'', ''S'', ''T'', or ''V''. We did not include separately payable drugs or biologicals in this analysis because those drugs or biologicals were not paid under the PFS under the CY 2017 interim final rule. As such, under the CY 2017 interim final rule, the PFS Relativity Adjuster did not apply to separately payable drugs and biologicals furnished by a nonexcepted PBD. Similarly, we excluded codes assigned an OPPS status indicator ''A'' because the services described by those codes were already paid at a rate under a fee schedule other than the OPPS and payment for those nonexcepted items and services was not changed by the rates established under the CY 2017 interim final rule. Next, for the same major codes (or analogous codes in the rare instance that different coding applies under the OPPS than the PFS), we compared the CY 2016 payment rate under the OPPS to a CY 2016 payment rate under the PFS attributable to the nonprofessional relative resource costs involved in furnishing the services.

The most frequently billed service with the ''PO'' modifier was described by HCPCS code G0463 (Hospital outpatient clinic visit for assessment and management of a patient), which is paid under APC 5012; the total number

of CY 2016 claim lines for that service was approximately 6.7 million as of August 2016. In CY 2016, the OPPS payment rate for APC 5012 was $102.12. Because there were multiple CPT codes (CPT codes 99201 through 99215) used under the PFS for billing that service, an exact comparison between the $102.12 OPPS payment rate for APC 5012 and the payment rate for a single CPT code billed under the PFS was not possible. However, for purposes of the analysis, we examined the difference between the nonfacility payment rates and the facility payment rates under the PFS for CPT codes 99213 and 99214, which were the billing codes for a Level III and a Level IV office visit. While we did not have data to precisely determine the equivalent set of PFS visit codes to use for the comparison, we believed that, based on the distribution of services billed for the visit codes under the PFS and the distribution of the visit codes under the OPPS from the last time period the CPT codes were used under the OPPS in CY 2014, those two codes provided reliable points of comparison. For CPT code 99213, the difference between the nonfacility payment rate and the facility payment rate under the PFS in CY 2016 was $21.86, which was 21 percent of the OPPS payment rate for APC 5012 of $102.12. For CPT code 99214, the difference between the nonfacility payment rate and the facility payment rate under the PFS in CY 2016 was $29.02, which was 28 percent of the OPPS payment rate for APC 5012. However, we recognized that, due to the more extensive packaging that occurred under the OPPS for services provided along with clinic visits relative to the more limited packaging that occurred under the PFS for office visits, those payment rates were not entirely comparable.

We then assessed the next 24 major codes most frequently billed on the 13X claim form by hospitals. We removed HCPCS code 36591 (Collection of blood specimen from a completely implantable venous access device) because, under current PFS policies, the code is used only to pay separately under the PFS when no other service was on the claim. We also removed HCPCS code G0009 (Administration of Pneumococcal Vaccine) because there was no payment for the code under the PFS. For the remaining 22 major codes most frequently billed, we estimated the amount that would have been paid to the physician in the office setting under the PFS for practice expenses not associated with the professional component of the service. As indicated in Table 9, this amount reflected (1) the difference between the PFS nonfacility payment rate and the PFS facility rate, (2) the technical component, or (3) in instances where payment would have been made only to the facility or only to the physician, the full nonfacility rate. This estimate ranged from zero percent to 137.8 percent of the OPPS payment rate for a code. Overall, the average (weighted by claim line volume times rate) of the nonfacility payment rate estimate for the PFS compared to the estimate for the OPPS for the 22 remaining major codes was 45 percent.

TABLE 9—COMPARISON OF CY 2016 OPPS PAYMENT RATE TO CY 2016 PFS PAYMENT RATE FOR TOP HOSPITAL CODES BILLED USING THE "PO" MODIFIER

HCPCS code	Code description	Total claim lines	CY 2016 OPPS payment rate	CY 2016 applicable PFS technical payment amount estimate	Col (5) as a percent of OPPS	PFS estimate
(1)	(2)	(3)	(4)	(5)		(6)
96372 ..	Injection beneath the skin or into muscle for therapy, diagnosis, or prevention.	338,444	$42.31	$25.42	60.1	Single rate paid exclusively to either practitioner or facility: Full nonfacility rate.
71020 ..	X-ray of chest, 2 views, front and side.	333,203	60.80	16.83	27.7	Technical component: Full nonfacility rate.
93005 ..	Routine electrocardiogram (EKG) with tracing using at least 12 leads.	318,099	55.94	8.59	15.4	Technical component: Full nonfacility rate.
96413 ..	Infusion of chemotherapy into a vein up to 1 hour.	254,704	280.27	136.41	48.7	Single rate paid exclusively to either practitioner or facility: Full nonfacility rate.
93798 ..	Physician services for outpatient heart rehabilitation with continuous EKG monitoring per session.	203,926	103.92	11.10	10.7	Nonfacility rate—Facility rate.
96375 ..	Injection of different drug or substance into a vein for therapy, diagnosis, or prevention.	189,140	42.31	22.56	53.3	Single rate paid exclusively to either practitioner or facility: Full nonfacility rate.
93306 ..	Ultrasound examination of heart including color-depicted blood flow rate, direction, and valve function.	179,840	416.80	165.77	39.8	Technical component: Full nonfacility rate.
77080 ..	Bone density measurement using dedicated X-ray machine.	155,513	100.69	31.15	30.9	Technical component: Full nonfacility rate.
77412 ..	Radiation treatment delivery	137,241	194.35	267.86	137.8	Technical component (Full nonfacility rate) based on weighted averages for the following PFS codes: G6011; G6012; G6013; and G6014.

TABLE 9—COMPARISON OF CY 2016 OPPS PAYMENT RATE TO CY 2016 PFS PAYMENT RATE FOR TOP HOSPITAL CODES BILLED USING THE ''PO'' MODIFIER—Continued

HCPCS code	Code description	Total claim lines	CY 2016 OPPS payment rate	CY 2016 applicable PFS technical payment amount estimate	Col (5) as a percent of OPPS	PFS estimate
(1)	(2)	(3)	(4)	(5)		(6)
90853 ..	Group psychotherapy	123,282	69.65	0.36	0.5	Nonfacility rate—Facility rate.
96365 ..	Infusion into a vein for therapy, prevention, or diagnosis up to 1 hour.	122,641	173.18	69.82	40.3	Nonfacility rate—Facility rate.
20610 ..	Aspiration and/or injection of large joint or joint capsule.	106,769	223.76	13.96	6.2	Nonfacility rate—Facility rate.
11042 ..	Removal of skin and tissue first 20 sq cm or less.	99,134	225.55	54.78	24.3	Nonfacility rate—Facility rate.
96367 ..	Infusion into a vein for therapy prevention or diagnosis additional sequential infusion up to 1 hour.	98,930	42.31	30.79	72.8	Single rate paid exclusively to either practitioner or facility: Full nonfacility rate.
93017 ..	Exercise or drug-induced heart and blood vessel stress test with EKG tracing and monitoring.	96,312	220.35	39.74	18.0	Technical component: Full nonfacility rate.
77386 ..	Radiation therapy delivery	81,925	505.51	347.30	68.7	Technical component: Nonfacility rate for CPT code G6015 (analogous code used under the PFS).
78452 ..	Nuclear medicine study of vessels of heart using drugs or exercise multiple studies.	79,242	1,108.46	412.82	37.2	Technical component: Full nonfacility rate.
74177 ..	CT scan of abdomen and pelvis with contrast.	76,393	347.72	220.20	63.3	Technical component: Full nonfacility rate.
71260 ..	CT scan chest with contrast	75,052	236.86	167.21	70.6	Technical component: Full nonfacility rate.
71250 ..	CT scan chest	74,570	112.49	129.61	115.2	Technical component: Full nonfacility rate.
73030 ..	X-ray of shoulder, minimum of 2 views.	71,330	60.80	19.33	31.8	Technical component: Full nonfacility rate.
90834 ..	Psychotherapy, 45 minutes with patient and/or family member.	70,524	125.04	0.36	0.3	Nonfacility rate—Facility rate.
Weighted Average (claim line volume*rate) of the PFS payment compared to OPPS payment for the 22 major codes:						45%

As noted with the clinic visits, we recognized that there were limitations to our data analysis, including that OPPS payment rates include the costs of packaged items or services billed with the separately payable code, and therefore the comparison to rates under the PFS was not a one-to-one comparison. Also, we included only a limited number of services, and noted that additional services may have different patterns than the services described. After considering the payment differentials for major codes billed by off-campus departments of hospitals with the ''PO'' modifier and based on the data limitations of our analysis, we adopted, with some exceptions noted below, a set of PFS payment rates that were based on a 50-percent PFS Relativity Adjuster to the OPPS payment rates (inclusive of packaging) for nonexcepted items and services furnished by nonexcepted off-campus PBDs in the CY 2017 interim final rule. Generally speaking, we arrived at the 50 percent PFS Relativity Adjuster by examining the 45-percent comparison noted above, the ASC payment rate—which was roughly 55 percent of the OPPS payment rate on average—and the payment rate differential for the large number of OPPS and PFS evaluation and management services, as described above. We recognized that the equivalent PFS nonfacility rates may be higher or lower on a code-specific basis than the rates that result from applying the overall PFS Relativity Adjuster to the OPPS payment rates on a code specific basis. However, we believed that, on the whole, the percentage reduction did not underestimate the overall relativity between the OPPS and the PFS based on the limited data that was available. We were concerned, however, that the 50 percent PFS Relativity Adjuster might overestimate PFS nonfacility payments relative to OPPS payments. For example, if we were able at the time to sufficiently estimate the effect of the packaging differences between the OPPS and PFS, we suspected that the equivalent portion of PFS payments for evaluation and management codes, and for PFS services on average, would likely have been less than 50 percent for the same services. We considered the 50 percent PFS Relativity Adjuster for CY 2017 to be a transitional policy until such time that we had more precise data to better

identify and value nonexcepted items and services furnished by nonexcepted off-campus PBDs and billed by hospitals.

We established several significant exceptions to the application of the 50 percent PFS Relativity Adjuster. For example, we did not apply the 50 percent PFS Relativity Adjuster to services that are currently paid under the OPPS based on payment rates from other Medicare fee schedules (including the PFS) on an institutional claim. The items and services that are assigned status indicator ''A'' in Addendum B to the CY 2017 OPPS/ASC final rule with comment period (available on the CMS Web site at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices-Items/CMS-1656-FC.html*) continue to be reported on an institutional claim and paid under the PFS, the CLFS, or the Ambulance Fee Schedule (ASC) without a payment reduction. Similarly, drugs and biologicals that are separately payable under the OPPS (identified by status indicator ''G'' or ''K'' in Addendum B to the CY 2017 OPPS/ASC final rule with comment period) are paid in accordance with section 1847A of the Act (that is, typically ASP + 6 percent), consistent with payment rules in the physician office setting. Drugs and biologicals that are unconditionally packaged under the OPPS and are not separately payable (that is, those drugs and biologicals assigned status indicator of ''N'' in Addendum B to the CY 2017 OPPS/ASC final rule with comment period) are bundled into the PFS payment and are not separately paid to hospitals billing for nonexcepted items and services furnished by nonexcepted off-campus PBDs. The full range of exceptions and adjustments to the otherwise applicable OPPS payment rate that were adopted in the new PFS site-of-service payment rates in the CY 2017 interim final rule can be found on the CMS Web site at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/CMS-1656-FC-2017-OPPS-Status-Indicator.zip.*

All nonexcepted items and services furnished by nonexcepted off-campus PBDs and billed by a hospital on an institutional claim with modifier ''PN'' (Nonexcepted service provided at an off-campus, outpatient, provider-based department of a hospital) are currently paid under the PFS at the rate established in the CY 2017 interim final rule. Specifically, nonexcepted off campus PBDs must report modifier ''PN'' on each UB–04 claim line to indicate a nonexcepted item or service, and otherwise continue to bill as they currently do. Further billing instructions on the PN modifier can be found in the January 2017 OPPS Quarterly Update (transmittal 3685, Change Request 9930) released December 22, 2016, available on the CMS Web site at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R3685CP.pdf.*

b. PFS Relativity Adjuster

As noted in the CY 2017 interim final rule, we considered the CY 2017 50 percent PFS Relativity Adjuster to be a transitional policy until such time that we had more precise data to better identify and value nonexcepted items and services furnished by nonexcepted off-campus PBDs and billed by hospitals. At present, we do not have more precise data than were available when we established the PFS Relativity Adjuster in the CY 2017 interim final rule, and we do not anticipate having such data until after the end of CY 2017, at the earliest. However, in developing a proposed policy for CY 2018, we have continued to explore options for modifying the calculation of the CY 2018 PFS Relativity Adjuster.

There is no consensus among stakeholders regarding the appropriate PFS Relativity Adjuster. Many stakeholders have suggested that making separate facility fee payments to hospitals under the PFS for all services that are separately paid under the OPPS itself undermines site-neutral payment because practitioners are only paid a single combined fee for many services when furnished in an office setting, while there are two separate fees (professional and facility) paid when the service is furnished in the hospital setting. We acknowledge that there are many cases where single fees are paid to practitioners for services furnished in an office setting while fees for comparable services when furnished in the hospital setting are paid to both the professional and facility entities. However, we do not agree that this necessarily means that overall payment cannot be site neutral. We point out that the sum of the professional and the facility portions of payment for a service furnished in a nonexcepted off-campus PBD or in a different institutional setting could be equivalent to a single fee paid to the professional in the office setting. In the case of some services, in fact, the single payment made under the PFS at the nonfacility rate exceeds the sum of the separate payments Medicare makes to the professional at the facility rate under the PFS and to the facility under the OPPS. We also note that there are many separately reportable services under the PFS (for example, the vast majority of services described by add-on codes) for which separate payment is made to physician offices but no separate payment is made under either the OPPS or under the site-specific PFS payments made to hospitals billing for nonexcepted items and services furnished by nonexcepted off-campus PBDs. For these reasons, we believe that the overall total payment made for services is more relevant to the goal of site neutrality than the quantity of individual payments made. Nonetheless, we continue to recognize and share stakeholders' concerns regarding the importance of equivalent overall payment for services, regardless of setting.

In considering the appropriate PFS Relativity Adjuster for CY 2018, we continue to believe that claims data from CY 2017, which are not yet available, are needed to guide potential changes to our general approach. In the absence of such data, however, we have continued to consider the appropriate PFS Relativity Adjuster based on the information that is available. In the analysis we used to establish the PFS Relativity Adjuster for CY 2017, we attempted to identify the appropriate value by comparing OPPS and PFS payment rates for services frequently reported in PBDs and described by the same codes under the two payment systems. As we acknowledged in the CY 2017 interim final rule, that data analysis did not include the most frequently billed service furnished in nonexcepted off-campus hospital PBDs, outpatient visits. Outpatient visits are reported using a single code under the OPPS and by one of ten different codes under the PFS.

Consistent with our previously stated concern that the PFS Relativity Adjuster for CY 2017 might be too small, generally resulting in greater overall payments to hospitals for services furnished by nonexcepted off-campus PBDs than would otherwise be paid under the PFS in the non-facility setting, we believe it is appropriate to propose changing the PFS Relativity Adjuster in order to ensure that payment made to these nonexcepted PBDs better aligns with these services that are the most frequently furnished in this setting.

For CY 2018, we propose to revise the PFS Relativity Adjuster for nonexcepted items and services furnished by nonexcepted off-campus PBDs to be 25 percent of the OPPS payment rate. We arrived at this proposed PFS Relativity Adjuster by making a code-level comparison for the service most

commonly billed in the off-campus PBD setting under the OPPS: A clinic visit reported using HCPCS code G0463. In order to determine the analogous payment for the technical aspects of this service under the PFS in nonfacility settings, we compared the CY 2017 OPPS national payment rate for HCPCS code G0463 ($102.12) to the difference between the nonfacility and facility PFS payment amounts under the PFS using CY 2017 rates for the weighted average of outpatient visits (CPT codes 99201–99205 and CPT codes 99211–99215) billed by physicians and other professionals in an outpatient hospital place of service.

This proposed 25 percent PFS Relativity Adjuster is based solely on the comparison for the visit services that reflect greater than 50 percent of services billed in off-campus PBDs. We continue to recognize that the comparison between the OPPS and PFS rates for other services varies greatly, and that there are other factors, including the specific mix of services furnished by non-excepted PBDs, policies related to packaging of codes under OPPS, and payment adjustments like MPPRs and bundling under the PFS that rely on empirical information about whether or not codes are billed on the same day, that contribute to the differences in aggregate payment amounts for a broader range of services. However, for CY 2018, as for CY 2017, we must set the PFS Relativity Adjuster prior to studying the CY 2017 claims data that might allow us to consider and incorporate many more factors, including the ones stated above. When we established the 50 percent PFS Relativity Adjuster for CY 2017, we stated that we did so with the goal of ensuring adequate payment but remained concerned that the resulting reduction was too small. For CY 2018, we are focused on ensuring that we do not overestimate the appropriate overall payments for these services. Until we are able to study claims data, we believe that the comparison between PFS and OPPS payment for the most common services furnished in off-campus PBDs, outpatient visits, is a better proxy than our previous approach.

We welcome stakeholder input with regard to this analysis and the resulting rate. We also request comment on whether we should adopt a different PFS Relativity Adjuster, such as 40 percent, that represents a relative middle ground between the CY 2017 PFS Relativity Adjuster, selected to ensure adequate payment to hospitals and our proposed CY 2018 PFS Relativity Adjuster, selected to ensure that hospitals are not paid more than others would be paid through the PFS nonfacility rate. We intend to continue to study this issue and welcome comments regarding potential future refinements to payment rates for non-excepted items and services furnished by non-excepted off-campus PBDs as we gain more experience with these new site-of-service PFS rates.

Finally, we note that for CY 2018, as in recent years, the proposed annual update to OPPS payments exceeds the proposed annual update to PFS payments. Because we are proposing to make a single, across-the-board and, by necessity, imprecise adjustment to OPPS payment rates to establish PFS payment rates for nonexcepted items and services furnished by nonexcepted off-campus PBDs, we expect that the actual difference between OPPS and PFS payment rates for nonexcepted items and services furnished by nonexcepted off-campus PBDs falls in a range which includes our proposed PFS Relativity Adjuster (that is, the actual differential may differ from our proposed PFS Relativity Adjuster). As such, taking into account the differential between the OPPS and PFS annual updates by making an adjustment to the PFS Relativity Adjuster our proposal for CY 2018 would presume a level of precision in our estimates that is simply not present in our analysis. Therefore, we will not adjust our proposal to reflect the relative updates to PFS and OPPS between CY 2017 and CY 2018, and instead note that the differential between the OPPS and PFS payment update for CY 2018 is a factor that suggests that the proposed PFS Relativity Adjuster may overestimate PFS nonfacility payment relative to OPPS payments; in future years, we intend to more precisely account for any differential between these two update factors.

c. Geographic Adjustments

For CY 2017, we established class-specific geographic practice cost indices (GPCIs) under the PFS exclusively used to adjust these site-specific, technical component rates for nonexcepted items and services furnished in nonexcepted off-campus PBDs. These class-specific GPCIs are parallel to the geographic adjustments made under the OPPS based on the hospital wage index. We believed it was appropriate to adopt the hospital wage index areas for purposes of geographic adjustment because non-excepted off-campus PBDs are still considered to be part of a hospital, and the PFS payments to these entities will be limited to the subset of PFS services furnished by hospitals. We also believed it was appropriate, as an initial matter for CY 2017, to adopt the actual wage index values for these hospitals in addition to the wage index areas. The PFS GPCIs that would otherwise currently apply are not based on the hospital wage index areas. For CY 2018, we are proposing to continue using the authority under section 1848(e)(1)(B) of the Act to maintain a class-specific set of GPCIs for these site-specific technical component rates that are based both on the hospital wage index areas and the hospital wage index value themselves. For purposes of payment to hospitals, this means that the geographic adjustments used under the OPPS continue to apply.

d. Coding Consistency

For most services, the same HCPCS codes are used to describe services paid under both the PFS and the OPPS. There are two notable exceptions that describe high-volume services. The first is the set of codes that describe evaluation and management (E/M) services which are reported under the PFS using the 5 levels of CPT codes describing new or established patient visits (for a total of 10 codes). However, since CY 2014, these visits have been reported under the OPPS using the single HCPCS code G0463 (Hospital Outpatient Clinic Visit) (see 78 FR 75042). We are proposing to maintain the current PFS payment rate for HCPCS code G0463 based on the OPPS payment rate modified by the PFS Relativity Adjuster.

The second is a set of radiation treatment delivery and imaging guidance services that are reported using different codes under the PFS and the OPPS. CMS established HCPCS Level II G codes to describe radiation treatment delivery services when furnished in the physician office setting (see 79 FR 67666 through 67667). However, these HCPCS G codes are not recognized under the OPPS; rather, CPT codes are used to describe these services when furnished in the HOPD. Both sets of codes were implemented for CY 2015 and were maintained for CY 2016. Under the PFS, there is a particular statutory provision under section 1848(c)(2)(K) of the Act that required maintenance of the CY 2016 coding and payment inputs for these services for CY 2017 and also for CY 2018. Accordingly, the proposed CY 2018 PFS rates for these services are calculated based on the maintenance of the CY 2016 coding and payment inputs. Because non-excepted items and services furnished by a nonexcepted off-campus PBD are paid under the PFS, and we are required to maintain the CY 2016 coding and payment inputs for these services under

the CY 2018 PFS, we are proposing to maintain payment amounts for nonexcepted items and services furnished by a nonexcepted off-campus PBD consistent with the payments that would be made to other facilities under the PFS. That is, nonexcepted off-campus PBDs submitting claims for these nonexcepted items and services will continue to bill the HCPCS G codes established under the PFS to describe radiation treatment delivery services. Under this proposal, the nonexcepted off-campus PBD must append modifier PN to each applicable claim line for these nonexcepted items and services, even though the PFS Relativity Adjuster will not apply. The payment amount for these services would be set to reflect the technical component rate for the code under the PFS.

4. OPPS Payment Adjustments

In the CY 2017 interim final rule, we adopted the packaging payment rates and multiple procedure payment reduction (MPPR) percentage that applied under the OPPS to establish the PFS payment rates for nonexcepted items and services furnished by nonexcepted off-campus PBDs and billed by hospitals. That is, the claims processing logic that was used for payments under the OPPS for comprehensive APCs (C–APCs), conditionally and unconditionally packaged items and services, and major procedures, was incorporated into the newly established PFS rates. We continue to believe it is necessary to incorporate the OPPS payment policies for C–APCs, packaged items and services, and the MPPR in order to maintain the integrity of the PFS Relativity Adjuster because the adjuster is intended in part to account for the methodological differences between the OPPS and the PFS rates that would otherwise apply. We also direct interested stakeholders to related proposed policies under the OPPS, since prospective changes in the applicable adjustments and policies would generally apply to non-excepted items and services furnished by nonexcepted off-campus PBDs for CY 2018. We are interested in comments regarding the applicability of particular prospective OPPS adjustments to non-excepted items and services.

In order to apply these OPPS payment policies and adjustments to non-excepted items and services, we propose that hospitals continue to bill on an institutional claim form that will pass through the Outpatient Code Editor and into the OPPS PRICER for calculation of payment. This approach will yield data based on claims for non-excepted items and services furnished by nonexcepted off-campus PBDs, which can be used to refine PFS payment rates for these services in future years.

There were several OPPS payment adjustments that we did not adopt in the CY 2017 interim final rule, including, but not limited to, outlier payments, the rural sole community hospital (SCH) adjustment, the cancer hospital adjustments, transitional outpatient payments, the hospital outpatient quality reporting payment adjustment, and the inpatient hospital deductible cap to the cost-sharing liability for a single hospital outpatient service. We believed these payment adjustments were expressly authorized for, and should be limited to, hospitals that are paid under the OPPS for covered OPD services in accordance with section 1833(t) of the Act. We continue to believe that these policies should not apply to non-excepted items and services furnished by nonexcepted off-campus PBDs, and are not proposing that they apply for CY 2018.

5. Partial Hospitalization Services

With respect to partial hospitalization programs (PHP) (intensive outpatient psychiatric day treatment programs furnished to patients as an alternative to inpatient psychiatric hospitalization or as a stepdown to shorten an inpatient stay and transition a patient to a less intensive level of care), section 1861(ff)(3)(A) of the Act specifies that a PHP is a program furnished by a hospital, to its outpatients, or by a CMHC. In the CY 2017 OPPS/ASC proposed rule (81 FR 45690), in the discussion of the proposed implementation of section 603 of Public Law 114–74, we noted that because CMHCs also furnish PHP services and are ineligible to be provider-based to a hospital, a nonexcepted off-campus PBD would be eligible for PHP payment if the entity enrolls and bills as a CMHC for payment under the OPPS. We further noted that a hospital may choose to enroll a nonexcepted off-campus PBD as a CMHC, provided it meets all Medicare requirements and conditions of participation.

Commenters expressed concern that without a clear payment mechanism for PHP services furnished by nonexcepted off-campus PBDs, access to partial hospitalization services would be limited, and pointed out the critical role PHPs play in the continuum of mental health care. Many commenters believed that Congress did not intend for partial hospitalization services to no longer be paid for by Medicare when such services are furnished by nonexcepted off-campus PBDs. Several commenters disagreed with the notion of enrolling as a CMHC in order to receive payment for PHP services. These commenters stated that hospital-based PHPs and CMHCs are inherently different in structure, operation, and payment, and noted that the conditions of participation for hospital departments and CMHCs are different. Several commenters requested that CMS find a mechanism to pay hospital-based PHPs in nonexcepted off-campus PBDs.

Because we shared the commenters' concerns, in the CY 2017 OPPS/ASC final rule with comment period and the CY 2017 interim final rule (81 FR 79727), we adopted payment for partial hospitalization items and services furnished by nonexcepted off-campus hospital-based PBDs under the PFS. When billed in accordance with the CY 2017 interim final rule, these partial hospitalization services are paid at the CMHC per diem rate for APC 5853, for providing three or more partial hospitalization services per day (81 FR 79727).

In the CY 2017 OPPS/ASC proposed rule (81 FR 45681), the CY 2017 OPPS/ASC final rule with comment period, and the CY 2017 interim final rule (81 FR 79727), we noted that when a beneficiary receives outpatient services in an off-campus department of a hospital, the total Medicare payment for those services is generally higher than when those same services are provided in a physician's office. Similarly, when partial hospitalization services are provided in a hospital-based PHP, Medicare pays more than when those same services are provided by a CMHC. Our rationale for adopting the CMHC per diem rate for APC 5853 as the PFS payment amount for nonexcepted off-campus PBDs providing PHP services is because CMHCs are freestanding entities that are not part of a hospital, but they provide the same PHP services as hospital-based PHPs (81 FR 79727). This is similar to the differences between freestanding entities paid under the PFS that furnish other services also provided by hospital-based entities. Similar to other entities currently paid for their technical component services under the PFS, we believe CMHCs would typically have lower cost structures than hospital-based PHPs, largely due to lower overhead costs and other indirect costs such as administration, personnel, and security. We believe that paying for nonexcepted hospital-based partial hospitalization services at the lower CMHC per diem rate aligns with section 603 of Pubic Law 114–74, while also preserving access to PHP services. In addition, nonexcepted off-campus PBDs will not be required to enroll as CMHCs

in order to bill and be paid for providing partial hospitalization services. However, a nonexcepted off-campus PBD that wishes to provide PHP services may still enroll as a CMHC if it chooses to do so and meets the relevant requirements. Finally, we recognize that because hospital-based PHPs are providing partial hospitalization services in the hospital outpatient setting, they can offer benefits that CMHCs do not have, such as an easier patient transition to and from inpatient care, and easier sharing of health information between the PHP and the inpatient staff. We are not proposing to require these PHPs to enroll as CMHCs but instead we are proposing to continue to pay non-excepted off-campus PBDs providing PHP items and services under the PFS. Further, we are proposing to continue to adopt the CMHC per diem rate for APC 5853 as the PFS payment amount for nonexcepted off-campus PBDs providing three or more PHP services per day in CY 2018.

6. Supervision Rules

The supervision rules that apply for hospitals continue to apply for nonexcepted off-campus PBDs that furnish nonexcepted items and services. The amendments made by section 603 of the Bipartisan Budget Act of 2015 (Pub. L. 114–74, enacted November 2, 2015) did not change the status of these PBDs, only the status of, and payment mechanism for, the services they furnish. These supervision requirements are specified in § 410.27.

7. Beneficiary Cost-Sharing

Under the PFS, the beneficiary copayment is generally 20 percent of the fee schedule amount, unless there is an applicable exception in accordance with the statute. All cost-sharing rules that apply under the PFS in accordance with section 1848(g) of the Act and section 1866(a)(2)(A) of the Act continue to apply for all nonexcepted items and services furnished by nonexcepted off-campus PBDs, regardless of the cost-sharing obligation under the OPPS.

8. CY 2019 and Future Years

We continue to believe the amendments made to the statute by section 603 of the Bipartisan Budget Act of 2015 intended to eliminate the Medicare payment incentive for hospitals to purchase physician offices, convert them to off-campus PBDs, and bill under the OPPS for items and services they furnish there. Therefore, we continue to believe the payment policy under this provision should ultimately equalize payment rates between nonexcepted off-campus PBDs and physician offices to the greatest extent possible, while allowing nonexcepted off-campus PBDs to bill in a straight-forward way for services they furnish.

We note that a full year of claims data regarding the mix of services reported using the ''PN'' modifier (from CY 2017) will first be available for use in PFS ratesetting for CY 2019. Under the current methodology, we would expect to use that data in order to ensure that Medicare payment to hospitals billing for non-excepted items and services furnished by nonexcepted off-campus PBDs under the PFS would reflect the relative resources involved in furnishing the items and services relative to other PFS services. We recognize that under our current approach, the payment rates would not be equal on a procedure-by-procedure basis, application of the PFS Relativity Adjuster would move toward equalizing payment rates in the aggregate between physician offices and nonexcepted off-campus PBDs to the extent appropriate. Therefore, for certain specialties, service lines, and nonexcepted off-campus PBD types, total Medicare payments for the same services might be either higher or lower when furnished by a nonexcepted off-campus PBD rather than in a physician office.

Depending on the mix of services for particular off-campus PBDs, we remain concerned that such specialty-specific patterns in payment differentials could result in continued incentives for hospitals to buy certain types of physician offices and convert them to nonexcepted off-campus PBDs; these are the incentives we believe Congress intended to avoid. However, continuing a policy similar to the one we are proposing in this proposed rule would allow hospitals to continue billing through a facility claim form and would allow for continuation of the packaging rules and cost report-based relative payment rate determinations under OPPS, which we believe are preferable to using the current valuation methodologies under the PFS that are not well-suited for nonexcepted items and services furnished by nonexcepted off-campus PBDs. Therefore, for CY 2019 and for future years, we intend to examine the claims data in order to determine not only the appropriate PFS Relativity Adjuster(s), but also to determine whether additional adjustments to the methodology are appropriate—especially with the goal of attaining site neutral payments to promote a level playing field under Medicare between physician office settings and nonexcepted off-campus PBD settings, without regard to the kinds of services furnished by particular off-campus PBDs. We solicit comments on potential changes to our methodology that would better account for these specialty-specific patterns.

H. Proposed Valuation of Specific Codes

1. Background: Process for Valuing New, Revised, and Potentially Misvalued Codes

Establishing valuations for newly created and revised CPT codes is a routine part of maintaining the PFS. Since inception of the PFS, it has also been a priority to revalue services regularly to make sure that the payment rates reflect the changing trends in the practice of medicine and current prices for inputs used in the PE calculations. Initially, this was accomplished primarily through the 5-year review process, which resulted in revised work RVUs for CY 1997, CY 2002, CY 2007, and CY 2012, and revised PE RVUs in CY 2001, CY 2006, and CY 2011. Under the 5-year review process, revisions in RVUs were proposed and finalized via rulemaking. In addition to the 5-year reviews, beginning with CY 2009, CMS and the RUC have identified a number of potentially misvalued codes each year using various identification screens, as discussed in section II.E.4 of this proposed rule. Historically, when we received RUC recommendations, our process had been to establish interim final RVUs for the potentially misvalued codes, new codes, and any other codes for which there were coding changes in the final rule for a year. Then, during the 60-day period following the publication of the final rule, we accepted public comment about those valuations. For services furnished during the calendar year following the publication of interim final rates, we paid for services based upon the interim final values established in the final rule. In the final rule with comment period for the subsequent year, we considered and responded to public comments received on the interim final values, and typically made any appropriate adjustments and finalized those values.

In the CY 2015 PFS final rule with comment period, we finalized a new process for establishing values for new, revised and potentially misvalued codes. Under the new process, we include proposed values for these services in the proposed rule, rather than establishing them as interim final in the final rule with comment period. Beginning with the CY 2017 PFS proposed rule, the new process was applicable to all codes, except for new codes that describe truly new services.

For CY 2017, we proposed new values in the CY 2017 PFS proposed rule for the vast majority of new, revised, and potentially misvalued codes for which we received complete RUC recommendations by February 10, 2016. To complete the transition to this new process, for codes where we established interim final values in the CY 2016 PFS final rule with comment period, we reviewed the comments received during the 60-day public comment period following release of the CY 2016 PFS final rule with comment period, and re-proposed values for those codes in the CY 2017 PFS proposed rule.

We considered public comments received during the 60-day public comment period for the proposed rule before establishing final values in the CY 2017 PFS final rule. As part of our established process we will adopt interim final values only in the case of wholly new services for which there are no predecessor codes or values and for which we do not receive recommendations in time to propose values. For CY 2017, we were not aware of any new codes that described such wholly new services. Therefore, we did not establish any code values on an interim final basis.

2. Methodology for Proposing Work RVUs

We conduct a review of each code identified in this section and review the current work RVU (if any), RUC-recommended work RVU, intensity, time to furnish the preservice, intraservice, and postservice activities, as well as other components of the service that contribute to the value. Our reviews of recommended work RVUs and time inputs have generally included, but have not been limited to, a review of information provided by the RUC, the Health Care Professionals Advisory Committee (HCPAC), and other public commenters, medical literature, and comparative databases, as well as a comparison with other codes within the PFS, consultation with other physicians and health care professionals within CMS and the federal government, as well as Medicare claims data. We have also assessed the methodology and data used to develop the recommendations submitted to us by the RUC and other public commenters and the rationale for the recommendations. In the CY 2011 PFS final rule with comment period (75 FR 73328 through 73329), we discussed a variety of methodologies and approaches used to develop work RVUs, including survey data, building blocks, crosswalks to key reference or similar codes, and magnitude estimation (see the CY 2011 PFS final rule with comment period (75 FR 73328 through 73329) for more information). When referring to a survey, unless otherwise noted, we mean the surveys conducted by specialty societies as part of the formal RUC process. We have used the building block methodology to construct, or deconstruct, the work RVU for a CPT code based on component pieces of the code.

Components that we have used in the building block approach may have included preservice, intraservice, or postservice time and post-procedure visits. When referring to a bundled CPT code, the building block components could be the CPT codes that make up the bundled code and the inputs associated with those codes. Magnitude estimation refers to a methodology for valuing work that determines the appropriate work RVU for a service by gauging the total amount of work for that service relative to the work for a similar service across the PFS without explicitly valuing the components of that work. In addition to these methodologies, we have frequently utilized an incremental methodology in which we value a code based upon its incremental difference between another code and another family of codes. The statute specifically defines the work component as the resources in time and intensity required in furnishing the service. Also, the published literature on valuing work has recognized the key role of time in overall work. For particular codes, we have refined the work RVUs in direct proportion to the changes in the best information regarding the time resources involved in furnishing particular services, either considering the total time or the intraservice time.

Several years ago, to aid in the development of preservice time recommendations for new and revised CPT codes, the RUC created standardized preservice time packages. The packages include preservice evaluation time, preservice positioning time, and preservice scrub, dress and wait time. Currently there are preservice time packages for services typically furnished in the facility setting (for example: Preservice time packages reflecting the different combinations of straightforward or difficult procedure, and straightforward or difficult patient). Currently, there are three preservice time packages for services typically furnished in the nonfacility setting.

We developed several standard building block methodologies to value services appropriately when they have common billing patterns. In cases where a service is typically furnished to a beneficiary on the same day as an E/M service, we believe that there is overlap between the two services in some of the activities furnished during the preservice evaluation and postservice time. Our longstanding adjustments have reflected a broad assumption that at least one-third of the work time in both the preservice evaluation and postservice period is duplicative of work furnished during the E/M visit. Accordingly, in cases where we have believed that the RUC has not adequately accounted for the overlapping activities in the recommended work RVU and/or times, we have adjusted the work RVU and/or times to account for the overlap. The work RVU for a service is the product of the time involved in furnishing the service multiplied by the intensity of the work. Preservice evaluation time and postservice time both have a long-established intensity of work per unit of time (IWPUT) of 0.0224, which means that 1 minute of preservice evaluation or postservice time equates to 0.0224 of a work RVU.

Therefore, in many cases when we have removed 2 minutes of preservice time and 2 minutes of postservice time from a procedure to account for the overlap with the same day E/M service, we have also removed a work RVU of 0.09 (4 minutes $\times$ 0.0224 IWPUT) if we have not believed the overlap in time had already been accounted for in the work RVU. The RUC has recognized this valuation policy and, in many cases, now addresses the overlap in time and work when a service is typically furnished on the same day as an E/M service.

We note that many commenters and stakeholders have expressed concerns with our ongoing adjustment of work RVUs based on changes in the best information we have had regarding the time resources involved in furnishing individual services. We have been particularly concerned with the RUC's and various specialty societies' objections to our approach given the significance of their recommendations to our process for valuing services and since much of the information we have used to make the adjustments is derived from their survey process. We are statutorily obligated to consider both time and intensity in establishing work RVUs for PFS services. As explained in the CY 2016 PFS final rule with comment period (80 FR 70933), we recognize that adjusting work RVUs for changes in time is not always a straightforward process, so we have applied various methodologies to identify several potential work values for individual codes.

We have observed that for many codes reviewed by the RUC, recommended work RVUs have appeared to be incongruous with recommended assumptions regarding the resource costs in time. This has been the case for a significant portion of codes for which we have recently established or proposed work RVUs that are based on refinements to the RUC-recommended values. When we have adjusted work RVUs to account for significant changes in time, we have begun by looking at the change in the time in the context of the RUC-recommended work RVU. When the recommended work RVUs have not appeared to account for significant changes in time, we have employed the different approaches to identify potential values that reconcile the recommended work RVUs with the recommended time values. Many of these methodologies, such as survey data, building block, crosswalks to key reference or similar codes, and magnitude estimation have long been used in developing work RVUs under the PFS. In addition to these, we have sometimes used the relationship between the old time values and the new time values for particular services to identify alternative work RVUs based on changes in time components.

In so doing, rather than ignoring the RUC-recommended value, we have used the recommended values as a starting reference and then applied one of these several methodologies to account for the reductions in time that we believe had not otherwise been reflected in the RUC-recommended value. When we have believed that such changes in time have already been accounted for in the RUC recommendation, then we have not made such adjustments. Likewise, we have not arbitrarily applied time ratios to current work RVUs to calculate proposed work RVUs. We have used the ratios to identify potential work RVUs and considered these work RVUs as potential options relative to the values developed through other options.

We do not imply that the decrease in time as reflected in survey values must equate to a one-to-one or linear decrease in newly valued work RVUs. Instead, we have believed that, since the two components of work are time and intensity, absent an obvious or explicitly stated rationale for why the relative intensity of a given procedure has increased, significant decreases in time should be reflected in decreases to work RVUs. If the RUC recommendation had appeared to disregard or dismiss the changes in time, without a persuasive explanation of why such a change should not be accounted for in the overall work of the service, then we have generally used one of the aforementioned referenced methodologies to identify potential work RVUs, including the methodologies intended to account for the changes in the resources involved in furnishing the procedure.

Several stakeholders, including the RUC, in general have objected to our use of these methodologies and deemed our actions in adjusting the recommended work RVUs as inappropriate; other stakeholders have also expressed concerns with CMS refinements to RUC recommended values in general. In the CY 2017 PFS final rule (81 FR 80272 through 80277) we responded in detail to several comments that we received regarding this issue. In the CY 2017 PFS proposed rule, we requested comments regarding potential alternatives to making adjustments that would recognize overall estimates of work in the context of changes in the resource of time for particular services; however, we did not receive any specific potential alternatives as requested.

In developing proposed values for new, revised, and potentially misvalued codes for CY 2018, we considered the lack of alternative approaches to making the adjustments, especially since many stakeholders have routinely urged us to propose and finalize the RUC recommended values. We also considered the RUC's consistent reassurance that these kinds of concerns (regarding changes in time, for example) had already been considered, and either incorporated or dismissed, as part of the development of their recommended values. These have led us to shift our approach to reviewing RUC recommendations, especially as we believe that the majority of practitioners paid under the PFS, though not necessarily those in any particular specialty, would prefer CMS rely more heavily on RUC recommended values in establishing payment rates under the PFS.

For CY 2018, we have generally proposed RUC-recommended work RVUs for new, revised, and potentially misvalued codes. We are proposing these values based on our understanding that the RUC generally considers the kinds of concerns we have historically raised regarding appropriate valuation of work RVUs. During our review of these recommended values, however, we identified some concerns similar to those we have recognized in prior years. Given the relative nature of the PFS and our obligation to ensure that the RVUs reflect relative resource use, we have included descriptions of potential approaches we might have taken in developing work RVUs that differ from the RUC recommended values. We are seeking comment on both the RUC-recommended values as well as the alternatives considered.

Table 10 contains a list of codes for which we proposed work RVUs; this includes all codes for which we received RUC recommendations by February 10, 2017. The proposed work RVUs, work time and other payment information for all proposed CY 2018 payable codes are available on the CMS Web site under downloads for the CY 2018 PFS proposed rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.* Table 10 also contains the CPT code descriptors for all proposed, new, revised, and potentially misvalued codes discussed in this section.

3. Methodology for Proposing the Direct PE Inputs To Develop PE RVUs

a. Background

On an annual basis, the RUC provides us with recommendations regarding PE inputs for new, revised, and potentially misvalued codes. We review the RUC-recommended direct PE inputs on a code by code basis. Like our review of recommended work RVUs, our review of recommended direct PE inputs generally includes, but is not limited to, a review of information provided by the RUC, HCPAC, and other public commenters, medical literature, and comparative databases, as well as a comparison with other codes within the PFS, and consultation with physicians and health care professionals within CMS and the federal government, as well as Medicare claims data. We also assess the methodology and data used to develop the recommendations submitted to us by the RUC and other public commenters and the rationale for the recommendations. When we determine that the RUC's recommendations appropriately estimate the direct PE inputs (clinical labor, disposable supplies, and medical equipment) required for the typical service, are consistent with the principles of relativity, and reflect our payment policies, we use those direct PE inputs to value a service. If not, we refine the recommended PE inputs to better reflect our estimate of the PE resources required for the service. We also confirm whether CPT codes should have facility and/or nonfacility direct PE inputs and refine the inputs accordingly.

Our review and refinement of RUC-recommended direct PE inputs includes many refinements that are common

across codes, as well as refinements that are specific to particular services. Table 11 details our proposed refinements of the RUC's direct PE recommendations at the code-specific level. In this proposed rule, we address several refinements that are common across codes, and refinements to particular codes are addressed in the portions of this section that are dedicated to particular codes. We note that for each refinement, we indicate the proposed impact on direct costs for that service. We note that, on average, in any case where the impact on the direct cost for a particular refinement is $0.30 or less, the refinement has no impact on the proposed PE RVUs. This calculation considers both the impact on the direct portion of the PE RVU, as well as the impact on the indirect allocator for the average service. We also note that nearly half of the proposed refinements listed in Table 11 result in changes under the $0.30 threshold and are unlikely to result in a change to the proposed RVUs.

We also note that the proposed direct PE inputs for CY 2018 are displayed in the CY 2018 direct PE input database, available on the CMS Web site under the downloads for the CY 2018 PFS proposed rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.* The inputs displayed there have also been used in developing the proposed CY 2018 PE RVUs as displayed in Addendum B.

b. Common Refinements

(1) Changes in Work Time

Some direct PE inputs are directly affected by revisions in work time. Specifically, changes in the intraservice portions of the work time and changes in the number or level of postoperative visits associated with the global periods result in corresponding changes to direct PE inputs. The direct PE input recommendations generally correspond to the work time values associated with services. We believe that inadvertent discrepancies between work time values and direct PE inputs should be refined or adjusted in the establishment of proposed direct PE inputs to resolve the discrepancies.

(2) Equipment Time

Prior to CY 2010, the RUC did not generally provide CMS with recommendations regarding equipment time inputs. In CY 2010, in the interest of ensuring the greatest possible degree of accuracy in allocating equipment minutes, we requested that the RUC provide equipment times along with the other direct PE recommendations, and we provided the RUC with general guidelines regarding appropriate equipment time inputs. We continue to appreciate the RUC's willingness to provide us with these additional inputs as part of its PE recommendations.

In general, the equipment time inputs correspond to the service period portion of the clinical labor times. We have clarified this principle over several years of rulemaking, indicating that we consider equipment time as the time within the intraservice period when a clinician is using the piece of equipment plus any additional time that the piece of equipment is not available for use for another patient due to its use during the designated procedure. For those services for which we allocate cleaning time to portable equipment items, because the portable equipment does not need to be cleaned in the room where the service is furnished, we do not include that cleaning time for the remaining equipment items, as those items and the room are both available for use for other patients during that time. In addition, when a piece of equipment is typically used during follow-up post-operative visits included in the global period for a service, the equipment time would also reflect that use.

We believe that certain highly technical pieces of equipment and equipment rooms are less likely to be used during all of the preservice or postservice tasks performed by clinical labor staff on the day of the procedure (the clinical labor service period) and are typically available for other patients even when one member of the clinical staff may be occupied with a preservice or postservice task related to the procedure. We also note that we believe these same assumptions would apply to inexpensive equipment items that are used in conjunction with and located in a room with non-portable highly technical equipment items since any items in the room in question would be available if the room is not being occupied by a particular patient. For additional information, we refer readers to our discussion of these issues in the CY 2012 PFS final rule with comment period (76 FR 73182) and the CY 2015 PFS final rule with comment period (79 FR 67639).

(3) Standard Tasks and Minutes for Clinical Labor Tasks

In general, the preservice, intraservice, and postservice clinical labor minutes associated with clinical labor inputs in the direct PE input database reflect the sum of particular tasks described in the information that accompanies the RUC-recommended direct PE inputs, commonly called the ''PE worksheets.'' For most of these described tasks, there are a standardized number of minutes, depending on the type of procedure, its typical setting, its global period, and the other procedures with which it is typically reported. The RUC sometimes recommends a number of minutes either greater than or less than the time typically allotted for certain tasks. In those cases, we review the deviations from the standards and any rationale provided for the deviations. When we do not accept the RUC-recommended exceptions, we refine the proposed direct PE inputs to conform to the standard times for those tasks. In addition, in cases when a service is typically billed with an E/M service, we remove the preservice clinical labor tasks to avoid duplicative inputs and to reflect the resource costs of furnishing the typical service.

We refer readers to section II.B. of this proposed rule for more information regarding the collaborative work of CMS and the RUC in improvements in standardizing clinical labor tasks.

(4) Recommended Items that are not Direct PE Inputs

In some cases, the PE worksheets included with the RUC recommendations include items that are not clinical labor, disposable supplies, or medical equipment or that cannot be allocated to individual services or patients. We have addressed these kinds of recommendations in previous rulemaking (78 FR 74242), and we do not use items included in these recommendations as direct PE inputs in the calculation of PE RVUs.

(5) New Supply and Equipment Items

The RUC generally recommends the use of supply and equipment items that already exist in the direct PE input database for new, revised, and potentially misvalued codes. Some recommendations, however, include supply or equipment items that are not currently in the direct PE input database. In these cases, the RUC has historically recommended that a new item be created and has facilitated our pricing of that item by working with the specialty societies to provide us copies of sales invoices. For CY 2018, we received invoices for several new supply and equipment items. Tables 13 and 14 detail the invoices received for new and existing items in the direct PE database. As discussed in section II.B. of this proposed rule, we encourage stakeholders to review the prices associated with these new and existing

items to determine whether these prices appear to be accurate. Where prices appear inaccurate, we encourage stakeholders to provide invoices or other information to improve the accuracy of pricing for these items in the direct PE database during the 60-day public comment period for this proposed rule. We expect that invoices received outside of the public comment period would be submitted by February 10th of the following year for consideration in future rulemaking, similar to our new process for consideration of RUC recommendations.

We remind stakeholders that due to the relativity inherent in the development of RVUs, reductions in existing prices for any items in the direct PE database increase the pool of direct PE RVUs available to all other PFS services. Tables 13 and 14 also include the number of invoices received, as well as the number of nonfacility allowed services for procedures that use these equipment items. We provide the nonfacility allowed services so that stakeholders will note the impact the particular price might have on PE relativity, as well as to identify items that are used frequently, since we believe that stakeholders are more likely to have better pricing information for items used more frequently. A single invoice may not be reflective of typical costs and we encourage stakeholders to provide additional invoices so that we might identify and use accurate prices in the development of PE RVUs.

In some cases, we do not use the price listed on the invoice that accompanies the recommendation because we identify publicly available alternative prices or information that suggests a different price is more accurate. In these cases, we include this in the discussion of these codes. In other cases, we cannot adequately price a newly recommended item due to inadequate information. Sometimes, no supporting information regarding the price of the item has been included in the recommendation. In other cases, the supporting information does not demonstrate that the item has been purchased at the listed price (for example, vendor price quotes instead of paid invoices). In cases where the information provided on the item allows us to identify clinically appropriate proxy items, we might use existing items as proxies for the newly recommended items. In other cases, we have included the item in the direct PE input database without any associated price. Although including the item without an associated price means that the item does not contribute to the calculation of the proposed PE RVU for particular services, it facilitates our ability to incorporate a price once we obtain information and are able to do so.

(6) Service Period Clinical Labor Time in the Facility Setting

Generally speaking, our proposed inputs did not include clinical labor minutes assigned to the service period because the cost of clinical labor during the service period for a procedure in the facility setting is not considered a resource cost to the practitioner since Medicare makes separate payment to the facility for these costs. We address proposed code-specific refinements to clinical labor in the individual code sections.

(7) Procedures Subject to the Multiple Procedure Payment Reduction (MPPR) and the OPPS Cap

We note that the public use files for the PFS proposed and final rules for each year display both the services subject to the MPPR lists on diagnostic cardiovascular services, diagnostic imaging services, diagnostic ophthalmology services and therapy services and the list of procedures that meet the definition of imaging under section 1848(b)(4)(B) of the Act, and therefore, are subject to the OPPS cap for the upcoming calendar year. The public use files for CY 2018 are available on the CMS Web site under downloads for the CY 2018 PFS proposed rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html* For more information regarding the history of the MPPR policy, we refer readers to the CY 2014 PFS final rule (78 FR 74261–74263). For more information regarding the history of the OPPS cap, we refer readers to the CY 2007 PFS final rule (71 FR 69659–69662).

4. Proposed Valuation of Specific Codes for CY 2018

(1) Anesthesia Services for Gastrointestinal (GI) Procedures (CPT codes 007X1, 007X2, 008X1, 008X2, and 008X3)

In the CY 2016 PFS proposed rule (80 FR 41686), we discussed that in reviewing Medicare claims data, a separate anesthesia service is typically reported more than 50 percent of the time that various colonoscopy procedures are reported. We discussed that given the significant change in relative frequency with which anesthesia codes are reported with colonoscopy services, we believed the relative values of the anesthesia services should be reexamined and proposed to identify CPT codes 00740 (Anesth upper gi visualize) and 00810 (Anesth low intestine scope) as potentially misvalued. For CY 2018, the CPT Editorial Panel is deleting CPT codes 00740 and 00810 and creating new codes for anesthesia services furnished in conjunction with and in support of gastrointestinal endoscopic procedures: Two codes for upper GI procedures (007X1 and 007X2), two codes for lower GI procedures (008X1 and 008X2), and one code for upper and lower GI procedures (008X3).

For CY 2018, we are proposing the RUC-recommended base units without refinement for CPT codes 007X1 (5.00 base units), 007X2 (6.00 base units), 008X1 (4.00 base units), 008X2 (4.00 base units) and 008X3 (5.00 base units). We considered 3.00 base units (the 25th percentile survey result) for CPT code 008X2 (Anesthesia for lower intestinal endoscopic procedures, endoscope introduced distal to duodenum; screening colonoscopy), based on our comparison of the surveyed post-induction anesthesia-intensity allocation for CPT code 008X2 to codes with similar allocations (CPT code 01382 (Anesth dx knee arthroscopy)). We found that CPT code 01382, which was also valued with 3.00 base units, had similar allocations compared to the survey results for CPT code 008X2. We are seeking comment on our proposed and alternative value for CPT code 008X2.

(2) Acne Surgery (CPT code 10040)

CPT code 10040 was identified as potentially misvalued on a screen of Harvard-valued codes with utilization over 30,000 in CY 2014. We are proposing the RUC-recommended work RVU of 0.91 for CPT code 10040 and the RUC-recommended work time values. We considered using the current number of 0.5 post-procedure office visits of CPT code 99212 (Office/outpatient visit est) rather than the RUC-recommended number of 1.0 post-procedure office visits. For CPT code 10040, the RUC states that it is a low intensity service that can be performed by a nurse under a physician's supervision, and that the average number of office visits in the follow-up period of acne surgery is 0.4. We are seeking public comments regarding the typical number of postoperative visits for this code, considering there have been no changes made to the code descriptor and we have not found evidence of changes to the typical patient population.

We are proposing the RUC-recommended direct PE inputs for CPT code 10040 without refinement. We considered refinements to the clinical

labor for ''Assist physician in performing procedure'' from 10 minutes to 3 minutes. CPT code 10040 previously used about one third of the intraservice work time for this clinical labor activity (5 minutes out of 14 minutes), and the RUC-recommended value of 10 minutes would have increased this to 100 percent of the intraservice work time without rationale for the change. We considered 3 minutes for this clinical labor activity, which is about one third of the intraservice work time (3 minutes out of 10 minutes) and would have maintained the current ratio between clinical labor time and work time.

For CY 2018, we are proposing the RUC-recommended work RVUs and direct PE inputs for CPT code 10040 and are seeking comment on our proposed and alternative values.

(3) Muscle Flaps (CPT codes 15734, 15736, 15738, 157X1, and 157X2)

CPT codes 15732 and 15736 were identified via a screen of high level E/M visits included in their global periods. This screen identified that a CPT code 99214 office visit was included for CPT codes 15732 and 15736 but not included in the other codes in this family. During the review process for this family of codes, CPT code 15732 was deleted and replaced with two new codes, CPT codes 157X1 and 157X2, to better differentiate and describe the work of large muscle flaps performed on patients with head and neck cancer depending on the site where the service was performed.

For CY 2018, we are proposing the RUC-recommended work RVUs for CPT codes 15734 (a work RVU of 23.00), 15736 (a work RVU of 17.04), 15738 (a work RVU of 19.04), 157X1 (a work RVU of 13.50), and 157X2 (a work RVU of 15.68). For CPT code 157X1, we considered a work RVU of 12.03, crosswalking to CPT code 36830 (Creation of arteriovenous fistula by other than direct arteriovenous anastomosis (separate procedure); nonautogenous graft (eg, biological collagen, thermoplastic graft)). We have concerns because the RUC-recommended work RVU of 13.50 would represent nearly double the intensity of CPT codes 15734 through 15738, as well as nearly double the intensity of deleted CPT code 15732. The RUC-recommended work RVU for CPT code 157X1 is also based on a direct crosswalk to CPT code 36832 (Revision, open, arteriovenous fistula; without thrombectomy, autogenous or nonautogenous dialysis graft (separate procedure)), which has the same intraservice time, but with 20 additional minutes of total time. We considered a potential crosswalk to another code in the same family, CPT code 36830, which also shares the same intraservice time with CPT code 157X1 but differs by only 8 minutes of total time. However, we seek comment on whether the RUC recommendation is appropriate given the significant variation in intensity among these services.

We considered a work RVU of 14.63 for CPT code 157X2 (survey 25th percentile), crosswalking to CPT code 36833 (Revision, open, arteriovenous fistula; with thrombectomy, autogenous or nonautogenous dialysis graft (separate procedure)), which has the same intraservice time, 1 minute of additional total time, and a work RVU of 14.50. We are seeking comment on the effect that an alternative work RVU of 14.50 would have on relativity among the codes in this family.

We considered refining the clinical labor time for ''Check dressings & wound/home care instructions'' for CPT code 157X1 from 10 minutes to 5 minutes. We are seeking comment on the typical time input for checking dressings, and whether removing and replacing dressings, would typically take place during the intraservice or postservice period.

We are also seeking comments regarding the use of the new ''plate, surgical, mini-compression, 4 hole'' (SD189) supply included in CPT code 157X1, including whether use of this supply would be typical, and if so, whether it should be included in the work description. We note that SD189 is mentioned in the direct PE recommendations, but the supply does not appear in the work description. In the work description, the fixation screws are applied to the orbital rim and lateral nasal wall, not the surgical plate.

(4) Application of Rigid Leg Cast (CPT code 29445)

CPT code 29445 appeared on a high growth screen of all services with total Medicare utilization of 10,000 or more that increased by at least 100 percent from 2008 through 2013. This screen also indicated that the code was last surveyed more than 10 years previously, and that the dominant specialty had changed during that time.

For CY 2018, we are proposing the RUC-recommended work RVU of 1.78 for CPT code 29445. For the direct PE inputs, we are proposing to refine the clinical labor time for ''Check dressings & wound/home care instructions'' from 5 minutes to 3 minutes. We believe that the additional 2 minutes of clinical labor time that we are proposing to remove would take place during the monitoring time following the procedure and be accounted for in that clinical labor time.

We also considered refining the clinical labor time for ''Remove cast'' from 22 minutes to 11 minutes: 1 minute for room prep, 10 minutes for assisting the physician, and 0 minutes for the additional activities described in the RUC recommendations, which would have only taken place during the initial casting. We have concerns that the RUC-recommended clinical labor regarding the ''remove cast'' task is based only on an initial visit where a new cast would be applied and 22 minutes may be an appropriate length of time. However, the RUC recommendations suggest that four to twelve cast changes are common for patients, and we are seeking comment on whether the initial application of a new cast would be typical for CPT code 29445. We reviewed the Medicare claims data for CPT code 29445 and found that three or more castings took place for 52 percent of beneficiaries, which suggests that three or more castings may be the typical case. A single casting only took place for 30 percent of services reported with CPT code 29445.

(5) Strapping Multi-Layer Compression (CPT codes 29580 and 29581)

The RUC reviewed CPT code 29580 since it appeared on the screen for high expenditure services and reviewed CPT code 29581 as part of this family of codes. For CY 2018, the CPT Editorial Panel is deleting two additional codes in the family: CPT codes 29582 (Application of multi-layer compression system; thigh and leg, including ankle and foot, when performed) and 29583 (Application of multi-layer compression system; upper arm and forearm).

For CY 2018, we are proposing the RUC-recommended work RVUs for CPT code 29580 (a work RVU of 0.55) and CPT code 29581 (a work RVU of 0.60).

However, we are concerned about the changes in preservice time reflected in the specialty surveys compared to the RUC-recommended work RVUs. For instance, for CPT code 29580, we considered a work RVU of 0.46, crosswalking to CPT code 98925 (Osteopathic manipulative treatment (OMT); 1–2 body regions involved)), which has a work RVU of 0.46 and shares a similar intraservice time. Compared to the specialty survey times, the RUC recommended a slight decrease (9 minutes) in preservice time for CPT code 29580, with the intraservice and immediate postservice times remaining unchanged.

For CPT code 29581, we considered a work RVU of 0.5 by using the RUC-recommended work RVU increment between CPT codes 29580 and 29581 (+0.05), added to the work RVU we considered for CPT code 29580 (0.46), and crosswalking to CPT code 97597 (Debridement (eg, high pressure waterjet with/without suction, sharp selective debridement with scissors, scalpel and forceps), open wound, (eg, fibrin, devitalized epidermis and/or dermis, exudate, debris, biofilm), including topical application(s), wound assessment, use of a whirlpool, when performed and instruction(s) for ongoing care, per session, total wound(s) surface area; first 20 sq cm or less)), which has similar intraservice and total times to the RUC-recommended services times for CPT code 29581. We are seeking comment on whether a work RVU of 0.51 would improve relativity among the codes in this family.

For CY 2018, we are proposing the RUC-recommended work RVUs for CPT codes 29580 and 29581 and are seeking comment on whether the alternative values we considered would be more appropriate.

(6) Resection Inferior Turbinate (CPT Code 30140)

CPT code 30140 was identified as potentially misvalued on a screen of Harvard-valued codes with utilization over 30,000 in CY 2014. During the review process, the RUC re-surveyed the code as a 0-day global period, based on the presence of a negative intensity value in the initial survey and highly variable postoperative office visits.

For CY 2018, we are proposing the RUC-recommended work RVU of 3.00 for CPT code 30140 as a 0-day global code. We also considered a work RVU of 2.68 for CPT code 30140 and are seeking comment on changes in practice patterns since the code was previously reviewed, service times of comparable services, and whether a work RVU of 2.68 would better maintain relativity among similar codes. We note that the RUC-recommended work RVU of 3.0 nearly doubles the derived intensity of the code as currently valued. We note that the RUC recommendations referenced services that had similar service times to CPT code 30140 (CPT code 31240 (Nasal/sinus endoscopy, surgical; with concha bullosa resection), with a work RVU of 2.61; and CPT code 31295 (Nasal/sinus endoscopy, surgical; with dilation of maxillary sinus ostium (eg, balloon dilation), transnasal or via canine fossa), with a work RVU of 2.70).

We note that the initial survey for CPT code 30140 as a 90-day global resulted in a RUC-recommended work RVU of 3.57, while the second survey for the code as a 0-day global resulted in a RUC-recommended work RVU of 3.00, despite the removal of two postoperative office visits of CPT code 99212 and a half discharge visit of CPT code 99238. These removed postoperative visits have a total work RVU of 2.58, which is notably higher than the difference in the RUC-recommended work RVU between the two surveys.

We are also proposing to create equipment codes for three new equipment items based on invoices submitted with the RUC recommendations for CPT code 30140. We are proposing to create three new equipment codes based on the invoices submitted for this code family: the 2mm reusable shaver blade (EQ383) at a price of $790, the microdebrider handpiece (EQ384) at a price of $4,760, and the microdebrider console (EQ385) at a price of $9,034.

(7) Control Nasal Hemorrhage (CPT Codes 30901, 30903, 30905, and 30906)

For CY 2018, we are proposing the RUC-recommended work RVUs for CPT codes 30901 (a work RVU of 1.10), 30903 (a work RVU of 1.54), 30905 (a work RVU of 1.97), and 30906 (a work RVU of 2.45). We are also proposing to use the RUC-recommended direct PE inputs for CPT codes 30901, 30903, 30905, and 30906, with standard refinements to the equipment times to account for patient monitoring times. We noted that as part of its recommendation, the RUC informed us that the specialty societies presented evidence stating that the 1995 valuations for these services factored in excessive times, specifically to account for infection control procedures that were necessary at that time due to the prevalence of HIV/AIDS. The specialty societies also noted that increased availability and use of blood thinner medications compared to those available in 1995, has increased the difficulty and intensity of these procedures. We are seeking additional information regarding the presumption that the relative resource intensity of these services, specifically, would be affected by the commercial availability of additional blood thinner medications. We believe that blood thinner medications were widely available before 1995 when these codes were last valued. Additionally, we seek comments on the prevalence of HIV/AIDS and whether the work related to infection control procedures would be relative across many PFS services or specifically related to nasal hemorrhage control procedures.

For CPT code 30901 (Control nasal hemorrhage, anterior, simple (limited cautery and/or packing) any method), we considered a work RVU of 1.00 (the 25th percentile survey result), crosswalking to CPT code 20606 (Drain/inj joint/bursa w/us), which has similar service times. The median survey total time (24 minutes) dropped by 2 minutes (from preservice time), to 24 minutes compared to the existing total time. The difference in total time reflected a small decrease in preservice time, with no change in intraservice time (10 minutes). Among codes with similar service times, we found only three codes that had a higher work RVU than the RUC-recommended value.

For CPT code 30903 (Control nasal hemorrhage, anterior, complex (extensive cautery and/or packing) any method), we considered a work RVU of 1.30 (the 25th percentile survey result), which would have been further supported by CPT codes 36584 and 51710 which have similar service times to the median survey results. The RUC recommended a decreased total time of 39 minutes compared to the existing total time (70 minutes), with intraservice time dropping from 30 to 15 minutes.

For CPT code 30905 (Control nasal hemorrhage, posterior, with posterior nasal packs and/or cautery, any method; initial), we considered a work RVU of 1.73, using the RUC-recommended work RVU increment between CPT code 30903 and CPT code 30905 (0.43), added to the work RVU we considered for CPT code 30903 (1.30), and crosswalking to CPT code 45321 (Proctosigmoidoscopy volvul), which has similar service times. The surveyed intraservice time dropped from 48 minutes to 20 minutes. The RUC recommendations indicated that surveyed service times for CPT code 30905 are longer than for CPT code 30903 since the service is performed to control an arterial posterior bleed. According to the specialty society, arterial posterior bleeds are more difficult to treat and require a more extensive procedure in comparison to services reported with CPT code 30903. We considered using the RUC-recommended work RVU increment between CPT code 30903 and CPT code 30905 (0.43), added to the work RVU we considered for CPT code 30903 (1.30), resulting in a work RVU of 1.73. We are seeking comment on whether a work RVU of 1.73 would potentially affect relativity among the codes in this family.

For CPT code 30906 (Control nasal hemorrhage, posterior, with posterior nasal packs and/or cautery, any method; subsequent), we considered a work RVU of 2.21, using the RUC-recommended work RVU increment between CPT codes 30905 and 30906 (0.48), added to the work RVU we considered for CPT code 30905 (1.73), and crosswalking to services with similar service times (CPT codes 19281 (Perq device breast 1st imag), 51727 (Cystometrogram w/up), 49185 (Sclerotx fluid collection), and 62305 (Myelography lumbar injection)). The surveyed median intraservice time dropped from 60 minutes to 30 minutes. We are seeking comment on whether a work RVU of 2.21 would potentially improve relativity among the codes in this family.

Given the RUC's consensus for CY 2018, we are proposing the RUC-recommended work RVUs for each code in this family and seeking comment on whether our alternative values would be more appropriate.

(8) Nasal Sinus Endoscopy (CPT Codes 31254, 31255, 31256, 31267, 31276, 31287, 31288, 31295, 31296, 31297, 31XX1, 31XX2, 31XX3, 31XX4, and 31XX5)

In October 2016, the CPT Editorial Panel created five new codes (CPT codes 31XX1, 31XX2, 31XX3, 31XX4 and 31XX5) and revised CPT codes 31238, 31254, 31255, 31276, 31287, 31288, 31296, and 31297. CPT codes 31XX2—31XX5 are newly bundled services representing services that are frequently reported together. CPT code 31XX1 represents a new service. The RUC reviewed this family of codes at their January 2017 meeting. For CY 2018, we are proposing the RUC-recommended work RVUs for all 15 CPT codes in this family as follows: 4.27 for CPT code 31254, 5.75 for CPT code 31255, 3.11 for CPT code 31256, 4.68 for CPT code 31267, 6.75 for CPT code 31276, 3.50 for CPT code 31287, 4.10 for CPT code 31288, 2.70 for CPT code 31295, 3.10 for CPT code 31296, 2.44 for CPT code 31297, 8.00 for CPT code 31XX1, 9.00 for CPT code 31XX2, 8.00 for CPT code 31XX3, 8.48 for CPT code 31XX4, and 4.50 for CPT code 31XX5.

For CPT code 31296, we considered a work RVU of 2.82, supported by a crosswalk to CPT code 36901 (Intro cath dialysis circuit) with an intraservice time of 25 minutes and total time of 66 minutes, similar to the service times for CPT code 31296. We are concerned about the decrease in service time compared to the work RVU and we seek comment on whether or not a work RVU of 2.82 might improve relativity with other PFS services.

For CPT code 31256, we considered a work RVU of 2.80, supported by a crosswalk to CPT code 43231 (Esophagoscopy, flexible, transoral; with endoscopic ultrasound examination), which has 30 minutes of intraservice time and 81 minutes of total time, similar to the RUC-recommended service times. We are concerned about the difference in total time between CPT code 31256 and the RUC-recommended crosswalk to CPT code 43247. CPT code 43247 has 30 minutes intraservice time and 58 minutes total time), and CPT code 31256 (30 minutes intraservice time and 83 minutes total time).

For CPT code 31254, we note the RUC's explanation that this service is more intense than the functional endoscopic sinus surgery on the maxillary or sphenoid sinuses due to the risk of major complications such as injury to the eye muscles, bleeding into the eye or brain fluid leak and, consequently, that the RUC concluded that it should be valued higher than either CPT code 31256 or CPT code 31287. Since CPT code 31256 has the same total time (30 minutes) and intraservice time (30 minutes) as CPT code 31254, we considered whether the incremental difference recommended by the RUC between these two codes (work RVU of 1.16) would reflect the intensity of the service. We considered a work RVU of 2.80 for CPT code 31256, and also considered an alternative work RVU of 3.97 for CPT code 31254.

For CPT code 31287, we considered a work RVU of 3.19 based on the difference between the RUC-recommended work RVU for the maxillary sinus surgery (CPT code 31256) and the sphenoid sinus surgery (CPT code 31287) (difference = 0.28) added to the work RVU that we considered for the base code (CPT code 31256, a work RVU of 2.80). We note that the magnitude of decreases in service times are greater than those for the work RVU, which potentially could affect relativity among PFS services.

For CPT code 31255, we considered a work RVU of 5.30, based on a crosswalk to CPT codes 36475 (Endovenous rf 1st vein) and 36478 (Endovenous laser 1st vein) since both of these services have the same intraservice times, total times, and work RVUs). We note that there are several CPT codes with similar total and intraservice times that have lower work RVUs than the crosswalk to CPT code 36246 (Ins cath abd/l-ext art 2nd) noted by the RUC, which has 45 minutes intraservice and 96 minutes total time, has work RVU of 5.02; CPT code 36475 (Endovenous rf 1st vein) has 94 minutes intraservice and 94 minutes total time and has work RVU of 5.30).

For CPT code 31276 (Nasal/sinus endoscopy, surgical; with frontal sinus exploration, including removal of tissue from frontal sinus, when performed), we considered a work RVU of 6.30, which is similar to other functional endoscopic surgeries. We note that the services reported with CPT code 31276 are the most intense and complex of the functional endoscopic surgeries due to the risks of working in the narrow confines in the frontal recess. However, we have concerns that a crosswalk to CPT code 52352 (Cystourethroscopy, with ureteroscopy and/or pyeloscopy; with removal or manipulation of calculus (ureteral catheterization is included)), and we seek comment on whether the RUC-recommended decrease in service times is appropriate since CPT code 52352 has 20 minutes more total time than CPT code 31276.

For CPT 31XX1 (nasal/sinus endoscopy, surgical; with ligation of Sphenopalatine artery), we have concerns and seek comment regarding the accuracy and applicability of the surveys as the RUC indicated that the specialty society did not use the survey instrument that contains questions about the number and types of visits and that this service requires a half day discharge day management as the patients typically stay overnight to be monitored for further bleeding. We seek comment on whether inclusion of a half day discharge day visit is typical for this service since services assigned 0-day global periods do not typically include discharge visits. We considered reducing the total time from 142 minutes to 123 minutes by removing the half day discharge. Using the alternative total time of 123 minutes, we found services with similar total and intraservice time (60 minutes) and total time (123 minutes).

We considered a work RVU of 7.30 for CPT code 31XX1, supported by a direct crosswalk to CPT code 36253 (Superselective catheter placement (one or more second order or higher renal artery branches) renal artery and any accessory renal artery(s) for renal angiography, including arterial puncture, catheterization, fluoroscopy, contrast injection(s), image postprocessing, permanent recording of images, and radiological supervision and interpretation, including pressure gradient measurements when performed, and flush aortogram when performed; unilateral), since CPT code 36253 has a similar total time compared to our alternative total time.

For CPT code 31XX3, we considered a work RVU of 7.30, based on a crosswalk to CPT code 36253 (Superselective catheter placement (one

or more second order or higher renal artery branches) renal artery and any accessory renal artery(s) for renal angiography, including arterial puncture, catheterization, fluoroscopy, contrast injection(s), image postprocessing, permanent recording of images, and radiological supervision and interpretation, including pressure gradient measurements when performed, and flush aortogram when performed; unilateral). We have similar concerns regarding the service times for this service, including the cited reference codes, compared to the recommended work RVU. We are seeking comment on whether a work RVU of 7.30 for CPT code 31XX3 would improve consistency among the combined CPT codes in this family.

CPT code 31XX4 is a new code representing a combination of the services previously described by CPT codes 31255 and 31288. We note the changes in overall service times compared to other codes in this family and other PFS services. We considered a work RVU of 7.85 for CPT code 31XX4, crosswalking to CPT code 93461 (R&l hrt art/ventricle angio), which has identical intraservice times. We are seeking comment on the effect that this alternative work RVU might have on consistency and rank order compared to the other bundled codes in this family.

CPT code 31XX5 represents a combination of CPT codes 31296 and 31297. We have concerns about the use of CPT codes 47532 and 58558, which were used by the RUC as comparison codes, due to differences in both intraservice and total time compared to the service times for CPT code 31XX5. We considered a work RVU of 4.10 for CPT code 31XX5, crosswalking to CPT code 44406 (Colonoscopy w/ ultrasound), which has similar service times.

For CY 2018, we are proposing the RUC-recommended work RVUs for each code in this family and are seeking comment on our alternative values.

Regarding the recommended direct PE inputs, we are concerned about one of the supply items used in furnishing services for several CPT codes in this family:, ''sinus surgery balloon (maxillary, frontal, or sphenoid) kit'' (SA106). In the current recommendations, half of one kit (each kit has sufficient supply for two sinuses) is included in the practice expense inputs for CPT codes 31295, 31296, and 31297. The new CPT code 31XX5 has one full kit, reflecting a service consisting of two sinuses, according to the RUC's explanation. The price of the full kit (two sinuses) of this disposable supply is $2599.06. Our analysis of 2016 Medicare claims data indicates that 48 percent of the time one of the three CPT codes (31295, 31296, and 31297) is billed, it is reported on a claim with either one or both of the other codes. Ten percent of the time one of the three CPT codes is billed, it is reported on a claim with both of the other two codes. Effectively, 10 percent of claims reporting these CPT codes are being paid for three sinuses.

We are seeking comments on the number of units of this supply item that are used for each service. We welcome suggestions about improved methodologies for identifying the quantity of this disposable supply used during these procedures and will continue to monitor utilization and reporting of these services.

In reviewing the RUC recommendations for this family of CPT codes, we note that CPT codes in this family are subject to the standard payment adjustment for multiple surgeries. In our analysis of the claims data, we noted that the average number of HCPCS codes in this family reported together on a claim line is approximately 2.89. In addition, about 15 percent of claims have two of the newly bundled CPT codes reported together on a claim line. We are concerned about the frequency with which the nasal sinus endoscopy CPT codes in this family are billed together. We are seeking comments on whether we should consider the endobase code adjustments as a better approach to adjusting payment for these services instead of the current multiple procedure reduction. For additional information about the payment adjustment under the special rule for multiple endoscopic services, we refer readers to the Medicare Claims Processing Manual, Chapter 23 (available on the CMS Web site at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c23.pdf*.).

We note that in developing the utilization crosswalk we use for purposes of PFS ratesetting, for this complex set of newly bundled codes, we adopted ratios that differ significantly from the ratios accompanying the RUC recommendations to better account for the reductions in overall reporting frequency. We direct readers to the file called ''CY 2017 Analytic Crosswalk to CY 2018'' on the CMS Web site under downloads for the CY 2018 PFS proposed rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*.

(9) Tracheostomy (CPT Codes 31600, 31601, 31603, 31605, and 31610)

CPT code 31600 was identified as part of a screen of high expenditure services with Medicare allowed charges of $10 million or more that had not been recently reviewed. CPT codes 31601, 31603, 31605, and 31610 were added and reviewed as part of the code family.

We are proposing the RUC-recommended work RVUs for all five codes in this family. We are proposing a work RVU of 5.56 for CPT code 31600, a work RVU of 8.00 for CPT code 31601, a work RVU of 6.00 for CPT code 31603, a work RVU of 6.45 for CPT code 31605, and a work RVU of 12.00 for CPT code 31610.

We considered a work RVU of 6.50 for CPT code 31601. We seek comment on the effect that this alternative value would have on relativity compared to other PFS services, especially since the survey data does not suggest an increase in the time required to perform the procedure.

We considered a work RVU of 4.77 for CPT code 31605, based on the survey 25th percentile from the combined survey total. We also considered an intraservice work time of 15 minutes, based on the median intraservice work time from the combined survey total for CPT code 31605. We are seeking comments on the methodology used to determine the RUC-recommended work RVU and intraservice work time. We are concerned that the number of respondents (20) is below the threshold typically required for submission of a survey, and the effect of using survey results only from physicians who had personal experience performing the procedure (20 respondents). CPT code 31605 has a lower intraservice and total time, but a higher work RVU than comparable codes under the PFS. We note that the next highest 0-day global code with 20 minutes of intraservice time is CPT code 16035 (Escharotomy; initial incision) at a work RVU of 3.74. All other 0-day global codes with a work RVU of 6.45 or greater have at least 40 minutes of intraservice time. We are seeking comment on the effect that an alternative work RVU of 4.77 would have on the relativity of this service compared to other services in this family of codes and compared to other PFS services, taking into account that CPT code 31605 describes a difficult and dangerous life-threatening emergency procedure.

We considered a work RVU of 6.50 for CPT code 31610 based on a direct crosswalk to CPT code 31601 (Incision of windpipe). We understand that the RUC considered the possibility of

recommending this code be assigned a 0-day global period based on concerns about negative derived intensity. We share the RUC's concerns with the current construction of CPT code 31610, particularly with the 242 minutes of work time included in the postoperative visits, which is an unusually large amount for a procedure with only 45 minutes of intraservice time. We did not identify any other comparable codes under the PFS with 45 minutes of intraservice time and more than 300 minutes of total time. We seek comment on whether the unusual volume of physician work time included in the postoperative visits for CPT code 31610 contributed to the negative derived intensity reported by the survey data. Considering that the other codes in this family have 0-day global periods, we considered and are seeking comment on whether a 0-day global period should be assigned to CPT code 31610. Removal of the postoperative E/M visits from CPT code 31610 would result in an intraservice time of 45 minutes and a total time of 125 minutes, similar to CPT code 31601 with 45 minutes of intraservice time and 135 minutes of total time.

We are proposing the RUC-recommended direct PE inputs for all five CPT codes in this family without refinements. As discussed earlier, we considered a 0-day global period for CPT code 31610, which would also have resulted in removal of the clinical labor associated with the postoperative E/M visits, along with the supplies and equipment utilized during those visits.

While we remain concerned about the global period assigned to CPT code 31610 and the changes in service times reflected in the specialty surveys compared to the RUC-recommended work RVUs, for CY 2018, we are proposing the RUC-recommended work RVUs and direct PE inputs for each code in this family and are seeking comment on our proposed and alternative values.

(10) Bronchial Aspiration of Tracheobronchial Tree (CPT Codes 31645 and 31646)

CPT code 31645 was identified as potentially misvalued on a screen of Harvard-valued codes with utilization over 30,000 in CY 2014. CPT code 31646 was added for review as part of the family of codes, and both were revised to reflect recent changes in how the services are typically performed. For CY 2018, we are proposing the RUC-recommended work RVU of 2.88 for CPT code 31645 and the RUC-recommended work RVU of 2.78 for CPT code 31646.

We considered a work RVU of 2.72 for CPT code 31645, crosswalking to CPT code 45347 (Sigmoidoscopy, flexible; with placement of endoscopic stent). We have concerns regarding the decrease in intraservice and total time compared to the current values (we also believe that it is important to note how these related codes have been affected by the creation of separately billable codes for moderate sedation (see CY 2017 PFS final rule (81 FR 80339)). The RUC-recommended values CPT code 31645 higher than CPT code 31622 (Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with cell washing, when performed), which is the base procedure for this wider group of codes. We agree that CPT code 31645 should be valued at a higher work RVU than CPT code 31622, however, we are seeking comment on whether the work of moderate sedation was inadvertently included in the development of the recommended work RVU. We note that as part of the CY 2017 PFS final rule (81 FR 80339), we finalized separate payment for moderate sedation.

Following the creation of separately billable codes for moderate sedation, CPT code 31622 is currently valued at a work RVU of 2.53, not 2.78 as it was previously valued, and we do not believe it would be appropriate to continue to value CPT code 31645 as though moderate sedation was still an inherent part of the work of this service. As a result, we considered a direct crosswalk to CPT code 45347, which has the same intraservice time and 8 additional minutes of total time, at a work RVU of 2.72.

We considered a work RVU of 2.53 for CPT code 31646, crosswalking to CPT code 31622 (Dx bronchoscope/wash). The RUC recommendation for CPT code 31646 indicated that the code was comparable to CPT code 31622, since they share the same intraservice time and similar total time, and that the recommended work RVU of 2.78 for CPT code 31646 was equal to the work RVU of CPT code 31622 before the CY 2017 changes to reporting of moderate sedation. We agree with the survey participants that these two codes are comparable to one another, but have concerns about valuation of CPT code 31646 using a cross reference to a code that included moderate sedation. We considered crosswalking CPT code 31646 (Bronchoscopy reclear airway) using the current CY 2017 valuation for CPT code 31622 (a work RVU of 2.53).

For the direct PE inputs, we are proposing to remove the oxygen gas (SD084) from CPT code 31645. This supply is included in the separately billable moderate sedation codes, and we are proposing to remove the oxygen gas as recommended by the RUC's PE Subcommittee as part of the removal of oxygen from non-moderate sedation post-procedure monitoring codes. We are proposing to remove the equipment time for the IV infusion pump (EQ032) from CPT code 31645. We do not agree that there would typically be a need for a separate infusion pump in CPT code 31645, as the infusion pump is contained in the separately reportable moderate sedation codes. We are also proposing to remove the equipment time for the CO_2 respiratory profile monitor (EQ004) and the mobile instrument table (EF027) from CPT code 31645. These equipment items are not contained in the current composition of the code, and there was no rationale provided in the RUC recommendations for their inclusion. As a result, we do not believe that their use would be typical for CPT code 31645.

We are proposing to increase the equipment time for the flexible bronchoscopy fiberscope (ES017) for CPT code 31645 consistent with standard equipment times for scopes. We are also proposing to increase the equipment time for the Gomco suction machine (EQ235) and the power table (EF031) consistent with standard equipment times for non-highly technical equipment.

For CY 2018, we are proposing the RUC-recommended work RVUs for both codes in this family and are seeking comment on whether we should finalize refined values consistent with the implementation of separately billable codes for moderate sedation.

(11) Cryoablation of Pulmonary Tumor (CPT Codes 32998 and 32X99)

For CY 2018, the CPT Editorial Panel modified the descriptor for CPT code 32998 (Ablation therapy for reduction or eradication of 1 or more pulmonary tumor(s) including pleura or chest wall when involved by tumor extension, percutaneous, including imaging guidance when performed, unilateral; radiofrequency) to include imaging guidance. In addition, the panel deleted Category III CPT Code 0304T and replaced it with a new CPT code 32X99, to describe ablation therapy for reduction of pulmonary tumor using cryoablation with imaging guidance. For CY 2018, we are proposing the RUC-recommended work RVUs for CPT codes 32998 (a work RVU of 9.03) and 32X99 (a work RVU of 9.03).

However, we have concerns about the descriptions of the codes and the recommended valuations assuming that imaging guidance is inherent to the

procedure. Based on our analysis of claims data from 2014, existing CPT code 32998 is currently reported with one of the three imaging guidance codes (CPT codes 76940, 77013, or 77022) less than 50 percent of the time. We seek comment on whether there is additional information that would help explain why the codes are being bundled despite what is reflected in the Medicare claims data. We considered a work RVU of 7.69 for CPT code 32998, that included approximately one half the value of the imaging guidance in the new codes that describe the work of both the procedure and the image guidance (that is, the sum of the current work RVU for CPT code 32998 and one-half of the work RVU for CPT code 77013 (the imaging guidance code most frequently billed with CPT code 32998 according to 2014 claims data)). We applied the same general rationale regarding the use of imaging guidance for new CPT code 32X99. Since the RUC recommended identical work RVUs for these codes, we also considered a work RVU of 7.69 for CPT 32X99.

For CPT codes 32998 and 32X99, we are proposing to use the RUC-recommended direct PE inputs with standard refinements.

For CY 2018, we are proposing the RUC-recommended work RVUs and direct PE inputs for both codes and are seeking comment on our proposed and alternative values.

(12) Artificial Heart System Procedures (CPT Codes 339X1, 339X2, and 339X3)

For CY 2018, the CPT Editorial Panel deleted Category III CPT Codes 0051T through 0053T and created CPT codes 339X1, 339X2, and 339X3 to report artificial heart system procedures. We are proposing the RUC-recommended work RVU of 49.00 for CPT code 339X1, and proposing to assign contractor-priced status to CPT codes 339X2 and 339X3 as recommended by the RUC.

We considered assigning contractor-priced status for CPT code 339X1. We have concerns regarding the accuracy of the RUC-recommended work valuation for CPT code 339X1, due to its low utilization and the resulting difficulties in finding enough practitioners with direct experience of the procedure for the specialty societies to survey. We seek comment on the sufficiency of the survey data, especially since new technologies and those with lower utilization are typically contractor-priced. For CY 2018, we are proposing the RUC-recommended work RVUs for CPT code 339X1. We are seeking comment on alternative pricing for this CPT code 339X1.

We are not proposing any direct PE inputs, as we did not receive RUC-recommended PE information for CPT codes 339X1, 339X2, and 339X3. These three codes will be placed on the RUC's new technology list and will be re-reviewed by the RUC in 3 years.

(13) Endovascular Repair Procedures (CPT Codes 34X01, 34X02, 34X03, 34X04, 34X05, 34X06, 34X07, 34X08, 34X09, 34X10, 34X11, 34X12, 34X13, 34812, 34X15, 34820, 34833, 34834, 34X19, and 34X20)

The CPT/RUC joint workgroup on codes recommended in October 2015 to bundle endovascular abdominal aortic aneurysm repair (EVAR) codes together with radiologic supervision and interpretation codes, since these codes were typically reported together at least 50 percent of the time. The CPT Editorial Panel bundled these services together in September 2016, creating 16 new codes, revising four existing codes, and deleting 14 other codes related to endovascular repair procedures.

We are proposing the RUC-recommended work RVUs for all 20 codes in this family. We are proposing a work RVU of 23.71 for CPT code 34X01, a work RVU of 36.00 for CPT code 34X02, a work RVU of 26.52 for CPT code 34X03, a work RVU of 45.00 for CPT code 34X04, a work RVU of 29.58 for CPT code 34X05, a work RVU of 45.00 for CPT code 34X06, a work RVU of 22.28 for CPT code 34X07, a work RVU of 36.50 for CPT code 34X08, a work RVU of 6.50 for CPT code 34X09, a work RVU of 15.00 for CPT code 34X10, a work RVU of 6.00 for CPT code 34X11, a work RVU of 12.00 for CPT code 34X12, a work RVU of 2.50 for CPT code 34X13, a work RVU of 4.13 for CPT code 34812, a work RVU of 5.25 for CPT code 34X15, a work RVU of 7.00 for CPT code 34820, a work RVU of 8.16 for CPT code 34833, a work RVU of 2.65 for CPT code 34834, a work RVU of 6.00 for CPT code 34X19, and a work RVU of 7.19 for CPT code 34X20.

We are also proposing the RUC-recommended direct PE inputs without refinement for all 20 codes in the family.

We considered a work RVU of 32.00 for CPT code 34X02 based on the survey 25th percentile, and further supported with a crosswalk to CPT code 48000 (Placement of drains, peripancreatic, for acute pancreatitis), which has the same intraservice time of 120 minutes and a work RVU of 31.95. When we compared the RUC-recommended work RVU to similar codes valued under the PFS, we were unable to find any 90-day global services with 120 minutes of intraservice time and approximately 677 minutes of total time that had a work RVU greater than 36.00.

We considered a work RVU of 40.00 for CPT code 34X04 based on the survey 25th percentile, crosswalking to CPT code 33534 (Coronary artery bypass, using arterial graft(s); 2 coronary arterial grafts) which has a work RVU of 39.88. CPT code 33534 has 193 minutes of intraservice time, but a lower total time of 717 minutes. When we compared the RUC-recommended work RVU for CPT code 34X04 to similar codes paid under the PFS, we were unable to find any 90-day global services with 180 minutes of intraservice time and approximately 737 minutes of total time that had a work RVU greater than 45.00.

We considered a work RVU of 40.00 for CPT code 34X06 based on the survey 25th percentile. CPT code 34X06 has nearly identical time values to CPT code 34X04, with 2 fewer minutes of intraservice time and total time, and the RUC-recommended work RVU was the same for both of these codes. The survey respondents also believe that these two codes had a comparable amount of work, as the survey 25th percentile work RVU is 40.00 for both codes.

We considered a work RVU of 30.00 for CPT code 34X08 based on the survey 25th percentile and seek comment on whether a work RVU of 30.00 would improve relativity among the codes in this family. CPT code 34X08 has identical intraservice and total times as CPT code 34X02. However, we note that the RUC-recommended work RVU of 36.50 for CPT code 34X08 is higher than the RUC-recommended work RVU of 36.00 for CPT code 34X02. This is the inverse of the relationship between CPT codes 34X07 and 34X01, which describe the same procedures in a non-emergent state when a rupture does not take place. CPT code 34X07 has a RUC-recommended work RVU of 22.28 while CPT code 34X01 has a RUC-recommended work RVU of 23.71. We seek comment on whether the RUC-recommended work RVUs would create a rank order anomaly within the family by reversing the relationship between these paired codes when performed in an emergent state. We note that if CPT codes 34X08 and 34X02 were valued at the survey 25th percentile, this potential rank order anomaly disappears; in this scenario, we considered valuing CPT code 34X08 at a work RVU of 30.00 and CPT code 34X02 at a work RVU of 32.00. We seek comment on whether these alternative work values would improve relativity with the RUC-recommended work RVUs for CPT code 34X07 (22.28) and CPT code 34X01 (23.71), with an increment of

approximately 1.50 to 2.00 RVUs between the two code pairs.

For the eight remaining codes that describe endovascular access procedures, we considered assignment of a 0-day global period, instead of the RUC-recommended add-on (ZZZ) global period and subsequently adding back the preservice and immediate postservice work time, and increasing the work RVU of each code accordingly using a building block methodology. We note that as add-on procedures, these eight codes would not be subject to the multiple procedure payment discount. We are concerned that the total payment for these services will be increasing in the aggregate based on changes in coding that alter MPPR adjustments, despite the information in the surveys that reflects a decrease in the intraservice time required to perform the procedures, and a decrease in their overall intensity as compared to the current values.

We considered a work RVU of 3.95 for CPT code 34X13, based on the RUC-recommended work RVU of 2.50 plus an additional 1.45 work RVUs. This additional work results from the addition of 38 total minutes of preservice work time and 30 minutes of postservice work time based on a crosswalk to CPT code 37224 (Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(s), unilateral; with transluminal angioplasty) as valued by using the building block methodology. Using the same method, we considered a work RVU of:

- 6.48 for CPT code 34812 based on maintaining the current 75 minutes of preservice work time and the current 30 minutes of postservice work time, with a total work RVU of 2.35, added to the RUC-recommended work RVU of 4.13;
- 7.53 for CPT code 34X15 with the addition of 75 minutes of preservice work time and 27 minutes of postservice work time to match CPT code 34833;
- 9.46 for CPT code 34820 based on maintaining the current 80 minutes of preservice work time and the current 30 minutes of postservice work time;
- 10.44 for CPT code 34833 based on maintaining the current 75 minutes of preservice work time and the current 27 minutes of postservice work time;
- 5.00 for CPT code 34834 based on maintaining the current 70 minutes of preservice work time and the current 35 minutes of postservice work time;
- 8.35 for CPT code 34X19 with the addition of 70 minutes of preservice work time and 35 minutes of postservice work time to match CPT code 34834; and
- 9.47 for CPT code 34X20 with the addition of 75 minutes of preservice work time and 27 minutes of postservice work time to match CPT code 34833.

(14) Selective Catheter Placement (CPT Codes 36215, 36216, 36217, and 36218)

CPT code 36215 was identified as potentially misvalued on a screen of Harvard-valued codes with utilization over 30,000 in CY 2014, as well as on a screen of high expenditure services across specialties with Medicare allowed charges of over $10 million. CPT codes 36216, 36217, and 36218 were added to the family to be reviewed together with CPT code 36215.

We are proposing the RUC-recommended work RVUs for each code in this family as follows: A work RVU of 4.17 for CPT code 36215, a work RVU of 5.27 for CPT code 36216, a work RVU of 6.29 for CPT code 36217, and a work RVU of 1.01 for CPT code 36218.

We also considered refinements to the intraservice work time for CPT code 36217 from 60 minutes to 50 minutes, consistent with the RUC's usual use of the survey median intraservice work time. We have concerns that the use of the recommended survey 75th percentile intraservice work time will not be clinically appropriate for this code, as the 75th percentile time was identical for both CPT code 36216 and 36217, and therefore, the use of this value would not preserve the incremental, linear consistency between the work RVU and the intraservice time within the family.

For the direct PE inputs, we are proposing to refine the clinical labor time for the ''Post-procedure doppler evaluation (extremity)'' activity from 3 minutes to 1 minute for CPT codes 36215, 36216, and 36217. We believe that 1 minute would be more typical for this task, as the practitioner would be able to quickly evaluate if there was an issue with the extremity because there would be visual signs of arterial insufficiency resulting from the procedure.

We are proposing to remove the equipment time for the mobile instrument table (EF027) from CPT codes 36215, 36216, and 36217. We believe that the mobile instrument table would be used for moderate sedation, which was removed from these procedures in CY 2017 (see CY 2017 PFS final rule (81 FR 80339)). While we recognize that 180 minutes of post-procedure monitoring time remains in these codes during which the stretcher (EF018), IV infusion pump (EQ032), and 3-channel ECG (EQ011) would remain in use, we do not agree that the mobile instrument table would typically be in use during this period of monitoring. As a result, we are proposing to remove this equipment time from these three codes.

While we remain concerned about the use of the survey 75th percentile intraservice work time for CPT code 36217, for CY 2018, we are proposing the RUC-recommended work RVUs for each code in this family and seek comment on whether our alternative values would be more appropriate.

(15) Treatment of Incompetent Veins (CPT Codes 36470, 36471, 364X3, 364X4, 364X5, and 364X6)

In September 2016, the CPT Editorial Panel created four new codes to describe the treatment of incompetent veins, and revised existing CPT codes 36470 and 36471. These six codes were reviewed together as part of the same family of procedures. For CY 2018, we are proposing the RUC-recommended work RVU for all six codes as follows: A work RVU of 0.75 for CPT code 36470, a work RVU of 1.50 for CPT code 36471, a work RVU of 3.50 for CPT code 364X3, and a work RVU of 1.75 for CPT code 364X4, a work RVU of 2.35 for CPT code 364X5, and a work RVU of 3.00 for CPT code 364X6.

We considered a work RVU of 4.38 for CPT code 364X3, which would have been based on the RUC-recommended work RVU of 3.50 plus half of the RUC-recommended work RVU of CPT code 364X4. We also considered assigning CPT code 364X4 a status indicator of ''bundled.'' The services that would be reported using CPT codes 364X3 and 364X4 in CY 2018, are currently reported with unlisted CPT code 37799 (Unlisted procedure, vascular surgery). We have concerns about the frequency that the current services include treatment of an initial vein (CPT code 364X3) as compared to the treatment of initial and subsequent veins (CPT codes 364X3 and 364X4 together). It may be more accurate to describe these services through the use of a single code, as in the rest of this code family, instead of a base code and add-on code pair. Under this potential scenario, we looked at the RUC-recommended crosswalk and noted that the add-on CPT code 364X4 was estimated to be billed 50 percent of the time together with CPT code 364X3. We therefore considered adding half of the RUC-recommended work RVU of CPT code 364X4 (0.88) to the RUC-recommended work RVU of CPT code 364X3 (3.50), resulting in a work RVU of 4.38.

We are proposing to remove the 2 minutes of clinical labor for the ''Setup scope'' (CA015) activity and add the same 2 minutes of clinical labor for the ''Prepare room, equipment and

supplies'' (CA013) activity for CPT codes 364X3, 364X5, and 364X6. The RUC-recommended materials stated that these 2 minutes were a proxy for setting up the ultrasound machine, and we believe that this 2 minutes is more accurately described by the ''Prepare room, equipment and supplies'' (CA013) activity code, since there is no scope equipment utilized in these procedures. We are proposing to maintain the Vascular Tech (L054A) clinical labor type for these 2 minutes. We are also proposing to refine the clinical labor for the ''Check dressings, catheters, wounds'' (CA029) activity for CPT codes 36470, 36471, 364X3, 364X5, and 364X6, consistent with the standard times for this clinical labor activity.

We are proposing to remove the six individual 4x4 sterile gauze (SG055) supplies and replace them with a 4x4 sterile gauze pack of 10 (SG056) for CPT codes 36470, 36471, 364X3, 364X5, and 364X6. The pack of 10 sterile gauze is cheaper than six individual pieces of sterile gauze, and we do not agree that it would be typical to pay a higher cost for fewer supplies. We are also proposing to create three new supply codes in response to the invoices submitted for this family of codes. We are proposing to establish a price of $1495 for the Venaseal glue (SD323) supply, a price of $3195 for the Varithena foam (SD324) supply, and a price of $40 for the Varithena admin pack (SA125) supply.

We are proposing to adjust the equipment times for the surgical light (EF014), the power table (EF031), and the portable ultrasound unit (EQ250) for CPT codes 364X3, 364X5, and 364X6 consistent with the standards for non-highly technical equipment and to reflect the changes in the clinical labor described in this section of the proposed rule.

While we remain concerned about the creation of a base code and add-on code pairing (CPT codes 364X3 and 364X4) out of services that are currently reported using an unlisted code, for CY 2018, we are proposing the RUC-recommended work RVUs for each code in this family and are seeking comment on whether our alternative values would be more appropriate.

(16) Therapeutic Apheresis (CPT Codes 36511, 36512, 36513, 36514, 36516, and 36522)

CPT code 36516 was nominated as potentially misvalued in the CY 2016 PFS proposed rule. The CPT Editorial Panel deleted CPT code 36515 and made revisions to CPT code 36516 to include immunoabsorption. CPT codes 36511, 36512, 36513, 36514, and 36522 were added to CPT code 36516 to be reviewed together as part of the therapeutic apheresis family.

For CY 2018, we are proposing the RUC-recommended work RVU for all six codes in the family as follows: A work RVU of 2.00 for CPT code 36511, a work RVU of 2.00 for CPT 36512, a work RVU of 2.00 for CPT code 36513, a work RVU of 1.81 for CPT code 36514, a work RVU of 1.56 for CPT code 36516, and a work RVU of 1.75 for CPT code 36522.

We are proposing to use the RUC-recommended direct PE inputs for these codes without refinement. We considered refining the clinical labor time for the ''Prepare room, equipment, supplies'' activity from 20 minutes to 10 minutes for CPT codes 36514 and 36522, and from 30 minutes to 10 minutes for CPT code 36516. We also considered refining the clinical labor for the ''Prepare and position patient/monitor patient/set up IV'' activity from 15 minutes to 10 minutes for these same three codes. In both cases, we considered maintaining the current clinical labor time for CPT codes 36514 and 36516, and adjusting the clinical labor time for CPT code 36522 to match the other two codes in the family. We have concerns about the lack of a rationale provided for these changes in clinical labor time, and whether these clinical labor tasks would typically require this additional time.

We are proposing the RUC-recommended work RVUs and to use the RUC-recommended direct PE inputs for each code in this family and seeking comment on whether our alternative values would be more appropriate. We are also seeking comment on whether these procedures are creating a new point of venous access or utilizing a previously placed access.

(17) Insertion of Catheter (CPT Codes 36555, 36556, 36620, and 93503)

CPT code 36556 was identified as part of a screen of high expenditure services with Medicare allowed charges of $10 million or more that had not been recently reviewed. CPT codes 36555, 36620, and 93503 were added for review as part of the code family. We are proposing the RUC-recommended work RVUs for each code in this family as follows: A work RVU of 1.93 for CPT code 36555, a work RVU of 1.75 for CPT code 36556, a work RVU of 1.00 for CPT code 36620, and a work RVU of 2.00 for CPT code 93503.

We are proposing to remove the clinical labor time for the ''Monitor pt. following procedure'' activity and the equipment time for the 3-channel ECG (EQ011) for CPT code 36555. CPT code 36555 no longer includes moderate sedation as part of the procedure (see CY 2017 PFS final rule (81 FR 80339). We are proposing to remove the direct PE inputs related to moderate sedation from CPT code 36555 as they would now be included in the separately reported moderate sedation services. We are also proposing to refine the equipment times for the exam table (EF023) and the exam light (EQ168) to reflect changes in the clinical labor time.

(18) Insertion of PICC Catheter (CPT Code 36569)

CPT code 36569 was identified as part of a screen of high expenditure services with Medicare allowed charges of $10 million or more that had not been recently reviewed. For CY 2018, we are proposing the RUC-recommended work RVU of 1.70 for CPT code 36569.

We are proposing to remove the equipment time for the exam table (EF023), as this equipment item is a component part of the radiographic-fluoroscopic room (EL014) included in CPT code 77001 (Fluoroscopic guidance for central venous access device placement, replacement (catheter only or complete), or removal). Because CPT code 36569 is typically billed together with CPT code 77001, we believe that the additional equipment time for the exam table would be duplicative.

(19) Bone Marrow Aspiration (CPT Codes 38220, 38221, 382X3, and 2093X)

CPT code 38221 was identified as part of a screen of high expenditure services with Medicare allowed charges of $10 million or more that had not been recently reviewed. The descriptors for CPT codes 38220 and 38221 were revised to reflect changes in practice patterns, and two new CPT codes (382X3 and 2093X) were created to more accurately describe new services that are now available. For CY 2018, we are proposing the RUC-recommended work RVUs for each code in this family as follows: A work RVU of 1.20 for CPT code 38220, a work RVU of 1.28 for CPT code 38221, a work RVU of 1.44 for CPT code 382X3, and a work RVU of 1.16 for CPT code 2093X.

We also received a recommendation from the RUC to change the global period for CPT codes 38220, 38221, and 382X3 from XXX global periods to 0-day global periods, even though these codes were surveyed under the XXX global period. We agree with the recommendation that for these three particular codes, their services are more accurately described when assigned 0-day global periods as opposed to the XXX global status. Therefore, we propose to assign a 0-day global period

to all three codes in this family. We note, however, that we believe that global period changes must be addressed on an individual basis, especially when the routine survey methodologies rely on assumptions regarding global periods for particular codes. Subsequently, we are proposing to refine the preservice work time from 15 minutes of evaluation time to 9 minutes of evaluation time, 1 minute of positioning time, and 5 minutes of scrub, dress, and wait time. We are proposing these refinements to the work times for these three codes to more closely align with the preservice times of other recently reviewed 0-day global procedures, such as CPT code 30903 (Control nasal hemorrhage, anterior, complex (extensive cautery and/or packing) any method). We also note that given our proposal to value CPT code 382X3, we are proposing to eliminate payment using HCPCS code G0364 for CY 2018 since the changes to the set of CPT codes will now accurately describe the services currently reported by G0364. For CPT code 2093X, we considered a work RVU of 1.00 based on a direct crosswalk to CPT codes 64494 (Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), lumbar or sacral; second level) and 64495 (Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), lumbar or sacral; third and any additional level(s)). CPT code 2093X is a global ZZZ add-on code for CPT code 38220, and we are concerned with maintaining relativity among PFS services, considering that an add-on code typically has significantly less intraservice time and total time compared to the base code. We considered an alternative crosswalk to CPT codes 64494 and 64495, which share the same intraservice and total time with CPT code 2093X and have a work RVU of 1.00.

We are also proposing to refine the clinical labor for ''Lab Tech activities'' from 12 minutes to 9 minutes for CPT code 38220, from 7.5 minutes to 7 minutes for CPT code 38221, and from 12.5 minutes to 10 minutes for CPT code 382X3. We are maintaining the current time value for the two existing codes, as we have no reason to believe that the typical duration has increased for these lab activities. We are assigning 10 minutes for CPT code 382X3 based on the statement in the RUC-recommended materials for the direct PE inputs that this activity takes 0.5 minutes longer than it does in the current version of CPT code 38220. We are also proposing to remove the breakout lines for the lab activities. We believe that the breakout of activities into numerous subactivities generally tends to inflate the total time assigned to clinical labor activities and results in values that are not consistent with the analogous times for other PFS services.

We considered refining the clinical labor for ''Provide preservice education/obtain consent'' for CPT codes 38220, 38221, and 382X3 from 12 minutes to 6 minutes. We have concerns regarding whether 12 minutes would be typical for education and consent prior to these procedures, as much of the patient education takes place following the procedure, in the clinical labor activity described under the ''Check dressings & wound/home care instructions'' heading.

We are proposing the RUC-recommended work RVUs for each code in this family and are seeking comment on whether our alternative values would be more appropriate.

(20) Esophagectomy (CPT Codes 43107, 43112, 43117, 432X5, 432X6, and 432X7)

CPT codes 432X5, 432X6, and 432X7 were created by the CPT Editorial Panel to report esophagectomy via laparoscopic and thoracoscopic approaches. CPT codes 43107, 43112, and 43117 were also reviewed as part of the family with the three new codes. CPT code 43112 was revised to clarify the nature of the service being performed. We are proposing the RUC-recommended work RVUs and work times for all six codes in the family as follows: A work RVU of 52.05 for CPT code 43107, a work RVU of 62.00 for CPT code 43112, a work RVU of 57.50 for CPT code 43117, a work RVU of 55.00 for CPT code 432X5, a work RVU of 63.00 for CPT code 432X6, and a work RVU of 66.42 for CPT code 432X7.

We are also proposing the RUC-recommended work times for all six codes in this family. We considered removing 20 minutes from the preservice evaluation work time from all six of the codes in this family. We have concerns as to whether this additional evaluation time should be included for surgical procedures, due to the lack of evidence indicating that it takes longer to review outside imaging and lab reports for surgical services than for non-surgical services. We also considered refining the preservice positioning work time and the immediate postservice work time for all six of the codes in this family consistent with standard preservice and postservice work times allocated to other PFS services.

We have concerns about the presence of two separate surveys conducted for the three new codes. We note that CPT codes 432X5, 432X6, and 432X7 were surveyed initially in January 2016, and then were surveyed again in October 2016 together with CPT codes 43107, 43112, and 43117 due to concerns about the description of the typical patient in the original vignette and a change in the codes on the reference service list (RSL). We note that CPT codes 432X5 and 432X6 had the same median intraservice time on both surveys, while CPT code 432X7 had a median intraservice time that was an hour longer on its second survey (420 minutes) as compared to its first survey (360 minutes). We also note that the total survey time for CPT code 432X5 decreased from 1058 minutes in the first survey to 972 minutes in the second survey, while the median work RVU increased from 50.00 to 65.00. We do not understand how the survey median intraservice time could increase so significantly from the first survey to the second survey for CPT code 432X7, or how the surveyed times for CPT code 432X5 could be decreasing while the work RVU was simultaneously increasing by 15.00 work RVUs.

Based on our analysis, it appears that the accompanying RSL is the main difference between the two surveys; the codes on the initial RSL had a median work RVU of 44.18, while the codes on the second RSL had a median work RVU of 59.64. This increase of 15.00 work RVUs between the two RSLs that accompanied the surveys appears to account for the increase in the work RVUs for the three new codes. We are concerned that the second survey may have overestimated the work required to perform these procedures, as the 25th percentile work RVU of the second survey is higher than the median work RVU of the initial survey for all three codes, despite no change in the median intraservice work time for CPT codes 432X5 and 432X6.

Given these concerns, we considered a work RVU of 50.00 for CPT code 432X5, a work RVU of 60.00 for CPT code 432X6, and a work RVU of 61.00 for CPT code 432X7, by using the survey median work RVU from the first survey for the three new codes. For CPT codes 43107 and 43117, we considered employing the intraservice time ratio between the laparoscopic version of the procedure represented by the new code and the open version of the same procedure represented by the existing code.

We considered a work RVU of 45.00 for CPT code 43107 based on the intraservice time ratio with CPT code 432X5 and a work RVU of 55.00 for CPT code 43117 based on the intraservice time ratio with CPT code 432X6. CPT code 43107 has 270 minutes of intraservice time as compared with 300 minutes of intraservice time for CPT code 432X5, which produces a ratio of 0.9, and when multiplied by a work RVU of 50.00 (CPT code 432X5), results in the proposed work RVU of 45.00. We considered using the same methodology for CPT codes 43117 and 432X6.

Finally, we considered a work RVU of 58.94 for CPT code 43112 based on a direct crosswalk to CPT code 46744 (Repair of cloacal anomaly by anorectovaginoplasty and urethroplasty, sacroperineal approach). We note that the intraservice time ratio when applied to CPT codes 43112 and 432X7, the paired McKeown esophagectomy procedures, would have produced a potential work RVU of 52.29, creating a rank order anomaly within the family by establishing a higher work RVU for CPT code 43117 than CPT code 43112, and are concerned with whether this is an appropriate valuation for the code. We are seeking comment on whether the alternative work RVUs that we considered may reflect the relative difference in work more accurately between the six codes in the family. We note, for example, that these valuations correct the rank order anomaly between CPT codes 43112 and 43121 as noted in the RUC recommendations.

We are proposing the RUC-recommended direct PE inputs for all six codes in the family without refinement. We considered changing the preservice clinical labor type for all six codes from an RN (L051) to an RN/LPN/MTA blend (L037D). We have concerns about whether the use of RN clinical labor would be typical for filling out referral forms or for scheduling space and equipment in the facility. We also considered removing the additional clinical labor time for the ''Additional coordination between multiple specialties for complex procedures (eg, tests, meds, scheduling)'' activity, consistent with preservice standards for codes with 90-day global periods. We are concerned that this time would not typically be included in non-surgical procedures performed by other specialties even when additional coordination is required.

We are seeking comment regarding the changes in the valuation between the two surveys, the preservice and immediate postservice work times, and the RN staffing type employed for routine preservice clinical labor.

(21) Transurethral Electrosurgical Resection of Prostate (CPT Code 52601)

CPT code 52601 appeared on a screen of potentially misvalued codes which indicated that it was performed less than 50 percent of the time in the inpatient setting, yet included inpatient hospital E/M services within the global period. For CY 2018, we are proposing the RUC-recommended work RVU of 13.16 for CPT code 52601 and proposing to use the RUC-recommended direct PE inputs without refinements.

We considered a work RVU of 12.29 for CPT code 52601 based on a direct crosswalk to CPT code 58541 (Laparoscopy, surgical, supracervical hysterectomy, for uterus 250 g or less), which is one of the reference codes. CPT code 58541 may potentially be a more accurate crosswalk for CPT code 52601 than the RUC-recommended direct crosswalk to CPT code 29828 (Arthroscopy, shoulder, surgical; biceps tenodesis). Although all three of these codes share the same intraservice time of 75 minutes, CPT code 58541 is a closer match in terms of the total time at only 10 minutes difference. CPT code 58541 also shares the same postoperative office visits as CPT code 52601, a pair of CPT code 99213 office visits, while CPT code 29828 also contains two CPT code 99212 office visits that are not present in the reviewed code.

We note that if we were to use a reverse building block methodology for CPT code 52601 and subtract out the value of the E/M visits being removed, the proposed work RVU would be 11.21. We are not proposing this work RVU, however, because as we noted in the CY 2017 PFS final rule (81 FR 80274), we agree that the per-minute intensity of work is not necessarily static over time or even necessarily during the course of a procedure. Instead, we utilize time ratios and building block methodologies to identify potential values that account for changes in time and compare these values to other PFS services for estimates of overall work. When the values we develop reflect a similar derived intensity, we agree that our values are the result of our assessment that the relative intensity of a given service has remained similar. For CPT code 52601, we are concerned as to how the RUC-recommended derived intensity of the procedure could be increasing by 30 percent over the current derived intensity, while at the same time the typical site of service is changing from inpatient to outpatient status. In other words, if it is now typical for CPT code 52601 to be performed on an outpatient basis, then we would generally expect the intensity of the procedure to be decreasing, not increasing. We considered a work RVU of 12.29 for CPT code 52601 based on a direct crosswalk to CPT code 58541 (Lsh uterus 250 g or less), and seek comment on whether this alternative value might better reflect relativity.

(22) Peri-Prostatic Implantation of Biodegradable Material (CPT Code 55X87)

In October 2016, the CPT Editorial Panel deleted CPT Category III code 0438T and created a new CPT code 55X87 (Transperineal placement of biodegradable material, peri-prostatic, single or multiple injection(s), including image guidance, when performed). For CY 2018, we are proposing the RUC-recommended work RVU of 3.03 for CPT code 55X87.

In reviewing the RUC recommendations, we noted a decrease in preservice time (30 minutes) compared to the current value. In order to account for this change in time, we considered calculating the intraservice time ratio between the key reference code (CPT code 49411), which has an intraservice time of 40 minutes, and the RUC-recommended intraservice time (30 minutes) and multiplying that against the work RVU for CPT code 49411 (3.57), which would have resulted in a work RVU of 2.68. A work RVU of 2.68 would have been further supported by a bracket of two crosswalk codes, CPT code 65779 (Placement of amniotic membrane on the ocular surface; single layer, sutured) which has a work RVU of 2.50 and CPT code 43252 (Esophagogastroduodenoscopy, flexible, transoral; with optical endomicroscopy), which has a work RVU of 2.96. Compared with CPT code 55X87, these codes have identical intraservice and similar total times. We are seeking comment on whether these alternative values should be considered, especially given the changes in time reflected in the survey data.

We received invoices with pricing information regarding two new supply items: ''endocavity balloon'' and ''biodegradeable material kit—periprostatic''. The invoice for endocavity balloon was $399.00 and the input price on the PE spreadsheet for this supply item was noted as such. We believe the input price noted on the PE spreadsheet was an error, given that the invoice noted that the price of $399.00 was for a box of ten and the specialty society requested a single unit of this supply item. Therefore, we are proposing to use this information to propose for supply item ''endocavity balloon'' a price of $39.90. The invoice

for the ''biodegradeable material kit—periprostatic'' totaled $2850.00. We are proposing to use this information to propose for the supply item ''biodegradeable material kit—periprostatic'' a price of $2850.00. We also received an invoice with pricing information regarding the new equipment item ''endocavitary US probe'' which totaled $16,146.00. We are proposing to use this information to propose for equipment item ''endocavitary US probe'', a per-minute price of $0.0639. We question, given an invoice price of $29,999.00 for this existing equipment item EQ250 (portable ultrasound unit), whether this equipment item includes probes. We are seeking public comments related to whether equipment item EQ250 (portable ultrasound) includes probes.

(23) Colporrhaphy With Cystourethroscopy (CPT Codes 57240, 57250, 57260 and 57265)

In October 2015, CPT code 57240 was identified by analysis of the Medicare data from 2011–2013 that indicated that services reported with CPT code 57240 were performed less than 50 percent of the time in the inpatient setting, yet include inpatient hospital E/M services within the global period. The RUC recommended that CPT codes 57240 (Anterior colporrhaphy, repair of cystocele with or without repair of urethrocele), 57250 (Posterior colporrhaphy, repair of rectocele with or without perineorrhaphy), 57260 (Combined anteroposterior colporrhaphy), and 57265 (Combined anteroposterior colporrhaphy; with enterocele repair) be referred to the CPT Editorial Panel. In September 2016, the CPT Editorial Panel revised 57240, 57260 and 57265 to preclude separate reporting of follow up cystourethroscopy after colporrhaphy (CPT code 52000).

For CY 2018, we are proposing the RUC-recommended work RVUs for CPT code 57240 (a work RVU of 10.08), CPT code 57250 (a work RVU of 10.08), CPT code 57260 (a work RVU of 13.25), and CPT code 57265 (a work RVU of 15.00).

We note that there were changes in service times reflected in the specialty surveys compared to the RUC-recommended work RVUs for CPT code 57240. Specifically, we note that the RUC recommended a 48 minute decrease in total time, compared to the specialty survey total time of 259 minutes. The difference in total time reflected a decrease in preservice time (29 minutes) and inpatient visits (0.5 visits = 19 minutes). We considered a work RVU of 9.77 for CPT code 57240, crosswalking to CPT code 50590 (Lithotripsy, extracorporeal shock wave), which has similar service times. We are seeking comment on whether CPT code 57250 would be a relevant comparator for CPT code 57240, based on the described elements of each service and existing or surveyed service times, compared to CPT code 57240.

We considered a work RVU of 11.47 for CPT code 57265, crosswalking to CPT code 47563 (Laparoscopy, surgical; cholecystectomy with cholangiography) with similar service times. We seek comment on how an alternative work RVU of 11.47 for CPT code 57265 would affect relativity among PFS services, and on whether CPT code 57260 is a relevant comparator for CPT code 57265, considering differences in the described procedures and service times.

We are proposing the RUC-recommended direct PE inputs for CPT codes 57240, 57250, 57260 and 57265 without refinements.

(24) Nerve Repair With Nerve Allograft (CPT Codes 64910, 64911, 64X91 and 64X92)

The CPT Editorial Panel created two new CPT Category I codes (64X91 and 64X92) to report the repair of a nerve using a nerve allograft. CPT codes 64910 and 64911 were also reviewed as part of this code family. CPT codes 64X91 and 64X92 will be placed on the new technology list to be re-reviewed by the RUC in 3 years to ensure correct valuation and utilization assumptions.

For CY 2018, we are proposing the RUC-recommended work RVUs for the following codes: A work RVU of 10.52 for CPT code 64910, a work RVU of 14.00 for CPT code 64911, a work RVU of 12.00 for CPT code 64X91, and a work RVU of 3.00 for CPT code 64X92.

We noted a decrease in preservice time (7 minutes) for CPT code 64910 and considered an alternate work RVU of 10.15, crosswalking to CPT code 15120 (Split-thickness autograft, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; first 100 sq cm or less, or 1 percent of body area of infants and children (except 15050)), which has similar service times. We seek comments on whether an alternative work RVU of 10.15 for CPT code 64910 would better reflect relativity among PFS services with similar service times.

For CPT code 64911 (Nerve repair; with autogenous vein graft (includes harvest of vein graft), each nerve)), we considered a work RVU of 13.50, crosswalking to CPT code 31591 (Laryngoplasty, medicalization, unilateral), which has similar service times. We seek comments on whether a work RVU of 13.50 for CPT code 64911 would better reflect relativity among other PFS services with similar service times.

The new coding structure for these services increases granularity by including add-on codes that describe each strand of nerve repair. While we recognize that additional granularity may be important and useful for purposes of data collection, the advantages to Medicare for such granularity for purposes of payment are unclear, especially since we are unaware of a payment-related reason for such coding complexity. We considered proposing a bundled status to the new add-on codes and incorporating the relative resources in furnishing the add-on code (CPT code 64X92) into the base code (CPT code 64X91) based on the utilization assumptions that accompanied the RUC recommendations. The RUC estimated that CPT code 64X91 would have 750 Medicare allowed services in CY 2018, and that the corresponding add-on CPT code 64X92 would have 150 Medicare allowed services in CY 2018. Therefore, the RUC estimates that CPT code 64X91 will be billed without add-on CPT code 64X92 for 80 percent (750/900) of the Medicare allowed services, and that CPT code 64X91 will be billed with add-on CPT code time 64X92 for 20 percent (150/900) of the Medicare allowed services in CY 2018. To account for the additional work involved in 20 percent of the allowed services, we added a work RVU of 0.60 (20 percent of a work RVU of 3.00 for CPT code 64X92) to the work RVU of 12.00 for CPT code 64X91, to get to an alternate work RVU of 12.60 for CPT code 64X91 and increased the intraservice time by 6 minutes to account for the bundling of services from CPT code 64X92. The alternative work RVU of 12.60 would have been further supported by a crosswalk to CPT code 14301 (Adjacent tissue transfer or rearrangement, any area; defect 30.1 sq cm to 60.0 sq cm), which has similar intraservice and total times.

We are proposing the RUC-recommended direct PE inputs for CPT codes 64910, 64911, 64X91 and 64X92 without refinements.

(25) CT Soft Tissue Neck (CPT Codes 70490, 70491, and 70492)

CPT codes 70490 and 70492 were identified through the high expenditure services across specialties with Medicare allowed charges of $10 million or more screen. CPT code 70491 was also included for review as part of this code family. For CY 2018, we are proposing the RUC-recommended work RVUs of 1.28 for CPT code 70490, 1.38

for CPT code 70491, and 1.62 for CPT code 70492.

For CPT code 70490, we considered a work RVU of 1.07 based on a crosswalk to CPT code 72125 (Computed tomography, cervical spine; without contrast material). CPT code 72125 is a non-contrast CT service on a similar anatomical area and has identical intraservice and total times to those recommended by the RUC for CPT code 70490. We also considered work RVUs of 1.17 for CPT code 70491 and 1.41 for CPT code 70492. We are seeking comment on how relativity among other CT services paid under the PFS would be affected by applying the alternative work RVUs described above for CPT codes in this family.

(26) Magnetic Resonance Angiography (MRA) Head (CPT Codes 70544, 70545, and 70546)

CPT code 70544 was identified by a screen of services across specialties with Medicare allowed charges of $10 million or more. Subsequently, CPT codes 70545 and 70546 were also reviewed as part of this code family. We are proposing the RUC-recommended work RVUs of 1.20 for CPT code 70544, 1.20 for CPT code 70545, and 1.48 for CPT code 70546.

We are also proposing the following refinements to the RUC-recommended direct PE inputs. For the service period clinical labor activity ''Provide preservice education/obtain consent,'' we are proposing 5 minutes for CPT code 70544, 7 minutes for CPT code 70545, and 7 minutes for CPT code 70546 so that the times for this activity are consistent with other magnetic resonance (MR) services performed without-contrast materials, with-contrast materials, and without-and-with contrast materials, respectively. For the clinical labor task ''Acquire images,'' we are proposing to use the RUC-recommended clinical time of 26 minutes for CPT code 70544. We considered proposing 20 minutes of clinical time to maintain the relativity among the three codes in this family and for consistency with other MRA and magnetic resonance imaging (MRI) codes, which do not typically assign more clinical labor time to this task for services without contrast material than for services with contrast material. We seek comments as to the appropriate time value for this clinical labor task.

(27) Magnetic Resonance Angiography (MRA) Neck (CPT Codes 70547, 70548, and 70549)

CPT code 70549 was identified through a high expenditure screen. CPT codes 70547 and 70748 were also reviewed as part of this family of codes. We are proposing the RUC-recommended work RVUs of 1.20 for CPT code 70547, 1.50 for CPT code 70548, and 1.80 for CPT code 70549.

We are also proposing several refinements to the RUC-recommended direct PE inputs for these services. For the service period clinical labor activity ''Provide preservice education/obtain consent'', we are proposing 5 minutes for CPT code 70547, 7 minutes for CPT code 70548, and 7 minutes for CPT code 70549 so that the times for this activity are consistent with other MR services performed without contrast material, with contrast material, and without-and-with contrast material, respectively.

For the intraservice clinical labor task acquire images, for CPT code 70547, we are proposing to use the RUC-recommended 26 minutes. We considered applying 20 minutes to this clinical labor task, which would have maintained consistency with the 20 minutes recommended by the RUC for CPT code 70548 (the service that includes with-contrast material). We are concerned about the lack of evidence that a non-contrast MRA would require more clinical labor time than the with-contrast MRA service. We are seeking comment as to the appropriate time value for this clinical labor task.

(28) CT Chest (CPT Codes 71250, 71260, and 71270)

CMS identified this code family through the high expenditures screen. We are proposing the RUC-recommended work RVUs of 1.16 for CPT code 71250, 1.24 for CPT code 71260, and 1.38 for CPT code 71270.

For CPT code 71250, we considered maintaining the CY 2017 work RVU of 1.02. We are concerned with the lack of evidence that the physician time or intensity of furnishing this service has changed since it was last valued. In addition, a comparison to other CT codes indicates that the RUC-recommended work values could be overvalued relative to other CT services and compared to similar, non-contrast CT studies such as CPT codes 72131 (Computed tomography, lumbar spine; without contrast material) and 73700 (Computed tomography, lower extremity; without contrast material), both of which have work RVUs of 1.00.

For CPT code 71260, we considered proposing a work RVU of 1.10 by applying the RUC-recommended increment between CPT code 71250 and 71260 (0.08) to CPT code 71260. For CPT code 71270, we considered a work RVU of 1.24 by applying the RUC-recommended increment between CPT codes 71260 and 71270 (0.22) to CPT code 71270. In addition to maintaining relatively among the codes in this family, we considered further supporting these alternative values based on a comparison to other CT studies, such as with-contrast material CT studies, and without-and-with contrast CT studies.

While we have concerns about the RUC-recommended work RVUs for these codes, for CY 2018, we are proposing the RUC recommended work RVUs for CPT code 71250, 71260, and 71270 and are seeking comment on whether our alternative values would improve relativity.

(29) MRI of Abdomen and Pelvis (CPT Codes 72195, 72196, 72197, 74181, 74182, and 74183)

CPT codes 74182 and 72196 were identified as part of the screen of high expenditure services across specialties with Medicare allowed charges of $10 million or more. CPT codes 74181, 74183, 72195, and 72197 were also reviewed as part of this code family. We are proposing the RUC-recommended work RVUs of 1.46 for CPT code 72195, 1.73 for CPT code 72196, 2.20 for CPT code 72197, 1.46 for CPT code 74181, 1.73 for CPT code 74182, and 2.20 for CPT code 74183.

While we are proposing the RUC-recommended direct PE inputs, we considered 30 minutes for clinical labor task ''Acquire images'' for CPT codes 74181 and 74182, which appears to be more consistent with the codes in this family and more consistent with other MR codes. We also note that for CPT codes 74181 and 74182, the clinical labor time for acquired images appears to have been developed through a consensus panel from the specialty society over 15 years ago. Given that these times are estimates based on expert panel consensus rather than survey data, we seek comments on whether using a structure that matches other MR code families would be more appropriate to value these clinical labor times.

(30) MRI Lower Extremity (CPT Codes 73718, 73719, and 73720)

CPT codes 73718 and 73720 were identified as part of the screen of high expenditure services, and CPT code 73719 was included for review as part of the code family. We are proposing the RUC-recommended work RVUs of 1.35 for CPT code 73718, 1.62 for CPT code 73719, and 2.15 for CPT code 73720.

We are also proposing the following refinements to the RUC-recommended direct PE inputs. For the service period clinical labor activity ''Provide preservice education/obtain consent,''

we are proposing 5 minutes for CPT code 73718, 7 minutes for CPT code 73719, and 7 minutes for CPT code 73720. Likewise, for the service period task ''Prepare room, equipment, supplies,'' we are proposing 3 minutes for CPT code 73718, 5 minutes for CPT code 73719, and 5 minutes for CPT code 73720. We are proposing these changes to maintain consistency with other MR services without contrast materials, with contrast materials, and without-and-with contrast materials, respectively.

(31) Abdominal X-ray (CPT Codes 74022, 740X1, 740X2, and 740X3)

CPT codes 74000 (Radiologic examination, abdomen; single anteroposterior view) and 74022 (Radiologic examination, abdomen; complete acute abdomen series, including supine, erect, and/or decubitus views, single view chest) were identified via a high expenditure screen. The CPT Editorial Panel created CPT codes 740X1, 740X2, and 740X3 to replace CPT codes 74000, 74010, and 74020. For CY 2018, we are proposing the RUC-recommended work values for these codes.

As part of their recommendations, the RUC's utilization crosswalk suggests that 25 percent of services currently reported with CPT code 74010 will be reported with CPT code 740X2 and 75 percent will be reported with CPT code 740X3; and 75 percent of services currently reported with CPT code 74020 will be reported with CPT code 740X2 and 25 percent will be reported with CPT code 740X3. However, we did not identify evidence or a rationale for these assumptions. For purposes of calculating the proposed RVUs, we used an even distribution of services previously reported as CPT codes 74010 and 74020 to CPT codes 740X2 and 740X3 instead of the RUC-recommended distribution because we think that the services previously reported with codes 74010 and 74020 will be reported in equal volume between the code representing two views and the code representing three views. We seek comment on information that would help us improve on this distribution for purposes of developing final RVUs, including rationale for the distribution reflected in the RUC's utilization crosswalk.

(32) Angiography of Extremities (CPT Codes 75710 and 75716)

This code family was identified through the $10 million or more screen of high expenditure services. We are proposing the RUC-recommended work RVUs of 1.75 for CPT code 75710 and 1.97 for CPT code 75716. We are also proposing to use the RUC-recommended direct PE inputs for both CPT codes 75710 and 75716, with the following refinements. For the clinical labor task ''Technologist QC's images in PACS, checking for all images, reformats, and dose page,'' we are proposing refinements consistent with the standard clinical labor times for tasks associated with the PACS Workstation.

We are also proposing to refine the clinical labor by removing the 2 minutes associated with the task ''prepare room, equipment, and supplies.'' CPT codes 75710 and 75716, which represent radiological supervision and interpretation, are billed with codes that include activities such as needle placement and imaging, and the ''prepare room, equipment, supplies,'' activity will be accounted for with the codes that are billed with these interpretation codes.

(33) Ophthalmic Biometry (CPT Codes 76516, 76519, and 92136)

In the CY 2016 PFS final rule with comment period, CMS identified CPT codes 76519 and 92136 as potentially misvalued on the high expenditure screen. For CY 2018, we are proposing the RUC-recommended work RVUs for each code in this family as follows: A work RVU of 0.40 for CPT code 76516, a work RVU of 0.54 for CPT code 76519, and a work RVU of 0.54 for CPT code 92136.

For both CPT codes 76519 and 92136, the RUC recommended adding an additional 8 minutes of immediate postservice time for dictating the report of the procedure for the medical record, review and sign report, communicate results to the patient, discussing lens implant options for desired post-operative refractive result, and entering an order for the intraocular lens implant. We considered time and work values that would not include the additional 8 minutes of immediate postservice time in either of these codes, due to the concern that the additional time may not reflect the typical case. Were we to not include those 8 minutes, each of these procedures would have a total time of 14 minutes. We considered applying the total time ratio (decrease from 17 minutes to 14 minutes; ratio of 0.824) to the RUC-recommended work RVU of 0.54, which would have resulted in a work RVU of 0.44 for both CPT codes 76519 and 92136. We are seeking comment on whether these alternative values would improve relativity.

(34) Ultrasound of Extremity (CPT Codes 76881 and 76882)

The RUC identified CPT codes 76881 and 76882 for review of PE inputs. For CPT code 76881, we are proposing the recommended inputs with refinements. We are proposing to remove 1 minute from the clinical labor task ''Exam documents scanned into PACS. Exam completed in RIS system to generate billing process and to populate images into Radiologist work queue,'' because this code does not include any equipment time for the PACS workstation proxy or professional PACS workstation. We note that the RUC-recommended inputs shift the general ultrasound room from the PE inputs for CPT code 76881 to the PE inputs for CPT code 76882. We are proposing to make this change, consistent with the RUC recommendations. We are also seeking comment on whether a portable ultrasound unit would be a more accurate PE input for both codes, given that the dominant specialty for both of these services is podiatry based on available 2016 Medicare claims data. However, we are proposing that these codes would not be subject to the phase-in of significant RVU reductions given the significance of this shift of resource costs between codes in the same family. In the CY 2016 PFS final rule (80 FR 70927 through 70931), we finalized a policy to identify services that are not subject to the phase-in because they are new or revised codes. We excluded as new and revised codes those codes that describe a different set of services in the update year when compared to the current year by virtue of changes in other related codes or codes that are part of a family with significant coding revisions. Significant coding revisions within a family of codes can change the relationships among codes to the extent that it changes the way that all services in the group are reported, even if some individual codes retain the same number or, in some cases, the same descriptor. Moving the general ultrasound room input from CPT code 76881 to CPT code 76882 as recommended by the RUC would represent a significant shift in direct PE due to the high cost nature of this equipment item. As a result, these codes describe different services in the update year than in the current year, producing a substantial revision in the valuation of the coding. We are seeking comment on this proposed application of the phase-in policy.

(35) Radiation Therapy Planning (CPT Codes 77261, 77262, and 77263)

CPT code 77263 was identified through a screen of high expenditure services across specialties. CPT codes 77261 and 77262 were included for review. For CY 2018, we are proposing the RUC-recommended work RVUs of

1.30 for CPT code 77261, 2.00 for CPT code 77262, and 3.14 for CPT code 77263.

However, we have concerns regarding the RUC-recommended work RVUs given the decreases in service times as recommended by the RUC and reflected in the survey data compared to the current values. For CPT code 77263, we considered a work RVU of 2.60 based on a crosswalk to CPT code 96111 (Developmental testing, (includes assessment of motor, language, social, adaptive, and/or cognitive functioning by standardized developmental instruments) with interpretation and report), which has an identical intraservice time, and similar total time to the RUC-recommended time values for CPT code 77263. We are concerned that despite a 15 minute decrease in intraservice time, the RUC did not recommend a work RVU decrease.

We note that the majority of the utilization among the codes in this family would be reported with CPT code 77263. Therefore, we considered using a work RVU of 2.60 for CPT code 77263 as a base for alternative valuations for CPT codes 77261 and 77262 by applying the ratio of the crosswalk work RVU of CPT code 96111 (Developmental test extend) to the RUC-recommended work RVU of CPT code 77263 (that is, 2.60/3.14 = 0.83) to the RUC-recommended work RVU for CPT code 77261 (that is, $0.83 \times 1.30 = 1.08$) and CPT code 77262 (that is, $0.83 \times 2.0 = 1.66$), which would have resulted in work RVUs of 1.08 for CPT code 77261 and 1.66 for CPT code 77262. We seek comments on whether the alternative valuation would be more appropriate for these codes.

(36) Pathology Consultation during Surgery (CPT Codes 88333 and 88334)

CPT codes 88333 and 88334 were surveyed for both work and PE for the CY 2018 rule cycle. We are proposing the RUC-recommended work RVU of 1.20 for CPT code 88333 and the RUC-recommended work RVU of 0.73 for CPT code 88334. For the direct PE inputs, we are proposing to remove the clinical labor for the ''Prepare room. Filter and replenish stains and supplies (including setting up grossing station with colored stains)'' activity from CPT code 88333. This clinical labor is not currently included in the direct PE inputs for CPT code 88333, and we continue to believe that this is a form of indirect PE that is not individually allocable to a particular patient for a particular service. While we agree that replenishing stains and supplies is a necessary task, under the established methodology, it is more appropriately classified as indirect PE.

We are proposing to refine the clinical labor time for ''Clean room/equipment following procedure'' activity for CPT code 88333, consistent with the standard clinical labor time assigned for room cleaning when used by laboratory services. We seek comments related to the equipment time assigned to the ''grossing station w-heavy duty disposal'' (EP015) for both CPT codes 88333 and 88334. Although the recommended equipment time of 10 minutes maintains the current equipment time assigned to the grossing station, and we have no reason to believe that this time is incorrect, it is unclear to us how this equipment time is derived.

(37) Tumor Immunohistochemistry (CPT Codes 88360 and 88361)

CPT codes 88360 and 88361 appeared on a high expenditure services screen across specialties with Medicare allowed charges of over $10 million. We are proposing the RUC-recommended work RVU of 0.85 for CPT code 88360 and the RUC-recommended work RVU of 0.95 for CPT code 88361. We are proposing to refine the clinical labor time for the ''Enter patient data, computational prep for antibody testing, generate and apply bar codes to slides, and enter data for automated slide stainer'' activity for both codes, consistent with the standard time for this clinical labor activity across different pathology services. For CPT code 88361, we are also proposing to remove the 1 minute of clinical labor time from the ''Performing instrument calibration, instrument qc and start up and shutdown'' and the ''Gate areas to be counted by the machine'' activities. These clinical labor activities do not appear in other recently reviewed computer-assisted pathology codes. We believe that these clinical labor activities would not be typical for CPT code 88361 and are already included in the allocation of indirect PE consistent with our established methodology.

We are proposing to remove the clinical labor time for ''Clean room/equipment following procedure'' for CPT codes 88360 and 88361, as we believe that this clinical labor is duplicative of the 4 minutes of clinical labor assigned to ''Clean equipment and work station in histology lab''. We are also proposing to remove the clinical labor time for the ''Verify results and complete work load recording logs'' and the ''Recycle xylene from tissue processor and stainer'' activities for CPT codes 88360 and 88361. As we have stated in previous rules, such as in the CY 2017 PFS final rule (81 FR 80319), we believe these clinical labor activities to be already included in the allocation of indirect PE consistent with our established methodology.

We are proposing to refine the equipment time for the ''Benchmark ULTRA auto slide prep & E-Bar Label system'' (EP112) from 18 minutes to 16 minutes for both codes. The RUC-recommended equipment time of 18 minutes was an increase of 3 minutes from the current EP112 equipment time to incorporate the equipment time of the ''E-Bar II Barcode Slide Label System'' (EP113), which the recommended materials have clarified is part of the EP112 equipment item. We are proposing to add 1 minute over the current value of 15 minutes to the EP112 equipment time to reach the aforementioned 16 minutes, as we believe that this would be more typical for the slide labeling taking place.

For CPT code 88361, we are proposing to maintain the current price of $195,000.00 for the DNA image analyzer (EP001) equipment, as the submitted invoice contains a series of unrelated items that have been crossed out, making it difficult to determine the cost of the equipment. We considered refining the equipment time for the DNA image analyzer from 30 minutes to 5 minutes. The equipment literature for the DNA image analyzer states that the machine can run 50 slides per hour, and CPT code 88361 only requires 3 slides per procedure. This works out to 3.6 minutes of equipment usage (3 slides divided by 50 slides per hour multiplied by 60 minutes in an hour), to which we considered adding 1 minute for preparing the slides. The resulting figure of 4.6 minutes would then round up to 5 minutes, which we considered as the potential equipment time for EP001 assigned to CPT code 88361. We seek comments on additional pricing information for the EP001 DNA image analyzer equipment, specifically invoices solely for this equipment containing a rationale for each component part, as well as the appropriate equipment time typically required for use in CPT code 88361.

(38) Cardiac Electrophysiology Device Monitoring Services (CPT Codes 93279, 93281, 93282, 93283, 93284, 93285, 93286, 93287, 93288, 93289, 93290, 93291, 93292, 93293, 93294, 93295, 93296, 93297, 93298, and 93299)

As part of the CY 2016 PFS final rule (80 FR 70914), several services in this family (reported with CPT codes 93288, 93293, 93294, 93295, and 93296) were identified as potentially misvalued through the high expenditure by

specialty screen. Seven of the 21 services in this family involve remote monitoring of cardiovascular devices, and two of these services (reported with CPT codes 93296 and 93299) are valued for practice expense only. For CY 2018, we are proposing the RUC-recommended work RVUs for the 19 CPT codes in this family that are valued with physician work as follows: 0.65 for CPT code 93279, 0.77 for CPT code 93280, 0.85 for CPT code 93281, 0.85 for CPT code 93282, 1.15 for CPT code 93283, 1.25 for CPT code 93284, 0.52 for CPT code 93285, 0.30 for CPT code 93286, 0.45 for CPT code 93287, 0.43 for CPT code 93288, 0.75 for CPT code 93289, 0.43 for CPT code 93290, 0.37 for CPT code 93291, 0.43 for CPT code 93292, 0.31 for CPT code 93293, 0.60 for CPT code 93294, 0.74 for CPT code 93295, 0.52 for CPT code 93297, and 0.52 for CPT code 93298.

For CPT code 93293, we considered a work RVU of 0.91 (25th percentile survey result) and seek comment on whether this alternative work RVU for this service would better maintain relativity between single and dual lead pacemaker systems and cardioverter defibrillator services. We considered reducing the work RVU for CPT code 93282 by 0.11 work RVUs and seek comments on whether this alternative value would better reflect relativity between the single and dual lead systems that exist within pacemaker services and within cardioverter defibrillator services. We also noted that there is a difference of 0.10 work RVUs between the RUC-recommended values for CPT codes 93289 and 93282. Therefore, we considered a proportionate reduction for CPT code 93289 to a work RVU of 0.69. For CPT code 93283, we considered a work RVU of 0.91, consistent with the 25th percentile from the survey results, and seek comment on whether this value would improve relativity.

As noted in this section of the proposed rule, several of the CPT codes (99392, 99294, 99295, 99297, and 99298) reviewed by the RUC in January 2017 involve remote monitoring services for cardiac devices. We agree with the RUC that these services are difficult to value considering that the monitoring duration (number of days between 30 and 90) and the average number of transmissions vary. We also note that these codes were surveyed twice, and in both cases the intraservice and total times were considered by the specialty societies to be inconsistent with existing times. The RUC explained that they extrapolated total and intraservice time data for these codes and warned against making comparisons. Without additional information about the methods and sources used for extrapolation, however, we have no basis for assuming the imputed values are of higher quality and/or accuracy than those from the survey. We do not agree, therefore, that survey results should not be used as a point of comparison in the context of other factors, particularly when they are used to support other considerations.

Although we are proposing the RUC-recommended work RVUs for each of these CPT codes, we considered alternative values. The RUC recommended a work RVU of 0.31 for CPT code 93293, which is 0.01 work RVUs lower than the existing work RVU for this code. We have concerns that the amount of the reduction in the work RVU recommended by the RUC may not be consistent with the decrease in total time of 7 minutes. We considered an alternative crosswalk for CPT code 93293 (Pm phone r-strip device eval) (5 minutes intraservice time and 13 minutes total time) to CPT code 94726 (Pulm funct tst plethysmograp), which has 5 minutes intraservice time and 15 minutes total time and a work RVU of 0.26. We seek comments our proposed and alternative valuations for this code.

For CPT code 93294, we considered a work RVU of 0.55, crosswalking from CPT code 76706 (Us abdl aorta screen aaa), and we seek comments on whether it would better align with the RUC-recommended service times. We are concerned that a work RVU of 0.60 may not account for the difference between existing service times and the RUC-recommended service times. Similarly, the RUC recommended a work RVU for CPT code 93294 of 0.60, which is 0.05 work RVUs less than the existing work RVU. The total time for furnishing services reported with CPT code 93294 decreased by 10 minutes, however, and we believe this reduction in time may not be appropriately reflected by a decrease of 0.05 work RVUs. Compared to services with similar total and intraservice times, we identified CPT code 76706 (Us abdl aorta screen aaa) as potentially a more appropriate crosswalk. CPT code 76706 has identical intraservice and total service times as CPT code 93294, with a work RVU of 0.55. We seek comments on whether our alternative value would better reflect the time and intensity involved in furnishing this service.

For CPT code 93295, we considered a work RVU of 0.69, crosswalking to CPT code 76586, which has identical intraservice and total times compared to CPT code 93295. We considered using a work RVU of 0.69 to maintain the differential between CPT code 93295 and the work RVU we considered for the previous code in this family (a work RVU of 0.11 for CPT code 93295). We are concerned about the decrease in service time compared to the work RVU. We note that the existing intraservice time is 22.5 minutes, compared to the RUC-recommended intraservice time of 10 minutes. We seek comments on whether our alternative value would better reflect the time and intensity involved in furnishing this service.

For CPT code 93298, the RUC recommended a work RVU of 0.52, which is unchanged from the current work RVU for this code. We are concerned about that recommendation given the reduction in both intraservice and total time for this service. The intraservice time decreased from 24 to 7 minutes, while total time decreased from 44 to 17 minutes. We acknowledge that the current times for this CPT code and others in this family are extrapolations. However, without additional information about the extrapolation of data from survey results, we question whether the survey results should be excluded from consideration altogether. We considered a work RVU of 0.37 for CPT code 93297, crosswalking to CPT code 96446 (Chemotx admn prtl cavity). We also considered a work RVU of 0.37 for CPT code 93298 based on a crosswalk to CPT code 96446, since the RUC indicated that the work RVUs for CPT codes 93297 and 93298 should be the same. We are seeking comment on our proposed valuation and whether our alternative valuation would be more appropriate for this code.

We propose the RUC-recommended direct PE inputs with the following refinements. We propose to remove 2 minutes for ''review charts'' from CPT codes 93279, 93281, 93282, 93283, 93284, 93285, 93286, 93287, 93288, 93289, 93290, 93291, and 93292 to maintain relativity since it is not typically incorporated for similar PFS codes. We also propose removing 2 minutes for ''complete diagnostic forms, lab & X-ray requisitions'' for the labor category ''med tech/asst'' (L026A) for these services because we believe the same activity is being performed by labor category RN/LPN/MTA (L037D). We seek comments regarding whether this row was included in error. Also for the same group of CPT codes, we also propose standard refinements for the time for equipment items EF023 and EQ198.

We propose to use the RUC-recommended direct practice expense inputs and times for all other CPT codes in this family (CPT codes 93293, 93294,

93295, 93296, 93297, 93298, and 93299) without refinement.

(39) Transthoracic Echocardiography (TTE) (CPT Codes 93306, 93307, and 93308)

In the CY 2016 PFS final rule with comment period (80 FR 70914), CMS identified CPT code 93306 through the high expenditures screen. Subsequently, the RUC reviewed CPT codes 93307 and 93308, in addition to CPT code 93306 as part of this family of codes that describe transthoracic echocardiograms. For CY 2018, we are proposing the RUC-recommended work RVUs for CPT codes 99306 (a work RVU of 1.50), 99307 (a work RVU of 0.92), and 99308 (a work RVU of 0.53), and proposing the RUC-recommended direct PE inputs for CPT codes 93306, 93307, and 93308 without refinement.

For CPT code 93306 (Echocardiography, transthoracic, real-time with image documentation (2D), includes M-mode recording, when performed, complete, with spectral Doppler echocardiography, and with color flow Doppler echocardiography), we considered maintaining the CY 2017 work RVU of 1.30. The surveyed total time for this code dropped slightly due to changes in the immediate postservice time. The median preservice and intraservice time remained unchanged.

For CPT code 93307 (Echocardiography, transthoracic, real-time with image documentation (2D), includes M-mode recording, when performed, complete, without spectral or color Doppler echocardiography), we considered a work RVU of 0.80, crosswalking to services with similar service times (CPT codes 93880 (Extracranial bilat study), 93925 (Lower extremity study), 93939, 93976 (Vascular study), and 93978 (Vascular study)). The surveyed total time dropped 3 minutes (from the intraservice time) compared to the existing service times for this code.

For CPT code 93308 (Echocardiography, transthoracic, real-time with image documentation (2D), includes M-mode recording, when performed, follow-up or limited study), we considered a work RVU of 0.43, crosswalking to CPT code 93292 (Wcd device interrogate) based on similar service times. The surveyed total time dropped by 5 minutes (from the intraservice time) compared to the existing service times for this code.

For CY 2018, we are proposing the RUC-recommended work RVUs for CPT codes 93306, 93307, and 93308 and seek comments on whether our alternative values would better reflect the time and intensity of these services.

(40) Stress Transthoracic Echocardiography (TTE) Complete (CPT Codes 93350 and 93351)

CPT code 93351 was identified as potentially misvalued and the RUC reviewed CPT code 93350 as part of the same code family. For CY 2018, we are proposing the RUC-recommended work RVUs for CPT codes 93350 (a work RVU of 1.46) and 93351 (a work RVU of 1.75).

We are proposing the following refinements to the RUC-recommended direct PE inputs for CPT codes 93350 and 93351. For both codes, we applied the standard formula in developing the minutes for equipment item ED053 (professional PACS workstation), which results in 18 minutes for CPT code 93350 and 25 minutes for CPT code 93351. We are also proposing standard clinical labor times for providing preservice education/obtaining consent. We are not proposing to include clinical labor time for the task setup scope since there is no scope used in the procedure and we do not agree with the RUC's statement that this replicates 5 minutes in CPT code 93015 when the RN prepares patients for 10-lead ECG. We have found that there is no corresponding time of 5 minutes for setup scope in the PE inputs for CPT code 93015. We are proposing refinements to the equipment time for ED050 (PACS workstation proxy) for CPT code 93351, consistent with our standard equipment times for PACS Workstation Proxy.

(41) Peripheral Artery Disease (PAD) Rehabilitation (CPT Code 93668)

We have issued a national coverage determination (NCD) for Medicare coverage of supervised exercise therapy (SET) for the treatment of peripheral artery disease (PAD). Information regarding the NCD can be found on the CMS Web site at *https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=287.* For the remainder of CY 2017, we anticipate that CPT code 93668, currently assigned PROCSTAT N (noncovered service by Medicare), will be payable before the end of CY 2017, retroactive to the effective date of the NCD to implement payment under the NCD.

For CY 2018, we are proposing to make payment for Medicare-covered SET for the treatment of PAD, consistent with the NCD, reported with CPT code 93668. For CPT code 93668, we are proposing to use the most recent RUC-recommended work and direct PE inputs. We are also seeking comment on the coding structure and valuation assumptions. Since the RUC has not reviewed CPT code 93668 since 2001, we seek comments on the direct PE inputs assigned to the code, which appear in the direct PE input database. We also note that CPT code 93668 is a PE only code and does not include physician work.

CPT prefatory language states that CPT code 93668 may be separately reported with appropriate E/M services, including office and/or outpatient services (CPT codes 99201 through 99215), initial hospital care (CPT codes 99221 through 99223), subsequent hospital care (CPT codes 99231 through 99233), and critical care services (CPT codes 99291 through 99292). Our understanding of CPT's prefatory language is that these E/M codes may only be billed when review or exam of the patient is medically indicated and must conform to all existing E/M documentation requirements. E/M visit codes should not be billed to account for supervision of SET for the treatment of PAD by a physician or other qualified healthcare practitioner. We seek comments on whether to develop professional coding to reflect the supervision of clinical staff, and on the potential overlap with CPT code 99211 (Office or other outpatient visit for the evaluation and management of an established patient, that may not require the presence of a physician or other qualified health care professional. Usually, the presenting problem(s) are minimal. Typically, 5 minutes are spent performing or supervising these services.) and any distinctions between time spent by clinical staff for CPT code 99211 and time spent by clinical staff for CPT code 93668.

(42) Pulmonary Diagnostic Tests (CPT Codes 94621, 946X2, and 946X3)

CPT code 94620 was identified as part of a screen of high expenditure services with Medicare allowed charges of $10 million or more that had not been recently reviewed. CPT code 94621 was added to the family for review. The CPT Editorial Panel deleted CPT code 94620 and split it into two new codes, CPT codes 946X2 and 946X3, to describe two different tests commonly performed for evaluation of dyspnea. We are proposing the RUC-recommended work RVUs of 1.42 for CPT code 94621, 0.70 for CPT code 946X2, and 0.48 for CPT code 946X3.

We are proposing to refine the clinical labor time for the ''Provide preservice education/obtain consent'' activity from 10 minutes to 5 minutes for CPT code 94621, which is the current time assigned for this task. While we agree that CPT code 94621 requires additional time above the standard for this clinical

labor activity, we do not believe that double the current time would be typical for this procedure. We are also proposing to refine the clinical labor time for the ''Prepare and position patient/monitor patient/set up IV'' activity from 5 minutes to 3 minutes for the same code. The standard time for this activity is 2 minutes, and we are proposing a value of 3 minutes to reflect 1 minute of additional preparation time above the standard. We believe that additional clinical labor time used for preparation would be included under the 10 minutes assigned to the ''Prepare room, equipment, supplies'' activity for this code.

We are proposing to refine the clinical labor time for the ''Complete diagnostic forms, lab & X-ray requisitions'' activity, consistent with the standard clinical labor time for this activity. We also propose to refine the equipment times for CPT codes 94621 and 946X2 to account for 1:4 patient monitoring time, and to refine the equipment times for CPT code 946X3 consistent with standards for non-highly technical equipment.

We considered refining the clinical labor time for the ''pre exercise ECG, VC, Min Vent. Calculation'' activity from 27 minutes to 15 minutes for CPT code 94621. We considered proposing this value of 15 minutes based on assigning 5 minutes apiece for the ECG, the MVV, and the spirometry. We believe that each of these three components of this clinical labor activity would typically take no longer than 5 minutes based on a comparison to the use of these tasks in other CPT codes. We also considered refining the clinical labor time for the ''Clinical staff performs procedure'' activity from 55 minutes to 35 minutes for CPT code 946X2 and from 14 minutes to 12 minutes for CPT code 94621. The RUC-recommended materials for the PE inputs state that this clinical labor task consists of performing 5 spirometries at 9 minutes each plus 10 minutes of exercise time for CPT code 946X2; we believe that the spirometries typically take 5 minutes each, which would reduce this activity from 55 minutes to 35 minutes. For CPT code 94621, we considered maintaining the current value of 12 minutes due to a lack of justification for increasing the time to 14 minutes.

While we remain concerned about the intraservice period clinical labor times, for CY 2018, we are proposing the RUC-recommended work RVUs for each code in this family and seek comment on whether our alternative clinical labor times would better reflect the work and times for these services.

(43) Percutaneous Allergy Skin Tests (CPT Code 95004)

In the CY 2016 PFS proposed rule (80 FR 41706), CPT code 95004 was identified through the high expenditures screen as potentially misvalued. The RUC suggested in its comments on the CY 2016 PFS proposed rule (80 FR 41706), that CPT code 95004 should be removed from the list of potentially misvalued codes because it has a work RVU of 0.01 and that it would serve little purpose to survey physician work for this code. The RUC and CMS previously determined that there is physician work involved in providing this service since the physician must interpret the test and prepare a report. In the CY 2016 PFS final rule with comment period (80 FR 70913), CMS reiterated an interest in the review of work and PE for this service. We note that our interest in stakeholder review of a particular code should not be considered a directive for survey under the RUC process. We intend to more clearly state our interests in the future, so that under similar circumstances, such effort need not be undertaken based on a mistaken impression. To reiterate, we believe that whether or not a code should be surveyed in response to our interest in receiving recommendations regarding the work RVUs should be at the RUC and the specialties' discretion. In many cases, we have used recommendations developed through means other than surveys in developing RVUs. For example, for many PFS services, the direct PE inputs are the primary drivers of overall RVUs and Medicare payment. In most of these cases, the recommended inputs are not derived from survey data. In some cases, especially for resource-intensive and highly technical services, we have expressed some concern about the lack of survey or other broad-based data that we have relied on in developing rates across the PFS for many years.

For CY 2018, we are proposing the RUC-recommended work RVU of 0.01 for CPT code 95004.

Regarding direct PE inputs, we are proposing to refine the equipment times for exam table (EF023) and mayo stand (EF015) to 79 minutes each to account for clinical 1:4 patient monitoring time. We received invoices with new pricing information for two supplies: SH101 ''negative control, allergy test'' ($5.17) and SH102 ''positive control, allergy test'' ($26.12). Using this information, we are proposing a price of $0.03 per test for supply item SH101 and a price of $0.13 per test for supply item SH102.

(44) Continuous Glucose Monitoring (CPT Codes 95250 and 95251)

CPT codes 95250 (Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; sensor placement, hook-up, calibration of monitor, patient training, removal of sensor, and printout of recording) and 95251 (Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; interpretation and report) are used to report the technical and professional component for continuous glucose monitoring. In April 2013, CPT code 95251 was identified through the high volume growth services screen and subsequently this code family was reviewed at the RUC's October 2016 meeting.

For CY 2018, we are proposing the RUC-recommended work RVU of 0.70 for CPT code 95251. However, we are concerned and seek comments on whether the 2 minutes of physician preservice time is necessary. Since CPT code 95251 is typically billed with an E/M service on the same day, we believe the 2 minutes of preservice time may be duplicative. Furthermore, we seek comment on whether it would be typical for the physician to spend 2 minutes to obtain the CGM reports for review since we believe the report would typically be obtained by clinical staff on behalf of the physician.

For the direct PE inputs, the RUC submitted 19 invoices to update the price of the medical supply item ''glucose monitoring (interstitial) sensor'' (SD114) for CPT code 95250. We are proposing to use these invoice prices for the glucose monitoring (interstitial) sensor (SD114), with an average cost of $53.08. Therefore, we are proposing to use the average price of $53.08 for this supply item.

As part of our review of this service, we obtained publicly available pricing information for the CGM system (EQ125). We reviewed the information provided in a study titled, ''The cost-effectiveness of continuous glucose monitoring in type 1 diabetes,'' (Huang, SE., O'Grady, M., Basu, A. et al., *Diabetes Care.* June 2010), which indicated the price of CGM technology (without sensors) from 3 different vendors, reflective of full retail prices with no insurer discounts, to be $600.00, $1119.00, and $1250.00, which equated to an average cost of $1016.00 for the CGM system. In addition, we obtained publicly available pricing information for two vendors. This information indicated the price of a

CGM system to be $1061.90 and $1279.17, which equated to an average cost of $1170.54. For CY 2018, we are proposing to price supply items SD114 at $53.08 and EQ125 at $1170.54. We seek comments on current pricing for equipment item ''continuous glucose monitoring system'' (EQ125).

(45) Parent, Caregiver-Focused Health Risk Assessment (CPT Codes 96160 and 96161)

In the CY 2017 PFS final rule (81 FR 80330), we discussed that in October 2015, the CPT Editorial Panel created two new PE-only codes, CPT code 96160 (Administration of patient focused health risk assessment instrument (*e.g.,* health hazard appraisal) with scoring and documentation, per standardized instrument) and CPT code 96161 (Administration of caregiver-focused health risk assessment instrument (*e.g.,* depression inventory) for the benefit of the patient, with scoring and documentation, per standardized instrument). We assigned an active payment status to both codes for CY 2017 and finalized use of the RUC-recommended values for these codes. We also assigned an add-on code status to both of these services. As add-on codes, CPT codes 96160 and 96161 describe additional resource components of a broader service furnished to the patient that are not accounted for in the valuation of the base code.

The RUC submitted updated recommendations for the direct PE inputs for CPT codes 96160 and 96161 after reviewing new specialty society surveys. The RUC recommended 7 total minutes of clinical staff time, and we are proposing to adopt this number of minutes in valuing the services. The PE worksheet included several distinct tasks with minutes for each; however, in keeping with the standardization of clinical labor tasks, we are proposing to designate all 7 minutes under ''administration, scoring, and documenting results of completed standardized instrument'' rather than dividing the minutes into the four categories as shown in the RUC recommendations.

(46) Chemotherapy Administration (CPT codes 96401, 96402, 96409, and 96411)

In the CY 2016 PFS proposed rule, CPT codes 96401 (Chemotherapy administration, subcutaneous or intramuscular; non-hormonal anti-neoplastic), 96402 (Chemotherapy administration, subcutaneous or intramuscular; hormonal anti-neoplastic), 96409 (Chemotherapy administration; intravenous, push technique, single or initial substance/drug), and 96411 (Chemotherapy administration; intravenous, push technique, each additional substance/drug (List separately in addition to code for primary procedure)) were identified through the high expenditure services screen across specialties with Medicare allowed charges of over $10 million.

For CY 2018, we are proposing the RUC-recommended work RVUs for CPT code 96401 (a work RVU of 0.21), CPT code 96402 (a work RVU of 0.19), CPT code 96409 (a work RVU of 0.24) and CPT code 96411 (a work RVU of 0.20).

For CPT code 96402, we are proposing the RUC-recommended equipment times with refinements for the biohazard hood (EP016) and exam table (EF023) from 31 minutes to 34 minutes to reflect the service period time associated with this code. We are proposing the RUC-recommended direct PE inputs for CPT codes 96401, 96409, and 96411 without refinements.

(47) Photochemotherapy (CPT Code 96910)

CPT code 96910 appeared on a high expenditure services screen across specialties with Medicare allowed charges of over $10 million, which is a PE-only code that does not have work RVUs.We are proposing to refine the clinical labor time for the ''Provide preservice education/obtain consent'' from 3 minutes to 1 minute for CPT code 96910. We believe that 1 minute would be typical for patient education, as CPT code 96910 is a repeat procedure where there would not be a need to obtain consent again. We are also proposing to remove the 2 minutes of clinical labor for the ''Complete diagnostic forms, lab & X-ray requisitions'' activity, as this item is considered indirect PE consistent with our established methodology. We are also proposing to create a new supply code (SB054) for the sauna suit, and proposing to price at $9.99 based on the submitted invoice. Finally, we are also proposing to adjust the equipment times to reflect changes in the clinical labor for CPT code 96910.

We are proposing the RUC-recommended clinical labor time of 15 minutes for the ''Prepare and position patient/monitor patient/set up IV'' activity, the RUC-recommended clinical labor time of 16 minutes for the ''Monitor patient during procedure'' activity, and the RUC-recommended clinical labor time of 15 minutes for the ''Clean room/equipment by physician staff'' activity, but seeking additional information regarding the rationale for these values. Given the lack of explanation, we considered using the current clinical labor time of 7 minutes for the ''Prepare and position patient/monitor patient/set up IV'' activity, the current clinical labor time of 4 minutes for the ''Monitor patient during procedure'' activity, and the current clinical labor time of 10 minutes for the ''Clean room/equipment by physician staff'' activity. We seek comment on whether maintaining the current values would improve relativity.

We considered removing the ''Single Patient Discard Bag, 400 ml'' (SD236) supply and replacing it with the ''biohazard specimen transport bag'' (SM008). We are concerned about whether the single patient discard bag is the appropriate size for storing the sauna suit used in this procedure, and whether use of a biohazard specimen transport bag would be typical. We seek comments on our proposed and alternative values for these direct PE inputs.

(48) Photodynamic Therapy (CPT Codes 96567, 96X73, and 96X74)

CPT code 96567 was identified as potentially misvalued through a CMS screen for codes with high expenditures. This code describes a service furnished by clinical staff and does not include physician work. For CY 2018, the CPT Editorial Panel created two new codes, CPT codes 96X73 and 96X74, to describe photodynamic therapy by external application of light to destroy premalignant skin lesions, including the physician work involved in furnishing the service. CPT codes 96567, 96X73, and 96X74 were reviewed during the RUC's January 2017 meeting.

For CY 2018, we are proposing the RUC-recommended work RVUs for CPT code 96X73 (a work RVU of 0.48) and CPT code 96X74 (a work RVU of 1.01).

We are proposing the RUC-recommended PE inputs with refinements due to inconsistencies between the stated description of clinical activities and the submitted spreadsheets. First, we propose to add assist physician clinical staff time to CPT codes 96X73 (10 minutes) and 96X74 (16 minutes), which is equivalent to the physician intraservice times for these services. For both CPT codes 96X73 and 96X74, we propose a reduction from 35 minutes to 17 minutes for clinical activity in the postservice time, consistent with the description of clinical work in the summary of recommendations, which states that the patient receives activation of the affected area with the BLU–U Photodynamic Therapy Illuminator for approximately 17 minutes. For CPT codes 96X73 and 96X74, we are

proposing to refine equipment formulas for two items: Power table (EF031) and LumaCare external light with probe set (EQ169), consistent with standards for nonhighly technical equipment. An explanation of the standards and formulas for equipment related to direct PE inputs is in the CY 2014 PFS final rule with comment period (79 FR 67557).

We identified several vendors with publically available prices available for supply item LMX 4 percent cream (SH092) for significantly less than the existing $1.60 per gram. Based on our research of vendors, we are proposing to set the price of supply item SH092 to $0.78 per gram. Other CPT codes affected by the proposed change in the price of supply item LMX 4 percent cream (SH092) are: CPT code 46607 (Anoscopy; with high-resolution magnification (HRA) (eg, colposcope, operating microscope) and chemical agent enhancement, with biopsy, single or multiple), CPT code 17000 (Destruction (eg, laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettement), premalignant lesions (eg, actinic keratoses); first lesion), CPT code 17003 (Destruction (eg, laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettement), premalignant lesions (eg, actinic keratoses); second through 14 lesions, each (List separately in addition to code for first lesion)), and CPT code 17004 (Destruction (eg, laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettement), premalignant lesions (eg, actinic keratoses), 15 or more lesions)).

In addition, the RUC forwarded an invoice for a new supply item, safety goggles, at $6.00 and requested three goggles each for CPT codes 96X73 and 96X74. Because we do not have a basis for distinguishing the requested new goggles from the existing UV-blocking goggles, we consider this invoice to be an additional price point for SJ027 rather than an entirely new item. We propose a price of $4.10 for supply item SJ027 (the average of the two prices for this supply item ($2.30 + $6.00)/2=$4.10)). Other CPT codes affected by the proposed change in the price of supply item UV-blocking goggles (SJ027) are: CPT code 36522 (Photopheresis, extracorporeal), CPT code 96910 (Photochemotherapy; tar and ultraviolet B (Goeckerman treatment) or petrolatum and ultraviolet B), CPT code 96912 (Photochemotherapy; psoralens and ultraviolet A (PUVA)), and CPT code 96913 (Photochemotherapy (Goeckerman and/or PUVA) for severe photoresponsive dermatoses requiring at least 4–8 hours of care under direct supervision of the physician (includes application of medication and dressings)), CPT code 96920 (Laser treatment for inflammatory skin disease (psoriasis); total area less than 250 sq cm), CPT code 96921 (Laser treatment for inflammatory skin disease (psoriasis); 250 sq cm to 500 sq cm), and CPT code 96922 (Laser treatment for inflammatory skin disease (psoriasis); over 500 sq cm). We seek comments on our proposed PE refinements, including our proposed supply item prices.

(49) Physical Medicine and Rehabilitation (PM&R) (CPT Codes 97012, 97016, 97018, 97022, 97032, 97033, 97034, 97035, 97110, 97112, 97113, 97116, 97140, 97530, 97533, 97535, 97537, 97542, and HCPCS code G0283)

In our CY 2015 PFS final rule (79 FR 67576) and CY 2016 PFS final rule (80 FR 70917), we identified a total of ten codes through the high expenditure by specialty screen for services primarily furnished by physical and occupational therapists: CPT codes 97032, 97035, 97110, 97112, 97113, 97116, 97140, 97530, 97535, and HCPCS code G0283. An additional nine codes in this PM&R family were identified for review by the physical therapy (PT) and occupational therapy (OT) specialty societies: CPT codes 97012, 97016, 97018, 97022, 97033, 97034, 97533, 97537, and 97542. Many of these code values had not been reviewed since they were established in 1994, 1995 or 1998.

After review during its January 2017 meeting, the HCPAC submitted recommendations for all 19 codes. While the HCPAC included recommendations for CPT code 97014, we note that this is a code we have not recognized for PFS payment since 2002 when we implemented our wound care electrical stimulation policies. For payment under the PFS, instead of CPT code 97014, we recognize HCPCS code G0281 for wound care electrical stimulation and HCPCS code G0283 for all other electrical stimulation scenarios, when covered. For CY 2018, we are proposing the HCPAC recommendations for CPT code 97014, HCPCS code G0283, and HCPCS code G0281.

CMS considers all 19 codes as ''always therapy'' which means they are always considered to be furnished under a physical therapy (PT), occupational therapy (OT), or speech-language pathology (SLP) plan of care regardless of who furnishes them and the payment amounts are counted towards the appropriate statutory therapy cap—either the therapy cap for PT and SLP services combined, or the single therapy cap for OT services. These always therapy codes are also subject to the therapy MPPR.

For CY 2018, we are proposing the HCPAC's recommended work RVUs for CPT codes 97012, 97016, 97018, 97022, 97032, 97033, 97533, 97034, 97035, 97110, 97112, 97113, 97116, 97140, 97530, 97533, 97535, 97537, 97542, and G0283 (97014).

For supervised modality services reported with CPT codes 97012, 97016, 97018, and 97022, and HCPCS code G0283 (97014), we considered maintaining the current values for these codes rather than the HCPAC recommendations. We note that the work times recommended by the HCPAC reflect use of the survey data even though the HCPAC explained in its recommendations that the survey results were not deemed credible because of a lack of evidence to support higher work RVUs of each survey's 25th percentile or median values. We note total time decreases among these codes ranging from 1 to 8 minutes.

While we are proposing the HCPAC-recommended work RVUs and work times for each code in this family, we seek comments on whether maintaining the current times, given the HCPAC's lack of confidence in the survey data, would better reflect the work times for these services.

We are proposing to maintain the existing CY 2017 PE inputs for all 19 codes. We note that section 1848(b)(7) of the Act requires a 50 percent therapy MPPR instead of the 25 percent therapy MPPR established during CY 201l PFS rulemaking. One of the primary rationales for the MPPR policy developed through the rulemaking process was that the direct PE inputs for these services did not fully recognize the redundant inputs when these services were furnished together, or in multiple units. After reviewing the recommended direct PE inputs, it is evident that they were developed based on an acknowledgement of the efficiencies of services typically furnished together as well as codes billed in multiple units. Given this assessment, we believe that were we to use the recommended inputs to develop the PE RVUs, the 50 percent MPPR on the PE for these services, as required by current law, would functionally duplicate the payment adjustments to account for efficiencies that had already been addressed through code-level valuation. Therefore, for CY 2018, we are proposing to retain the existing CY 2017 PE inputs for these services and seek comments on whether there is an

alternative approach that would avoid duplicative downward payment adjustments while still allowing for the direct PE inputs to be updated to better reflect current practice.

We note that we believe that the always therapy codes subject to the therapy MPPR on PE are unique from other therapeutic and diagnostic procedure codes paid under the PFS and subject to MPPRs. For example, unlike most surgical services, these ''always therapy'' codes are typically billed either with other therapy codes or in multiple units, or both. Generally, MPPRs are used when codes are often, but not typically, furnished with other particular codes. When full sets of related codes are almost all typically billed with other codes, or billed in multiple units, coding and valuation have changed to reflect these practices. For example, new codes have been introduced to describe combined services or some related services are described by add-on codes. In other cases, the MPPR is considered in the valuation for individual services.

(50) Management and/or Training: Orthotics and Prosthetics (CPT Codes 97760, 97761, and 977X1)

For CY 2018, the CPT Editorial Panel revised the set of codes that comprise the CPT manual's PM&R subsection for orthotic management and prosthetic management at its September 2016 meeting. According to the CPT Editorial Panel, these revisions were made at the request of the specialty societies representing physical and occupational therapists to differentiate between the initial and subsequent encounters and to describe the ongoing management and/or training that is involved in subsequent encounters. These changes include:

- Revising the code descriptors by adding the term ''initial encounter'' to CPT code 97760 (Orthotic(s) management and training (including assessment and fitting when not otherwise reported), upper extremity(ies), lower extremity(ies) and/or trunk, initial orthotic(s) encounter, each 15 minutes), and CPT code 97761 (Prosthetic(s) training, upper and/or lower extremity(ies), initial prosthetic(s) encounter, each 15 minutes);
- Creating a new CPT code 977X1 (Orthotic(s)/prosthetic(s) management and/or training, upper extremity(ies), lower extremity(ies), and/or trunk, subsequent orthotic(s)/prosthetic(s) encounter, each 15 minutes); and
- Deleting CPT code 97762 (checkout for orthotic/prosthetic use, established patient, each 15 minutes).

Intended for the management and/or training of patients with orthotics and/or prosthetics, CPT codes 97760 and 97761 were previously used to report both the initial and subsequent encounters, that, when furnished under the Medicare outpatient therapy services benefit, included services occurring during the same PT or OT episode of care. CPT code 97762 was used to separately report the assessment and fitting (including any adjustments) of an orthotic or prosthetic for an established patient when these services were not bundled into another code or service. For CY 2018, CPT codes 97760 and 97761 are intended to be reported only for the initial encounter, and CPT code 977X1 is intended to be reported for all other orthotic and/or prosthetic services for an established patient that occur on a ''subsequent encounter'' or a different date of service from that of the initial encounter service.

The HCPAC submitted work and PE recommendations for CPT codes 97760, 97761, and 977X1 from their January 2017 meeting. For CY 2018, we propose the HCPAC recommended work RVU of 0.5 for CPT code 97760, a work RVU of 0.5 for CPT code 97761, and a work RVU of 0.48 for CPT code 977X1. We note that for budget neutrality purposes, the HCPAC recommendations also included utilization crosswalks for each of the three codes that were each assigned a one-to-one crosswalk to the utilization of the prior codes: All the prior services of CPT codes 97760 and 97761 were each crosswalked to the same newly revised codes; and, all the utilization from CPT code 97762 was crosswalked to the new CPT code 977X1.

For CPT code 977X1, we considered a work RVU of 0.33, crosswalking to CPT code 92508 (Speech/hearing therapy), which has a similar total therapist time (22 minutes). We are concerned and seek comments on the HCPAC one-to-one utilization crosswalk recommendations for all three codes in this family since the utilization assumptions are potentially flawed when viewed in the context of the new CPT code descriptors. For instance, for CPT code 977X1, the new descriptor indicates that the services inherent to CPT code 97762 (over 14,000 in 2015), as well as the new services for subsequent encounters previously reported via CPT codes 97760 and 97761 will also be encompassed, although it is difficult to estimate the number of additional services the latter represents. We are concerned that the HCPAC's valuation is inconsistent with the submitted information regarding how services will be reported under the new coding. We seek comments on our proposed and alternative values for CPT code 977X1. We are also interested in receiving comments from stakeholders and clinicians with expertise in furnishing these orthotic management and/or prosthetics training services about the utilization and types of services that would be furnished under the new CPT coding structure, particularly those of the newly created CPT code 977X1 and how these services differ from the services reported with the predecessor CPT code 97762.

We propose to maintain the current PE inputs for CPT codes 97760, 97761, and 977X1, as we discussed in our proposals for the PM&R codes discussed above; the same therapy MPPR applies. We are proposing the current direct PE inputs for CPT code 97762 and for new CPT code 977X1, though we are seeking comment as to whether or not a different crosswalk or other adjustment would be appropriate given the change in code descriptor.

We also note that these codes are designated as always therapy, meaning that they always represent therapy services regardless of who furnishes them; and that a GO or GP therapy modifier is always required to indicate that the services are furnished under an OT or PT plan of care, respectively. As always therapy, these codes are subject to the therapy MPPR and the statutory therapy caps.

(51) Cognitive Function Intervention (CPT Code 97X11)

We received HCPAC recommendations for new CPT code 97X11 that describes services currently reported under CPT code 97532 (Development of cognitive skills to improve attention, memory, problem solving (includes compensatory training), direct (one-on-one) patient contact, each 15 minutes). CPT code 97532 is scheduled to be deleted for CY 2018 and replaced by CPT code 97X11.

The existing code is reported per 15 minutes and the new code is reported once. Under current coding, Medicare utilization for these services is heterogeneous and indicates that practitioners of different disciplines incur significantly different resource costs (especially in time) when furnishing these services to Medicare beneficiaries. As described by both the existing and new code, the service might be appropriately furnished both by therapists under the outpatient therapy (OPT) services benefit (includes physical therapy (PT), occupational therapy (OT) or speech-language pathology (SLP)); and outside the therapy benefit by physicians, certain

NPPs, and psychologists. As an OPT service, it can (1) be billed by physicians, certain NPPs, or private practice therapists including physical therapists (PT–PPs), occupational therapists (OT–PPs) and speech-language pathologists (SLP–PPs) in private practice, or (2) be billed by institutional providers (for example, skilled nursing facilities, rehabilitation agencies, outpatient hospitals, etc.) when furnished by therapists working for the institutional providers.

According to the HCPAC, professional claims data indicate that CPT code 97532 was most often billed in 4 units. The HCPAC recommended a work RVU of 1.50 for CPT code 97X11, which is only 3.4 times greater than the work RVU for the predecessor code (0.44). Assuming professional billing patterns remain the same, the recommended coding and valuation could result in a significant reduction in overall Medicare payment under the PFS.

However, our analysis of the claims data indicates that the number of units typically reported for the current code suggests a significant difference in the amount of time spent with the patient, depending on which discipline (and implicitly under which benefit) bills Medicare for services described by this single code.

Based on our review of claims data by specialty, SLP–PPs, OT–PPs and PT–PPs furnishing the same services under the OPT benefit would receive overall payment increases due simply to the change in coding because they typically bill for fewer than 4 units, while overall payment for clinical psychologists furnishing therapeutic interventions for cognitive function would decrease because they typically bill in units of four or more.

We are seeking additional information regarding the potential impact of this coding and payment change prior to proposing its use under the PFS. For CY 2018, we are proposing to maintain the current coding and valuation for these cognitive function services. If the CPT Editorial Panel deletes the existing CPT code for CY 2018, we would effectuate this proposal through use of a new a G-code, GXXX1, which would maintain the descriptor and values from existing CPT code 97532. Under this proposal, new CPT code 97X11 would be given a procedure status of ''I'' (Invalid for Medicare).

We also note that this change in coding and payment could have significant impact for payment to Medicare institutions for OPT services. Under section 1834(k) of the Act, when reported by Medicare institutional providers, OPT services are paid at PFS non-facility payment rates. Institutional claims data for CPT code 97532 when furnished by the three therapist disciplines show a much higher utilization overall than that for professional claims but significantly fewer 15 minute units reported. This suggests that professionals generally spend significantly less time with patients in the institutional setting. Use of the new CPT code could therefore result in significant additional expenditure to the Medicare program, as well as other payers, including Medicaid programs, based on the change in coding alone.

(52) INR Monitoring (CPT Codes 993X1 and 993X2)

In October 2015, AMA staff assembled a list of all services with total Medicare utilization of 10,000 or more that have increased by at least 100 percent from 2008 through 2013 and these services were identified on that list. The RUC recommended that HCPCS codes G0248, G0249 and G0250, which describe related INR monitoring services, be referred to the CPT Editorial Panel to create Category I codes to describe these services. For CY 2018, the CPT Editorial Panel is deleting CPT codes 99363 and 99364 and creating new CPT codes 993X1 (Patient/caregiver training for initiation of home INR monitoring under the direction of a physician or other qualified health care professional, including face-to-face, use and care of the INR monitor, obtaining blood sample, instructions for reporting home INR test results, and documentation of patient's/caregiver's ability to perform testing and report results) and 993X2 (Anticoagulant management for a patient taking warfarin, must include review and interpretation of a new home, office, or lab International Normalized Ratio (INR) test result, patient instructions, dosage adjustment (as needed), and scheduling of additional test(s) when performed). CPT code 993X1 is a technical component-only code. With the creation CPT codes 993X1 and 993X2, the RUC recommended that CMS delete HCPCS codes G0248, G0249 and G0250.

For CPT code 993X2, we are proposing the RUC-recommended work RVU of 0.18. Because HCPCS codes G0248, G0249 and G0250 are used to report related services under a national coverage determination, we do not intend to delete the G-codes.

In reviewing the recommended PE inputs for these services, we obtained updated invoices for prices for particular items. We are proposing to use the invoices to update the price of the supply ''INR test strip'' (SJ055). We obtained publically available pricing information from two vendors. The pricing from one vendor indicated the price for a box of 24 of supply item SJ055 item (INR test strip) to be $150.00, which equated to a unit price of $6.25. Pricing from a second vendor indicated the price of a box of 48 of the supply item SJ055 to be $233.00, which equated to a unit price of $5.06. The average price of these two unit prices is $5.66.

Therefore, we are proposing to re-price SJ055 from $21.86 to $5.66 for CPT code 993X1. We are seeking public comments on current pricing for the INR test strip supply.

(53) Psychiatric Collaborative Care Management Services (CPT Codes 994X1, 994X2, 994X3, and HCPCS Code G0507)

In the CY 2017 PFS final rule (81 FR 80230), we established separate payment for three services (HCPCS codes G0502, G0503, and G0504) under the psychiatric collaborative care model that paralleled CPT codes that were being created to report these services as well as a G-code for general behavioral health integration (BHI) services (HCPCS code G0507).

For CY 2018, the CPT Editorial Panel is creating CPT codes 994X1, 994X2, 994X3, and 99XX5 to describe these services. We are proposing the RUC-recommended work RVUs for each of these services, which are identical to the current values for HCPCS codes G0502, G0503, G0504, and G0507.

We are proposing the RUC-recommended PE inputs, with one refinement. The RUC-recommended values included clinical labor inputs in the facility setting, but we are not proposing to include these minutes in developing the facility PE RVUs.

Were we to develop facility PE RVUs for these services that included clinical staff time, when a practitioner working in a provider-based department of a hospital was furnishing these services, both the professional and the hospital would be paid for the same clinical labor costs. We presume that this aspect of the RUC's recommendation reflects the circumstance where the patient receiving the services spends a significant period of time in a facility setting, but the billing practitioner is nonetheless incurring the cost associated with the non-face-to-face clinical staff time over the course of a month. We recognize that the binary site of service differential may not recognize the different models of this kind of care and may not be appropriate in some cases. We seek comments on how to best address this valuation issue for these and other monthly care

management services. We could consider a range of options for future rulemaking, including allowing separate billing for the professional, technical, and global components of these services to allow practitioners to bill the component of the service they furnish.

We stated in the CY 2017 PFS final rule (81 FR 80236) that the general BHI code (CPT code 99XX5) may be used to report a range of models of BHI services and that we expected this code to be refined over time as we receive more information about other BHI models in use. We remain interested in how this code is being used and look forward to hearing from stakeholders regarding its use in reporting different models of BHI services. Additionally, we have received inquiries from stakeholders about whether or not professionals who cannot report E/M services to Medicare might nonetheless serve as a primary hub for BHI services. For example, stakeholders have suggested that a clinical psychologist might serve as the primary practitioner that integrates medical care and psychiatric expertise. For purposes of future rulemaking, we are seeking comment on the circumstances under which this model of care is happening and whether additional coding would be needed to accurately describe and value other models of care.

(54) Hyperbaric Oxygen Therapy (HCPCS Code G0277)

In the CY 2016 PFS final rule (80 FR 71005), we discussed the CY 2015 valuation of hyperbaric oxygen therapy services (79 FR 67677). Prior to CY 2015, CPT code 99183 was used to report both the professional attendance and supervision, and the costs associated with treatment delivery were included in the nonfacility direct PE inputs for the code. We created HCPCS code G0277 to be used to report the treatment delivery separately, consistent with the OPPS coding mechanism, to allow the use of the same coding structure across settings. In establishing interim final direct PE inputs for HCPCS code G0277, we used the RUC-recommended direct PE inputs for CPT code 99183, which assumed a 120-minute treatment interval and adjusted them to align with the 30-minute treatment interval of HCPCS code G0277. We observed that the quantity of oxygen increased significantly relative to the previous inputs for CPT code 99183.

To better understand why the oxygen supply increased, we reviewed the instruction manual for the Sechrist Model 3600E Hyperbaric Chamber, which was the model noted on the invoice that was included with the RUC recommendations for use in pricing the capital equipment. The instruction manual for the Sechrist 3600E model provided guidance regarding the quantity of oxygen to be used in furnishing the service described by HCPCS code G0277. Based on our review at that time, we determined that 12,000 liters, rather than 47,000 liters, was the typical number of units for the oxygen gas. Therefore, in aligning the direct PE inputs as described in this section of the proposed rule, we first adjusted the units of oxygen to 12,000 liters for the recommended 120 minute time, and subsequently adjusted it to align with the 30-minute G-code by dividing by 4. We stated that we agreed that an initial high purge flow rate is needed to reach maximum pressure/O_2; however, we still had not seen data that demonstrated the need to continue the high purge flow rate throughout the entire session. According to the manufacturer's instruction manual for this model, ''once the nitrogen has been purged from the chamber and the internal oxygen concentration has exceeded 95 percent, high flows are no longer needed to maintain the patient's saturation level.'' The manual also stated that ''the plateau purge flow can be set to 80 liters per minute (lpm).'' We calculated that 13 minutes at 400 lpm plus 120 minutes at 80 lpm equals 14,800 liters of oxygen. We stated that based on information in the manufacturer's manual that was publicly available at the time, we believed that this represented the typical usage for a 120-minute treatment. That amount represented an increase from the interim final amount of 12,000 liters. We aligned this total oxygen requirement to the 30-minute G-code by dividing 14,800 liters of oxygen by 4 and stated we were updating the direct PE inputs to 3,700 liters of oxygen for HCPCS code G0277.

For CY 2018, we received requests from stakeholders to update the direct PE inputs for HCPCS code G0277. In the CY 2016 PFS final rule (80 FR 71005), we explained that we had previously established values for this service based on information suggesting that the Sechrist Model 3600E Hyperbaric Chamber was typically used in furnishing the service in the non-facility setting. As we noted in that rule, we established the amount of oxygen used in furnishing the service based on use of the equipment item described as part of the RUC recommendation, instead of the RUC-recommended amount of oxygen, which appeared to be based on use of a different equipment product, the Sechrist Model 3200. Based on information received from stakeholders, we are proposing to update both the equipment item and the amount of oxygen so that the amount of oxygen conforms to the RUC-recommended value of 47,600 liters of oxygen, which we divided by 4 to conform to the 30-minute service period for HCPCS code G0277, and that the equipment item is consistent with that recommendation. The proposed direct PE inputs for HCPCS code G0277 are displayed in the proposed CY 2018 direct PE input database, available on the CMS Web site under the downloads for the CY 2018 PFS proposed rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.*

We are also proposing to exclude this change in direct PE inputs from calculation of the misvalued code target since we view this proposed change as a refinement of a single recommendation over several years. Since the initial recommendation (79 FR 67677) was undertaken in a year without the misvalued code target, we believe it would be consistent with our previously established policy (80 FR 70923) to exclude this change from the calculation. We note that this change would represent an increase from the current PE RVUs for this service.

(55) Physician Coding for Insertion and Removal of Subdermal Drug Implants for the Treatment of Opioid Addiction (HCPCS Codes GDDD1, GDDD2, and GDDD3)

We met with representatives from the American Society of Addiction Medicine (ASAM) in April 2016 to discuss the possibility of making separate payment for insertion and removal of buprenorphine hydrochloride, formulated as a 4-rod, 80 mg, long-acting subdermal drug implant for the treatment of opioid addiction. There are existing CPT codes that broadly describe the insertion and removal of non-biodegradable drug delivery implants (CPT codes 11981 through 11983). However, ASAM contended that the resources associated with the administration of this particular drug are greater than that of other drug delivery implants, stating that the physician must insert four rods using a newly designed applicator and obturator and use a specially designed clamp to remove the four rods, which in some cases requires careful shaving of tissue that has attached to the rods during the 6-month period that the rods have been inserted. They noted that these procedures can have unique

challenges associated with treating patients with opioid addiction, who often have complications and/or co-morbidities. They also noted that the FDA has recognized the complexity of the technology and patient needs by establishing regulatory standards to adhere to the protocol and imposing special training requirements on physicians. ASAM indicated that they would pursue an application to the CPT Editorial Panel for new CPT codes.

ASAM informed CMS that the CPT Editorial Panel did not approve their application; therefore, they repeated their request that CMS establish separate payment for the insertion, removal, and removal with reinsertion of the buprenorphine subdermal implants.

To improve payment accuracy, for CY 2018, we are proposing to make separate payment for the insertion, removal, and removal with reinsertion of Buprenorphine subdermal implants using HCPCS G codes:

- HCPCS code GDDD1: Insertion, non-biodegradable drug delivery implants, 4 or more.
- HCPCS code GDDD2: Removal, non-biodegradable drug delivery implants, 4 or more.
- HCPCS code GDDD3: Removal with reinsertion, non-biodegradable drug delivery implants, 4 or more.

For HCPCS code GDDD1, ASAM states that performing the procedure according to the FDA-required Risk Evaluation and Mitigation Strategies (REMS) program takes approximately 23–25 minutes for the a physician who is not a trainer/proctor for this procedure. They state that in developing crosswalk recommendations for physician work values, they used a total time of 35–40 minutes, which is based on a preservice time of 10 minutes, an intraservice time of 20–25 minutes, and a postservice time of 5 minutes. Based on ASAM's recommendations, we are proposing a work RVU of 1.82 for HCPCS code GDDD1, which is supported by a direct crosswalk to CPT code 64644 (Chemodenervation of one extremity; 5 or more muscles).

For HCPCS code GDDD2, ASAM states that data from physicians who perform this procedure indicated that it takes approximately 15–20 additional minutes compared to the insertion procedure (HCPCS code GDDD1) based on the FDA-required REMS program for removal of the implant. They note that this procedure is of a higher intensity compared to CPT code 11982 as this service requires identification and removal of multiple subdermal implants. They state that in developing crosswalk recommendations for physician work values, they used a total time of 45–60 minutes, which is based on a preservice time of 10 minutes, an intraservice time of 30–45 minutes, and a postservice time of 5 minutes. Based on ASAM's recommendations, we are proposing a work RVU of 2.10 for HCPCS code GDDD2, which is supported by a direct crosswalk to CPT code 96922 (Laser treatment for inflammatory skin disease (psoriasis); over 500 sq cm).

For HCPCS code GDDD3, ASAM indicated that there is minimal consolidation of effort since the removal of the implants from one arm is followed by insertion of a new set of implants in the contralateral arm. Physician data from those who have performed this procedure indicated that it takes approximately 70 minutes of total intra-service time. They state that in developing crosswalk recommendations for physician work values, they assumed a preservice evaluation time of 10 minutes (7 minutes for removal and 3 minutes for insertion), positioning of 4 minutes (2 minutes for each arm), and wait time of 2 minutes (1 minute for each arm). They state that using the multiple surgical procedure rule, they calculated an intraservice time of 40–58 minutes based on 100 percent of the intraservice time for HCPCS code GDDD2 (30–45 minutes) and 50 percent of the intraservice time for HCPCS code GDDD1 ($0.5 \times (20 - 25) = 10 - 13$). They used a postservice time of 8 minutes based on 100 percent of the postservice time for the removal arm and 50 percent of the postservice time for the insertion arm, equaling a total time of 58–76 minutes. Based on ASAM's recommendations, we are proposing a work RVU of 3.55 for HCPCS code GDDD3, which is supported by a direct crosswalk to CPT code 31628 (Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with transbronchial lung biopsy(s), single lobe).

We are proposing to use the direct PE inputs requested by ASAM for HCPCS codes GDDD1, GDDD2, and GDDD3, which are reflected in the Direct PE Inputs public use files for clinical labor, supplies, and equipment, available on the CMS Web site at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html.*

In addition to seeking comment on the proposal to make separate payment for these services using HCPCS G codes, we are also seeking comment on the appropriateness and accuracy of our proposed work RVUs and direct PE inputs.

(56) Superficial Radiation Treatment Planning and Management (HCPCS Code GRRR1)

In the CY 2015 PFS final rule with comment period (79 FR 67666 through 67667), we noted that changes to the CPT prefatory language limited the codes that could be reported when describing services associated with superficial radiation treatment (SRT) delivery, described by CPT code 77401 (radiation treatment delivery, superficial and/or ortho voltage, per day). The changes effectively meant that many other related services were bundled with CPT code 77401, instead of being separately reported. For example, CPT guidance clarified that certain codes used to describe clinical treatment planning, treatment devices, isodose planning, physics consultation, and radiation treatment management cannot be reported when furnished in association with superficial radiation treatment. Stakeholders stated that these changes to the CPT prefatory language prohibited them from billing Medicare for codes that were previously frequently billed in addition to CPT code 77401. We solicited comments as to whether the coding for SRT allowed for accurate reporting of the associated services.

In the CY 2016 PFS final rule with comment period (80 FR 70955), we noted that the RUC did not review the inputs for superficial radiation therapy procedures, and therefore, did not assess whether changes in its valuation were appropriate in light of the bundling of associated services. In addition, we solicited recommendations from stakeholders regarding whether or not it would be appropriate to add physician work for this service, even though physician work is not included in other radiation treatment services. As commenters were not in agreement as to whether the service should be valued with physician work, we introduced the possibility of creating a HCPCS G code to describe total work associated with the course of treatment for these services.

The 2016 National Correct Coding Initiative (NCCI) Policy Manual for Medicare Services states that radiation oncology services may not be separately reported with E/M codes. While this edit is no longer active, stakeholders have stated that MACs have denied claims for E/M services associated with SRT based on the NCCI policy manual language. According to stakeholders, the bundling of services associated with SRT, as well as the confusion regarding the appropriate use of E/M coding to report associated physician work, means

that practitioners are not being accurately paid for planning and treatment management associated with furnishing SRT.

In recognition of these concerns, we are proposing to make separate payment for the professional planning and management associated with SRT using HCPCS code GRRR1 (Superficial radiation treatment planning and management related services, including but not limited to, when performed, clinical treatment planning (for example, 77261, 77262, 77263), therapeutic radiology simulation-aided field setting (for example, 77280, 77285, 77290, 77293), basic radiation dosimetry calculation (for example, 77300), treatment devices (for example, 77332, 77333, 77334), isodose planning (for example, 77306, 77307, 77316, 77317, 77318), radiation treatment management (for example, 77427, 77431, 77432, 77435, 77469, 77470, 77499), and associated evaluation and management per course of treatment). We intend for this code to describe the range of professional services associated with a course of SRT, including services similar to those not otherwise separately reportable under CPT guidance and the NCCI manual.

To value this code, we are including the physician work and work time associated with radiation management-related services that we think would be typical for a course of SRT treatment. These services include: CPT code 77261 (Therapeutic radiology treatment planning; simple), CPT code 77280 (Therapeutic radiology simulation-aided field setting; simple), CPT code 77300 (Basic radiation dosimetry calculation, central axis depth dose calculation, TDF, NSD, gap calculation, off axis factor, tissue inhomogeneity factors, calculation of non-ionizing radiation surface and depth dose, as required during course of treatment, only when prescribed by the treating physician), CPT code 77306 (Teletherapy isodose plan; simple (1 or 2 unmodified ports directed to a single area of interest), includes basic dosimetry calculation(s)), CPT code 77332 (Treatment devices, design and construction; simple (simple block, simple bolus)), and CPT code 77427 (Radiation treatment management, 5 treatments). Therefore, for CY 2018, we are proposing a work RVU of 7.93 for HCPCS code GRRR1.

To develop the proposed direct PE inputs for this code, we are proposing to use the RUC-recommended direct PE inputs from the aforementioned codes with several adjustments. We are proposing to apply the staff type ''RN/LPN/MTA'' for all of the clinical labor inputs for this code because we believe that the typical office performing SRT will be staffed with this labor type, rather than with another clinical labor type such as radiation therapists, and we seek comments as to the appropriateness of the staff type ''RN/LPN/MTA'' for this SRT-related service. Some stakeholders have suggested that many services related to SRT are personally performed by the billing practitioner rather than by clinical staff.

We are proposing to remove the supply items ''gown, patient'' and ''pillow case'' that are associated with CPT code 77280, as these items are included in the minimum multi-specialty visit pack that is associated with CPT code 77427. We are not proposing to include the equipment items ''radiation virtual simulation system,'' ''room, CT'' and ''PACS Workstation Proxy'' that are associated with CPT code 77280, as we do not believe that a typical office furnishing SRT uses this kind of equipment. Instead, we are including additional time for the capital equipment used in delivering SRT in the proposed direct PE inputs. For ''radiation dose therapy plan,'' we are proposing to apply the clinical labor time that is associated with CPT code 77300 to HCPCS code GRRR1 for purposes of developing a proposed value, but we seek comments as to whether the clinical staff would typically perform the radiation dose therapy planning for this service, or if the physician would perform this and/or other tasks, and, in the case of the latter, what the appropriate physician time would be. Likewise, we are soliciting comment as to whether the clinical labor associated with the teletherapy isodose plan would be performed by the physician. We are proposing to assign 14 minutes each to the equipment items ''radiation therapy dosimetry software (Argus QC)'', ''computer workstation'', and ''3D teletherapy treatment planning'' as these are the times assigned to these equipment items for CPT code 77300.

We are not proposing to include inputs related to radiation physics consultation, described by CPT code 77336, as we think that a typical course of SRT would not require this service, and the typical practitioner providing SRT would not be performing physics consultation, and we are seeking comment as to whether inputs associated with this code or other inputs used in furnishing analogous services should be included. We are not proposing to include the post-operative office visits included in the valuation of CPT code 77427, as we do not believe that a typical course of SRT will require post-operative visits; however, we are seeking comment regarding the amount of face-to-face time typically spent by the practitioner with the patient for radiation treatment management associated with SRT.

As discussed in the CY 2016 PFS final rule (80 FR 70924 through 70927), in the case of new codes that describe services that were previously included in the payment for other codes, we finalized the policy that these new codes are excluded from the misvalued code target when they were previously bundled into a set of broadly reported E/M codes and services that include E/M visits. We noted that we did not believe that the change to separate payment for these kinds of services should be counted as increases that are included in calculating ''net reductions'' in expenditure attributable to adjustments for misvalued codes. Therefore, we are proposing to exclude HCPCS code GRRR1 from the misvalued code target.

(57) Payment Accuracy for Prolonged Preventive Services (HCPCS Codes GYYY1 and GYYY2)

Most services paid under the PFS are coded to reflect differential resource costs associated with different levels of care. However, this level of granularity is not applied evenly across the PFS. For example, there are far fewer Evaluation and Management (E/M) visit codes than there are codes that describe procedures. While not a comprehensive solution to address the differential resource costs of certain E/M visits, prolonged services codes can be used to report medically necessary E/M visits that require additional amounts of time. Like E/M visit codes, many of the Medicare-covered preventive services codes describe a service that has an atypically broad range of potential resource costs, including differential amounts of time required to furnish services. However, unlike for most E/M visit codes, there are not prolonged services codes that apply to Medicare-covered preventive services.

Some stakeholders have expressed concerns to CMS that there is no coding mechanism for practitioners to report the additional time sometimes required to appropriately furnish care to a patient receiving a Medicare-covered preventive service. We note that Medicare covers a broad range of preventive services, such as a ''Welcome to Medicare Preventive Visit'', yearly wellness visits, cancer screenings, and many types of counseling. Medicare beneficiary coinsurance and deductible payments are not applicable for certain Medicare-covered preventive services. Additional information about preventive services

covered under Medicare, including whether beneficiary coinsurance or deductible apply, is available on the CMS Web site at *https://www.cms.gov/Medicare/Prevention/PrevntionGenInfo/Downloads/MPS-QuickReferenceChart-1TextOnly.pdf.* To more accurately reflect the differential resource costs when additional time is required to furnish a Medicare-covered preventive service, we are proposing to make payment for prolonged preventive services using two new HCPCS G codes that could be billed along with the Medicare-covered preventive service codes, when a clinician provides a prolonged Medicare-covered preventive service.

- *GYYY1:* Prolonged preventive service(s) (beyond the typical service time of the primary procedure) in the office or other outpatient setting requiring direct patient contact beyond the usual service; first 30 minutes (List separately in addition to code for preventive service)), and
- *GYYY2:* Prolonged preventive service(s) (beyond the typical service time of the primary procedure) in the office or other outpatient setting requiring direct patient contact beyond the usual service; each additional 30 minutes (List separately in addition to code for preventive service)). These proposed services (HCPCS codes GYYY1 and GYYY2) are only permitted to be billed with Medicare-covered preventive services. Beneficiary coinsurance and deductible would not be applicable for HCPCS codes GYYY1 and GYYY2 because the codes can only be reported to describe prolonged portions of services where beneficiary coinsurance and deductible are not applicable.

We are proposing to use prolonged services codes in 30-minute increments instead of the 60-minute increments that apply for the parallel office/outpatient prolonged services codes, since some Medicare-covered preventive services have a shorter duration than E/M visits. For purposes of valuation for both initial and additional 30 minute codes, we are proposing to use one half of the current work RVUs and direct PE inputs for CPT code 99354 (Prolonged evaluation and management or psychotherapy service(s) beyond the typical service time of the primary procedure) in the office or other outpatient setting requiring direct patient contact beyond the usual service; first hour (List separately in addition to code for office or other outpatient Evaluation and Management or psychotherapy service)). CPT code 99354 has a total time of 60 minutes and a work RVU of 2.33. Therefore, we are proposing a work RVU of 1.17 and 30 minutes of total work time for HCPCS codes GYYY1 and GYYY2. We are proposing to use one half of the direct PE inputs for CPT code 99354, which results in a proposal of 7 minutes of clinical labor type L037D (RN/LPN/MTA) and 15 minutes for equipment type EF031 (table, power) for HCPCS code GYYY1 and HCPCS code GYYY2 as the best reflection of typical direct PE costs. We understand that these specific clinical labor and equipment types may be functioning as proxy inputs for some Medicare-covered preventive services.

As described in this section of the rule, we propose that HCPCS codes GYYY1 and GYYY2 be billed for prolonged preventive services beyond the typical service time of the primary procedure. For preventive services with both physician work and practice expense, we are considering the typical service time of the primary procedure to be the intraservice work time used for the purposes of ratesetting. For Medicare-covered preventive services with no face-to-face physician work, the typical time is the service period clinical staff time that best represents the face-to-face time with the patient. The counted time requirements (derived from the typical times assumed for ratesetting) for all eligible companion Medicare-covered preventive services are available in the file called ''CY 2018 Preventive Services Billed with Prolonged Preventives Code'' on the CMS Web site under downloads for the CY 2018 PFS proposed rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.*

TABLE 10—PROPOSED CY 2018 WORK RVUS FOR NEW, REVISED AND POTENTIALLY MISVALUED CODES

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
007X1	Anesthesia for upper gastrointestinal endoscopic procedures, endoscope introduced proximal to duodenum; not otherwise specified.	NEW	0.00	0.00	No.
007X2	Anesthesia for upper gastrointestinal endoscopic procedures, endoscope introduced proximal to duodenum; endoscopic retrograde cholangiopancreatography (ERCP).	NEW	0.00	0.00	No.
008X1	Anesthesia for lower intestinal endoscopic procedures, endoscope introduced distal to duodenum; not otherwise specified.	NEW	0.00	0.00	No.
008X2	Anesthesia for lower intestinal endoscopic procedures, endoscope introduced distal to duodenum; screening colonoscopy.	NEW	0.00	0.00	No.
008X3	Anesthesia for combined upper and lower gastrointestinal endoscopic procedures, endoscope introduced both proximal to and distal to the duodenum.	NEW	0.00	0.00	No.
10040	Acne surgery (*e.g.*, marsupialization, opening or removal of multiple milia, comedones, cysts, pustules).	1.21	0.91	0.91	No.
15734	Muscle, myocutaneous, or fasciocutaneous flap; trunk	19.86	23.00	23.00	No.
15736	Muscle, myocutaneous, or fasciocutaneous flap; upper extremity	17.04	17.04	17.04	No.
15738	Muscle, myocutaneous, or fasciocutaneous flap; lower extremity	19.04	19.04	19.04	No.
157X1	Midface flap (*i.e.*, zygomaticofacial flap) with preservation of vascular pedicle(s)	NEW	13.50	13.50	No.
157X2	Muscle, myocutaneous, or fasciocutaneous flap; head and neck with named vascular pedicle (*i.e.*, buccinators, genioglossus, temporalis, masseter, sternocleidomastoid, levator scapulae).	NEW	15.68	15.68	No.
192X1	Preparation of tumor cavity with placement of a radiation therapy applicator for intraoperative radiation therapy (IORT) concurrent with partial mastectomy.	NEW	3.00	3.00	No.
19303	Mastectomy, simple, complete	15.85	15.00	15.00	No.
2093X	Bone marrow aspiration for bone grafting, spine surgery only, through separate skin or fascial incision.	NEW	1.16	1.16	No.
29445	Application of rigid total contact leg cast	1.78	1.78	1.78	No.
29580	Strapping; Unna boot	0.55	0.55	0.55	No.
29581	Application of multi-layer compression system; leg (below knee), including ankle and foot	0.25	0.60	0.60	No.
30140	Submucous resection inferior turbinate, partial or complete, any method	3.57	3.00	3.00	No.
30901	Control nasal hemorrhage, anterior, simple (limited cautery and/or packing) any method	1.10	1.10	1.10	No.
30903	Control nasal hemorrhage, anterior, complex (extensive cautery and/or packing) any method	1.54	1.54	1.54	No.
30905	Control nasal hemorrhage, posterior, with posterior nasal packs and/or cautery, any method; initial	1.97	1.97	1.97	No.

TABLE 10—PROPOSED CY 2018 WORK RVUS FOR NEW, REVISED AND POTENTIALLY MISVALUED CODES—Continued

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
30906	Control nasal hemorrhage, posterior, with posterior nasal packs and/or cautery, any method; subsequent.	2.45	2.45	2.45	No.
31XX1	Nasal/sinus endoscopy, surgical; with ligation of sphenopalatine artery	NEW	8.00	8.00	No.
31XX2	Nasal/sinus endoscopy, surgical with ethmoidectomy; total (anterior and posterior), including frontal sinus exploration, with removal of tissue from frontal sinus, when performed.	NEW	9.00	9.00	No.
31XX3	Nasal/sinus endoscopy, surgical with ethmoidectomy; total (anterior and posterior), including sphenoidotomy.	NEW	8.00	8.00	No.
31XX4	Nasal/sinus endoscopy, surgical with ethmoidectomy; total (anterior and posterior), including sphenoidotomy, with removal of tissue from the sphenoid sinus.	NEW	8.48	8.48	No.
31XX5	Nasal/sinus endoscopy, surgical; with dilation of frontal and sphenoid sinus ostia (*e.g.*, balloon dilation).	NEW	4.50	4.50	No.
31254	Nasal/sinus endoscopy, surgical with ethmoidectomy; partial (anterior)	4.64	4.27	4.27	No.
31255	Nasal/sinus endoscopy, surgical with ethmoidectomy; total (anterior and posterior)	6.95	5.75	5.75	No.
31256	Nasal/sinus endoscopy, surgical, with maxillary antrostomy	3.29	3.11	3.11	No.
31267	Nasal/sinus endoscopy, surgical, with maxillary antrostomy; with removal of tissue from maxillary sinus.	5.45	4.68	4.68	No.
31276	Nasal/sinus endoscopy, surgical, with frontal sinus exploration, including removal of tissue from frontal sinus, when performed.	8.84	6.75	6.75	No.
31287	Nasal/sinus endoscopy, surgical, with sphenoidotomy	3.91	3.50	3.50	No.
31288	Nasal/sinus endoscopy, surgical, with sphenoidotomy; with removal of tissue from the sphenoid sinus.	4.57	4.10	4.10	No.
31295	Nasal/sinus endoscopy, surgical; with dilation of maxillary sinus ostium (*e.g.*, balloon dilation), transnasal or canine fossa.	2.70	2.70	2.70	No.
31296	Nasal/sinus endoscopy, surgical; with dilation of frontal sinus ostium (*e.g.*, balloon dilation)	3.29	3.10	3.10	No.
31297	Nasal/sinus endoscopy, surgical; with dilation of sphenoid sinus ostium (*e.g.*, balloon dilation)	2.64	2.44	2.44	No.
31600	Tracheostomy, planned (separate procedure)	7.17	5.56	5.56	No.
31601	Tracheostomy, planned (separate procedure); younger than 2 years	4.44	8.00	8.00	No.
31603	Tracheostomy, emergency procedure; transtracheal	4.14	6.00	6.00	No.
31605	Tracheostomy, emergency procedure; cricothyroid membrane	3.57	6.45	6.45	No.
31610	Tracheostomy, fenestration procedure with skin flaps	9.38	12.00	12.00	No.
31645	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed with therapeutic aspiration of tracheobronchial tree, initial.	2.91	2.88	2.88	No.
31646	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed with therapeutic aspiration of tracheobronchial tree, subsequent, same hospital stay.	2.47	2.78	2.78	No.
32998	Ablation therapy for reduction or eradication of 1 or more pulmonary tumor(s) including pleura or chest wall when involved by tumor extension, percutaneous, including imaging guidance when performed, unilateral; radiofrequency.	5.68	9.03	9.03	No.
32X99	Ablation therapy for reduction or eradication of 1 or more pulmonary tumor(s) including pleura or chest wall when involved by tumor extension, percutaneous, including imaging guidance when performed, unilateral; cryoablation.	NEW	9.03	9.03	No.
339X1	Implantation of a total replacement heart system (artificial heart) with recipient cardiectomy	NEW	49.00	49.00	No.
339X2	Removal and replacement of total replacement heart system (artificial heart)	NEW	C	C	No.
339X3	Removal of a total replacement heart system (artificial heart) for heart transplantation	NEW	C	C	No.
34812	Open femoral artery exposure for delivery of endovascular prosthesis by groin incision, unilateral	6.74	4.13	4.13	No.
34820	Open iliac artery exposure for delivery of endovascular prosthesis or iliac occlusion by abdominal or retroperitoneal incision, unilateral.	9.74	7.00	7.00	No.
34833	Open iliac artery exposure with creation of conduit for delivery of endovascular prosthesis or for establishment of cardiopulmonary bypass, by abdominal or retroperitoneal incision, unilateral.	11.98	8.16	8.16	No.
34834	Open brachial artery exposure for delivery of endovascular prosthesis unilateral	5.34	2.65	2.65	No.
34X01	Endovascular repair of infrarenal aorta by deployment of an aorto-aortic tube endograft including pre-procedure sizing and device selection, all nonselective catheterization(s), all associated radiological supervision and interpretation, all endograft extension(s) placed in the aorta from the level of the renal arteries to the aortic bifurcation, and all angioplasty/stenting performed from the level of the renal arteries to the aortic bifurcation; for other than rupture (*e.g.*, for aneurysm, pseudoaneurysm, dissection, penetrating ulcer).	NEW	23.71	23.71	No.
34X02	Endovascular repair of infrarenal aorta by deployment of an aorto-aortic tube endograft including pre-procedure sizing and device selection, all nonselective catheterization(s), all associated radiological supervision and interpretation, all endograft extension(s) placed in the aorta from the level of the renal arteries to the aortic bifurcation, and all angioplasty/stenting performed from the level of the renal arteries to the aortic bifurcation; for rupture including temporary aortic and/or iliac balloon occlusion when performed (*e.g.*, for aneurysm, pseudoaneurysm, dissection, penetrating ulcer, traumatic disruption).	NEW	36.00	36.00	No.
34X03	Endovascular repair of infrarenal aorta and/or iliac artery(ies) by deployment of an aorto-uniiliac endograft including pre-procedure sizing and device selection, all nonselective catheterization(s), all associated radiological supervision and interpretation, all endograft extension(s) placed in the aorta from the level of the renal arteries to the iliac bifurcation, and all angioplasty/stenting performed from the level of the renal arteries to the iliac bifurcation; for other than rupture (*e.g.*, for aneurysm, pseudoaneurysm, dissection, penetrating ulcer).	NEW	26.52	26.52	No.
34X04	Endovascular repair of infrarenal aorta and/or iliac artery(ies) by deployment of an aorto-uniiliac endograft including pre-procedure sizing and device selection, all nonselective catheterization(s), all associated radiological supervision and interpretation, all endograft extension(s) placed in the aorta from the level of the renal arteries to the iliac bifurcation, and all angioplasty/stenting performed from the level of the renal arteries to the iliac bifurcation; for rupture including temporary aortic and/or iliac balloon occlusion when performed (*e.g.*, for aneurysm, pseudoaneurysm, dissection, penetrating ulcer, traumatic disruption).	NEW	45.00	45.00	No.

TABLE 10—PROPOSED CY 2018 WORK RVUS FOR NEW, REVISED AND POTENTIALLY MISVALUED CODES—Continued

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
34X05	Endovascular repair of infrarenal aorta and/or iliac artery(ies) by deployment of an aorto-biiliac endograft including pre-procedure sizing and device selection, all nonselective catheterization(s), all associated radiological supervision and interpretation, all endograft extension(s) placed in the aorta from the level of the renal arteries to the iliac bifurcation, and all angioplasty/stenting performed from the level of the renal arteries to the iliac bifurcation; for other than rupture (*e.g.*, for aneurysm, pseudoaneurysm, dissection, penetrating ulcer).	NEW	29.58	29.58	No.
34X06	Endovascular repair of infrarenal aorta and/or iliac artery(ies) by deployment of an aorto-biiliac endograft including pre-procedure sizing and device selection, all nonselective catheterization(s), all associated radiological supervision and interpretation, all endograft extension(s) placed in the aorta from the level of the renal arteries to the iliac bifurcation, and all angioplasty/stenting performed from the level of the renal arteries to the iliac bifurcation; for rupture including temporary aortic and/or iliac balloon occlusion when performed (*e.g.*, for aneurysm, pseudoaneurysm, dissection, penetrating ulcer, traumatic disruption).	NEW	45.00	45.00	No.
34X07	Endovascular repair of iliac artery by deployment of an ilio-iliac tube endograft including pre-procedure sizing and device selection, all nonselective catheterization(s), all associated radiological supervision and interpretation, and all endograft extension(s) proximally to the aortic bifurcation and distally to the iliac bifurcation, and treatment zone angioplasty/stenting when performed, unilateral; for other than rupture (*e.g.*, for aneurysm, pseudoaneurysm, dissection, arteriovenous malformation).	NEW	22.28	22.28	No.
34X08	Endovascular repair of iliac artery by deployment of an ilio-iliac tube endograft including pre-procedure sizing and device selection, all nonselective catheterization(s), all associated radiological supervision and interpretation, and all endograft extension(s) proximally to the aortic bifurcation and distally to the iliac bifurcation, and treatment zone angioplasty/stenting when performed, unilateral; for rupture including temporary aortic and/or iliac balloon occlusion when performed (*e.g.*, for aneurysm, pseudoaneurysm, dissection, arteriovenous malformation, traumatic disruption).	NEW	36.50	36.50	No.
34X09	Placement of extension prosthesis(es) distal to the common iliac artery(ies) or proximal to the renal artery(ies) for endovascular repair of infrarenal abdominal aortic or iliac aneurysm, false aneurysm, dissection, penetrating ulcer, including pre-procedure sizing and device selection, all nonselective catheterization(s), all associated radiological supervision and interpretation, and treatment zone angioplasty/stenting when performed, per vessel treated.	NEW	6.50	6.50	No.
34X10	Delayed placement of distal or proximal extension prosthesis for endovascular repair of infrarenal abdominal aortic or iliac aneurysm, false aneurysm, dissection, endoleak, or endograft migration, including pre-procedure sizing and device selection, all nonselective catheterization(s), all associated radiological supervision and interpretation, and treatment zone angioplasty/stenting when performed; initial vessel treated.	NEW	15.00	15.00	No.
34X11	Delayed placement of distal or proximal extension prosthesis for endovascular repair of infrarenal abdominal aortic or iliac aneurysm, false aneurysm, dissection, endoleak, or endograft migration, including pre-procedure sizing and device selection, all nonselective catheterization(s), all associated radiological supervision and interpretation, and treatment zone angioplasty/stenting when performed; each additional vessel treated.	NEW	6.00	6.00	No.
34X12	Transcatheter delivery of enhanced fixation device(s) to the endograft (*e.g.*, anchor, screw, tack) and all associated radiological supervision and interpretation.	NEW	12.00	12.00	No.
34X13	Percutaneous access and closure of femoral artery for delivery of endograft through a large sheath (12 French or larger), including ultrasound guidance, when performed, unilateral.	NEW	2.50	2.50	No.
34X15	Open femoral artery exposure with creation of conduit for delivery of endovascular prosthesis or for establishment of cardiopulmonary bypass, by groin incision, unilateral.	NEW	5.25	5.25	No.
34X19	Open axillary/subclavian artery exposure for delivery of endovascular prosthesis by infraclavicular or supraclavicular incision, unilateral.	NEW	6.00	6.00	No.
34X20	Open axillary/subclavian artery exposure with creation of conduit for delivery of endovascular prosthesis or for establishment of cardiopulmonary bypass, by infraclavicular or supraclavicular incision, unilateral.	NEW	7.19	7.19	No.
36215	Selective catheter placement, arterial system; each first order thoracic or brachiocephalic branch, within a vascular family.	4.67	4.17	4.17	No.
36216	Selective catheter placement, arterial system; initial second order thoracic or brachiocephalic branch, within a vascular family.	5.27	5.27	5.27	No.
36217	Selective catheter placement, arterial system; initial third order or more selective thoracic or brachiocephalic branch, within a vascular family.	6.29	6.29	6.29	No.
36218	Selective catheter placement, arterial system; additional second order, third order, and beyond, thoracic or brachiocephalic branch, within a vascular family.	1.01	1.01	1.01	No.
36470	Injection of sclerosant; single incompetent vein (other than telangiectasia)	1.10	0.75	0.75	No.
36471	Injection of sclerosant; multiple incompetent veins (other than telangiectasia), same leg	1.65	1.50	1.50	No.
364X3	Endovenous ablation therapy of incompetent vein, extremity, by transcatheter delivery of a chemical adhesive (*e.g.*, cyanoacrylate) remote from the access site, inclusive of all imaging guidance and monitoring, percutaneous; first vein treated.	NEW	3.50	3.50	No.
364X4	Endovenous ablation therapy of incompetent vein, extremity, by transcatheter delivery of a chemical adhesive (*e.g.*, cyanoacrylate) remote from the access site, inclusive of all imaging guidance and monitoring, percutaneous; subsequent vein(s) treated in a single extremity, each through separate access sites.	NEW	1.75	1.75	No.
364X5	Injection of non-compounded foam sclerosant with ultrasound compression maneuvers to guide dispersion of the injectate, inclusive of all imaging guidance and monitoring; single incompetent extremity truncal vein (*e.g.*, great saphenous vein, accessory saphenous vein).	NEW	2.35	2.35	No.
364X6	Injection of non-compounded foam sclerosant with ultrasound compression maneuvers to guide dispersion of the injectate, inclusive of all imaging guidance and monitoring; multiple incompetent truncal veins (*e.g.*, great saphenous vein, accessory saphenous vein), same leg.	NEW	3.00	3.00	No.
36511	Therapeutic apheresis; for white blood cells	1.74	2.00	2.00	No.
36512	Therapeutic apheresis; for red blood cells	1.74	2.00	2.00	No.
36513	Therapeutic apheresis; for platelets	1.74	2.00	2.00	No.
36514	Therapeutic apheresis; for plasma pheresis	1.74	1.81	1.81	No.

TABLE 10—PROPOSED CY 2018 WORK RVUS FOR NEW, REVISED AND POTENTIALLY MISVALUED CODES—Continued

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
36516	Therapeutic apheresis; with extracorporeal selective adsorption or selective filtration and plasma reinfusion.	1.22	1.56	1.56	No.
36522	Photopheresis, extracorporeal	1.67	1.75	1.75	No.
36555	Insertion of non-tunneled centrally inserted central venous catheter; younger than 5 years of age	2.43	1.93	1.93	No.
36556	Insertion of non-tunneled centrally inserted central venous catheter; age 5 years or older	2.50	1.75	1.75	No.
36569	Insertion of peripherally inserted central venous catheter (PICC), without subcutaneous port or pump; age 5 years or older.	1.82	1.70	1.70	No.
36620	Arterial catheterization or cannulation for sampling, monitoring or transfusion (separate procedure); percutaneous.	1.15	1.00	1.00	No.
38220	Diagnostic bone marrow; aspiration(s)	1.08	1.20	1.20	Yes.
38221	Diagnostic bone marrow; biopsy(ies)	1.37	1.28	1.28	Yes.
382X3	Diagnostic bone marrow; biopsy(ies) and aspiration(s)	NEW	1.44	1.44	Yes.
3857X	Laparoscopy, surgical; with bilateral total pelvic lymphadenectomy and peri-aortic lymph node sampling peritoneal washings, peritoneal biopsy(s), omentectomy, and diaphragmatic washings, including biopsy(s) when performed.	NEW	20.00	20.00	No.
43107	Total or near total esophagectomy, without thoracotomy; with pharyngogastrostomy or cervical esophagogastrostomy, with or without pyloroplasty (transhiatal).	44.18	52.05	52.05	No.
43112	Total or near total esophagectomy, with thoracotomy; with pharyngogastrostomy or cervical esophagogastrostomy, with or without pyloroplasty (*i.e.*, McKeown esophagectomy, or tri-incisional esophagectomy).	47.48	62.00	62.00	No.
43117	Partial esophagectomy, distal two-thirds, with thoracotomy and separate abdominal incision, with or without proximal gastrectomy; with thoracic esophagogastrostomy, with or without pyloroplasty (Ivor Lewis).	43.65	57.50	57.50	No.
432X5	Esophagectomy, total or near total, with laparoscopic mobilization of the abdominal and mediastinal esophagus and proximal gastrectomy, with laparoscopic pyloric drainage procedure if performed, with open cervical pharyngogastrostomy or esophagogastrostomy (*i.e.*, laparoscopic transhiatal esophagectomy).	NEW	55.00	55.00	No
432X6	Esophagectomy, distal two-thirds, with laparoscopic mobilization of the abdominal and lower mediastinal esophagus and proximal gastrectomy, with laparoscopic pyloric drainage procedure if performed, with separate thoracoscopic mobilization of the middle and upper mediastinal esophagus and thoracic esophagogastrostomy (*i.e.*, laparoscopic thoracoscopic esophagectomy, Ivor Lewis esophagectomy).	NEW	63.00	63.00	No.
432X7	Esophagectomy, total or near total, with thoracoscopic mobilization of the upper, middle, and lower mediastinal esophagus, with separate laparoscopic proximal gastrectomy, with laparoscopic pyloric drainage procedure if performed, with open cervical pharyngogastrostomy or esophagogastrostomy (*i.e.*, thoracoscopic, laparoscopic and cervical incision esophagectomy, McKeown esophagectomy, tri-incisional esophagectomy).	NEW	66.42	66.42	No.
51798	Measurement of post-voiding residual urine and/or bladder capacity by ultrasound, non-imaging	0.00	0.00	0.00	No.
52601	Transurethral electrosurgical resection of prostate, including control of postoperative bleeding, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, and internal urethrotomy are included).	15.26	13.16	13.16	No.
55X87	Transperineal placement of biodegradable material, peri-prostatic, single or multiple injection(s), including image guidance, when performed.	NEW	3.03	3.03	No.
57240	Anterior colporrhaphy, repair of cystocele with or without repair of urethrocele, including cystourethroscopy, when performed.	11.50	10.08	10.08	No.
57250	Posterior colporrhaphy, repair of rectocele with or without perineorrhaphy	11.50	10.08	10.08	No.
57260	Combined anteroposterior colporrhaphy, including cystourethroscopy, when performed	14.44	13.25	13.25	No.
57265	Combined anteroposterior colporrhaphy, including cystourethroscopy, when performed; with enterocele repair.	15.94	15.00	15.00	No.
5857X	Laparoscopy, surgical, total hysterectomy; with or without salpingo-oophorectomy, unilateral or bilateral, with resection of malignancy (tumor debulking), with omentectomy.	NEW	32.60	32.60	No.
64418	Injection, anesthetic agent; suprascapular nerve	1.32	1.10	1.10	No.
64553	Percutaneous implantation of neurostimulator electrode array; cranial nerve	2.36	6.13	6.13	No
64555	Percutaneous implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve).	2.32	5.76	5.76	No.
64910	Nerve repair; with synthetic conduit or vein allograft (*e.g.*, nerve tube), each nerve	11.39	10.52	10.52	No.
64911	Nerve repair; with autogenous vein graft (includes harvest of vein graft), each nerve	14.39	14.00	14.00	No
64X91	Nerve repair; with nerve allograft, each nerve, first strand (cable)	NEW	12.00	12.00	No.
64X92	Nerve repair; with nerve allograft, each additional strand	NEW	3.00	3.00	No.
67820	Correction of trichiasis; epilation, by forceps only	0.71	0.32	0.32	No.
70490	Computed tomography, soft tissue neck; without contrast material	1.28	1.28	1.28	No.
70491	Computed tomography, soft tissue neck; with contrast material(s)	1.38	1.38	1.38	No.
70492	Computed tomography, soft tissue neck; without contrast material followed by contrast material(s) and further sections.	1.45	1.62	1.62	No.
70544	Magnetic resonance angiography, head; without contrast material(s)	1.20	1.20	1.20	No.
70545	Magnetic resonance angiography, head; with contrast material(s)	1.20	1.20	1.20	No.
70546	Magnetic resonance angiography, head; without contrast material(s), followed by contrast material(s) and further sequences.	1.80	1.48	1.48	No.
70547	Magnetic resonance angiography, neck; without contrast material(s)	1.20	1.20	1.20	No.
70548	Magnetic resonance angiography, neck; with contrast material(s)	1.20	1.50	1.50	No.
70549	Magnetic resonance angiography, neck; without contrast material(s), followed by contrast material(s) and further sequences.	1.80	1.80	1.80	No.
710X1	Radiologic examination, chest; single view	NEW	0.18	0.18	No.
710X2	Radiologic examination, chest; 2 views	NEW	0.22	0.22	No.
710X3	Radiologic examination, chest; 3 views	NEW	0.27	0.27	No.
710X4	Radiologic examination, chest; 4 or more views	NEW	0.31	0.31	No.
71100	Radiologic examination, ribs, unilateral; 2 views	0.22	0.22	0.22	No.
71101	Radiologic examination, ribs, unilateral; including posteroanterior chest, minimum of 3 views	0.27	0.27	0.27	No.
71110	Radiologic examination, ribs, bilateral; 3 views	0.27	0.29	0.29	No.
71111	Radiologic examination, ribs, bilateral; including posteroanterior chest, minimum of 4 views	0.32	0.32	0.32	No.

TABLE 10—PROPOSED CY 2018 WORK RVUS FOR NEW, REVISED AND POTENTIALLY MISVALUED CODES—Continued

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
71250	Computed tomography, thorax; without contrast material	1.02	1.16	1.16	No.
71260	Computed tomography, thorax; with contrast material(s)	1.24	1.24	1.24	No.
71270	Computed tomography, thorax; without contrast material, followed by contrast material(s) and further sections.	1.38	1.38	1.38	No.
72195	Magnetic resonance (*e.g.*, proton) imaging, pelvis; without contrast material(s)	1.46	1.46	1.46	No.
72196	Magnetic resonance (*e.g.*, proton) imaging, pelvis; with contrast material(s)	1.73	1.73	1.73	No.
72197	Magnetic resonance (*e.g.*, proton) imaging, pelvis; without contrast material(s), followed by contrast material(s) and further sequences.	2.26	2.20	2.20	No.
73100	Radiologic examination, wrist; 2 views	0.16	0.16	0.16	No.
73110	Radiologic examination, wrist; complete, minimum of 3 views	0.17	0.17	0.17	No.
73120	Radiologic examination, hand; 2 views	0.16	0.16	0.16	No.
73130	Radiologic examination, hand; minimum of 3 views	0.17	0.17	0.17	No.
73140	Radiologic examination, finger(s), minimum of 2 views	0.13	0.13	0.13	No.
73718	Magnetic resonance (*e.g.*, proton) imaging, lower extremity other than joint; without contrast material(s).	1.35	1.35	1.35	No.
73719	Magnetic resonance (*e.g.*, proton) imaging, lower extremity other than joint; with contrast material(s).	1.62	1.62	1.62	No.
73720	Magnetic resonance (*e.g.*, proton) imaging, lower extremity other than joint; without contrast material(s), followed by contrast material(s) and further sequences.	2.15	2.15	2.15	No.
74022	Radiologic examination, abdomen; complete acute abdomen series, including supine, erect, and/or decubitus views, single view chest.	0.32	0.32	0.32	No.
740X1	Radiologic examination, abdomen; 1 view	NEW	0.18	0.18	No.
740X2	Radiologic examination, abdomen; 2 views	NEW	0.23	0.23	No.
740X3	Radiologic examination, abdomen; 3 or more views	NEW	0.27	0.27	No.
74181	Magnetic resonance (*e.g.*, proton) imaging, abdomen; without contrast material(s)	1.46	1.46	1.46	No.
74182	Magnetic resonance (*e.g.*, proton) imaging, abdomen; with contrast material(s)	1.73	1.73	1.73	No.
74183	Magnetic resonance (*e.g.*, proton) imaging, abdomen; without contrast material(s), followed by with contrast material(s) and further sequences.	2.26	2.20	2.20	No.
75635	Computed tomographic angiography, abdominal aorta and bilateral iliofemoral lower extremity runoff, with contrast material(s), including noncontrast images, if performed, and image postprocessing.	2.40	2.40	2.40	No.
75710	Angiography, extremity, unilateral, radiological supervision and interpretation	1.14	1.75	1.75	No.
75716	Angiography, extremity, bilateral, radiological supervision and interpretation	1.31	1.97	1.97	No.
76510	Ophthalmic ultrasound, diagnostic; B-scan and quantitative A-scan performed during the same patient encounter.	1.55	0.70	0.70	No.
76511	Ophthalmic ultrasound, diagnostic; quantitative A-scan only	0.94	0.64	0.64	No.
76512	Ophthalmic ultrasound, diagnostic; B-scan (with or without superimposed non-quantitative A-scan)	0.94	0.56	0.56	No.
76516	Ophthalmic biometry by ultrasound echography, A-scan	0.54	0.40	0.40	No.
76519	Ophthalmic biometry by ultrasound echography, A-scan; with intraocular lens power calculation	0.54	0.54	0.54	No.
76881	Ultrasound, extremity, nonvascular, real-time with image documentation; complete	0.63	0.63	0.63	No.
76882	Ultrasound, extremity, nonvascular, real-time with image documentation; limited, anatomic specific	0.49	0.49	0.49	No.
77261	Therapeutic radiology treatment planning; simple	1.39	1.30	1.30	No.
77262	Therapeutic radiology treatment planning; intermediate	2.11	2.00	2.00	No.
77263	Therapeutic radiology treatment planning; complex	3.14	3.14	3.14	No.
78300	Bone and/or joint imaging; limited area	0.62	0.62	0.62	No.
78305	Bone and/or joint imaging; multiple areas	0.83	0.83	0.83	No.
78306	Bone and/or joint imaging; whole body	0.86	0.86	0.86	No.
88333	Pathology consultation during surgery; cytologic examination (*e.g.*, touch prep, squash prep), initial site.	1.20	1.20	1.20	No.
88334	Pathology consultation during surgery; cytologic examination (*e.g.*, touch prep, squash prep), each additional site.	0.73	0.73	0.73	No.
88360	Morphometric analysis, tumor immunohistochemistry (*e.g.*, Her-2/neu, estrogen receptor/progesterone receptor), quantitative or semiquantitative, per specimen, each single antibody stain procedure; manual.	1.10	0.85	0.85	No.
88361	Morphometric analysis, tumor immunohistochemistry (*e.g.*, Her-2/neu, estrogen receptor/progesterone receptor), quantitative or semiquantitative, per specimen, each single antibody stain procedure; using computer-assisted technology.	1.18	0.95	0.95	No.
92136	Ophthalmic biometry by partial coherence interferometry with intraocular lens power calculation	0.54	0.54	0.54	No.
93279	Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified health care professional; single lead pacemaker system.	0.65	0.65	0.65	No.
93280	Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified health care professional; dual lead pacemaker system.	0.77	0.77	0.77	No.
93281	Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified health care professional; multiple lead pacemaker system.	0.90	0.85	0.85	No.
93282	Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified health care professional; single lead transvenous implantable defibrillator system.	0.85	0.85	0.85	No.
93283	Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified health care professional; dual lead transvenous implantable defibrillator system.	1.15	1.15	1.15	No.

TABLE 10—PROPOSED CY 2018 WORK RVUS FOR NEW, REVISED AND POTENTIALLY MISVALUED CODES—Continued

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
93284	Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified health care professional; multiple lead transvenous implantable defibrillator system.	1.25	1.25	1.25	No.
93285	Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified health care professional; implantable loop recorder system.	0.52	0.52	0.52	No.
93286	Peri-procedural device evaluation (in person) and programming of device system parameters before or after a surgery, procedure, or test with analysis, review and report by a physician or other qualified health care professional; single, dual, or multiple lead pacemaker system.	0.30	0.30	0.30	No.
93287	Peri-procedural device evaluation (in person) and programming of device system parameters before or after a surgery, procedure, or test with analysis, review and report by a physician or other qualified health care professional; single, dual, or multiple lead implantable defibrillator system.	0.45	0.45	0.45	No.
93288	Interrogation device evaluation (in person) with analysis, review and report by a physician or other qualified health care professional, includes connection, recording and disconnection per patient encounter; single, dual, or multiple lead pacemaker system.	0.43	0.43	0.43	No.
93289	Interrogation device evaluation (in person) with analysis, review and report by a physician or other qualified health care professional, includes connection, recording and disconnection per patient encounter; single, dual, or multiple lead transvenous implantable defibrillator system, including analysis of heart rhythm derived data elements.	0.92	0.75	0.75	No.
93290	Interrogation device evaluation (in person) with analysis, review and report by a physician or other qualified health care professional, includes connection, recording and disconnection per patient encounter; implantable cardiovascular monitor system, including analysis of 1 or more recorded physiologic cardiovascular data elements from all internal and external sensors.	0.43	0.43	0.43	No.
93291	Interrogation device evaluation (in person) with analysis, review and report by a physician or other qualified health care professional, includes connection, recording and disconnection per patient encounter; implantable loop recorder system, including heart rhythm derived data analysis.	0.43	0.37	0.37	No.
93292	Interrogation device evaluation (in person) with analysis, review and report by a physician or other qualified health care professional, includes connection, recording and disconnection per patient encounter; wearable defibrillator system.	0.43	0.43	0.43	No.
93293	Transtelephonic rhythm strip pacemaker evaluation(s) single, dual, or multiple lead pacemaker system, includes recording with and without magnet application with analysis, review and report(s) by a physician or other qualified health care professional, up to 90 days.	0.32	0.31	0.31	No.
93294	Interrogation device evaluation(s) (remote), up to 90 days; single, dual, or multiple lead pacemaker system with interim analysis, review(s) and report(s) by a physician or other qualified health care professional.	0.65	0.60	0.60	No.
93295	Interrogation device evaluation(s) (remote), up to 90 days; single, dual, or multiple lead implantable defibrillator system with interim analysis, review(s) and report(s) by a physician or other qualified health care professional.	1.29	0.74	0.74	No.
93296	Interrogation device evaluation(s) (remote), up to 90 days; single, dual, or multiple lead pacemaker system or implantable defibrillator system, remote data acquisition(s), receipt of transmissions and technician review, technical support and distribution of results.	0.00	0.00	0.00	No.
93297	Interrogation device evaluation(s), (remote) up to 30 days; implantable cardiovascular monitor system, including analysis of 1 or more recorded physiologic cardiovascular data elements from all internal and external sensors, analysis, review(s) and report(s) by a physician or other qualified health care professional.	0.52	0.52	0.52	No.
93298	Interrogation device evaluation(s), (remote) up to 30 days; implantable loop recorder system, including analysis of recorded heart rhythm data, analysis, review(s) and report(s) by a physician or other qualified health care professional.	0.52	0.52	0.52	No.
93299	Interrogation device evaluation(s), (remote) up to 30 days; implantable cardiovascular monitor system or implantable loop recorder system, remote data acquisition(s), receipt of transmissions and technician review, technical support and distribution of results.	0.00	0.00	0.00	No.
93306	Echocardiography, transthoracic, real-time with image documentation (2D), includes M-mode recording, when performed, complete, with spectral Doppler echocardiography, and with color flow Doppler echocardiography.	1.30	1.50	1.50	No.
93307	Echocardiography, transthoracic, real-time with image documentation (2D), includes M-mode recording, when performed, complete, without spectral or color Doppler echocardiography.	0.92	0.92	0.92	No.
93308	Echocardiography, transthoracic, real-time with image documentation (2D), includes M-mode recording, when performed, follow-up or limited study.	0.53	0.53	0.53	No.
93350	Echocardiography, transthoracic, real-time with image documentation (2D), includes M-mode recording, when performed, during rest and cardiovascular stress test using treadmill, bicycle exercise and/or pharmacologically induced stress, with interpretation and report.	1.46	1.46	1.46	No.
93351	Echocardiography, transthoracic, real-time with image documentation (2D), includes M-mode recording, when performed, during rest and cardiovascular stress test using treadmill, bicycle exercise and/or pharmacologically induced stress, with interpretation and report; including performance of continuous electrocardiographic monitoring, with supervision by a physician or other qualified health care professional.	1.75	1.75	1.75	No.
93503	Insertion and placement of flow directed catheter (*e.g.*, Swan-Ganz) for monitoring purposes	2.91	2.00	2.00	No.
93613	Intracardiac electrophysiologic 3-dimensional mapping	6.99	5.23	5.23	No.
93668	Peripheral arterial disease (PAD) rehabilitation, per session	N	0.00	0.00	No.
94621	Cardiopulmonary exercise testing, including measurements of minute ventilation, CO2 production, O2 uptake, and electrocardiographic recordings.	1.42	1.42	1.42	No.
946X2	Exercise test for bronchospasm, including pre- and post-spirometry and pulse oximetry	NEW	0.70	0.70	No.
946X3	Pulmonary stress testing (*e.g.*, 6-minute walk test), including measurement of heart rate, oximetry, and oxygen titration, when performed.	NEW	0.48	0.48	No.
95004	Percutaneous tests (scratch, puncture, prick) with allergenic extracts, immediate type reaction, including test interpretation and report, specify number of tests.	0.01	0.01	0.01	No.

TABLE 10—PROPOSED CY 2018 WORK RVUS FOR NEW, REVISED AND POTENTIALLY MISVALUED CODES—Continued

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
95250	Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; sensor placement, hook-up, calibration of monitor, patient training, removal of sensor, and printout of recording.	0.00	0.00	0.00	No.
95251	Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; interpretation and report.	0.85	0.70	0.70	No.
95930	Visual evoked potential (VEP) testing central nervous system except glaucoma, checkerboard or flash, with interpretation and report.	0.35	0.35	0.35	No.
96160	Administration of patient-focused health risk assessment instrument (*e.g.*, health hazard appraisal) with scoring and documentation, per standardized instrument.	0.00	0.00	0.00	No.
96161	Administration of caregiver-focused health risk assessment instrument (*e.g.*, depression inventory) for the benefit of the patient, with scoring and documentation, per standardized instrument.	0.00	0.00	0.00	No.
96360	Intravenous infusion, hydration; initial, 31 minutes to 1 hour	0.17	0.17	0.17	No.
96361	Intravenous infusion, hydration; each additional hour	0.09	0.09	0.09	No.
96372	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular.	0.17	0.17	0.17	No.
96374	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); intravenous push, single or initial substance/drug.	0.18	0.18	0.18	No.
96375	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); each additional sequential intravenous push of a new substance/drug.	0.10	0.10	0.10	No.
96377	Application of on-body injector (includes cannula insertion) for timed subcutaneous injection	0.00	0.17	0.17	No.
96401	Chemotherapy administration, subcutaneous or intramuscular; non-hormonal anti-neoplastic	0.21	0.21	0.21	No.
96402	Chemotherapy administration, subcutaneous or intramuscular; hormonal anti-neoplastic	0.19	0.19	0.19	No.
96409	Chemotherapy administration; intravenous, push technique, single or initial substance/drug	0.24	0.24	0.24	No.
96411	Chemotherapy administration; intravenous, push technique, each additional substance/drug	0.20	0.20	0.20	No.
96910	Photochemotherapy; tar and ultraviolet B (Goeckerman treatment) or petrolatum and ultraviolet B	0.00	0.00	0.00	No.
96X73	Photodynamic therapy by external application of light to destroy premalignant lesions of the skin and adjacent mucosa with application and illumination/activation of photosensitizing drug(s), per day.	NEW	0.48	0.48	No.
96X74	Debridement of premalignant hyperkeratotic lesion(s) (*i.e.*, targeted curettage, abrasion) followed with photodynamic therapy by external application of light to destroy premalignant lesions of the skin and adjacent mucosa with application and illumination/activation of photosensitizing drug(s), per day.	NEW	1.01	1.01	No.
97012	Application of a modality to 1 or more areas; traction, mechanical	0.25	0.25	0.25	No.
97014	Application of a modality to 1 or more areas; electrical stimulation (unattended)	0.18	0.18	0.18	No.
97016	Application of a modality to 1 or more areas; vasopneumatic devices	0.18	0.18	0.18	No.
97018	Application of a modality to 1 or more areas; paraffin bath	0.06	0.06	0.06	No.
97022	Application of a modality to 1 or more areas; whirlpool	0.17	0.17	0.17	No.
97032	Application of a modality to 1 or more areas; electrical stimulation (manual), each 15 minutes	0.25	0.25	0.25	No.
97033	Application of a modality to 1 or more areas; iontophoresis, each 15 minutes	0.26	0.26	0.26	No.
97034	Application of a modality to 1 or more areas; contrast baths, each 15 minutes	0.21	0.21	0.21	No.
97035	Application of a modality to 1 or more areas; ultrasound, each 15 minutes	0.21	0.21	0.21	No.
97110	Therapeutic procedure, 1 or more areas, each 15 minutes; therapeutic exercises to develop strength and endurance, range of motion and flexibility.	0.45	0.45	0.45	No.
97112	Therapeutic procedure, 1 or more areas, each 15 minutes; neuromuscular reeducation of movement, balance, coordination, kinesthetic sense, posture, and/or proprioception for sitting and/or standing activities.	0.45	0.50	0.50	No.
97113	Therapeutic procedure, 1 or more areas, each 15 minutes; aquatic therapy with therapeutic exercises.	0.44	0.48	0.48	No.
97116	Therapeutic procedure, 1 or more areas, each 15 minutes; gait training (includes stair climbing)	0.40	0.45	0.45	No.
97140	Manual therapy techniques (*e.g.*, mobilization/manipulation, manual lymphatic drainage, manual traction), 1 or more regions, each 15 minutes.	0.43	0.43	0.43	No.
97530	Therapeutic activities, direct (one-on-one) patient contact (use of dynamic activities to improve functional performance), each 15 minutes.	0.44	0.44	0.44	No.
97533	Sensory integrative techniques to enhance sensory processing and promote adaptive responses to environmental demands, direct (one-on-one) patient contact, each 15 minutes.	0.44	0.48	0.48	No.
97535	Self-care/home management training (*e.g.*, activities of daily living (ADL) and compensatory training, meal preparation, safety procedures, and instructions in use of assistive technology devices/adaptive equipment) direct one-on-one contact, each 15 minutes.	0.45	0.45	0.45	No.
97537	Community/work reintegration training (*e.g.*, shopping, transportation, money management, avocational activities and/or work environment/modification analysis, work task analysis, use of assistive technology device/adaptive equipment), direct one-on-one contact, each 15 minutes.	0.45	0.48	0.48	No.
97542	Wheelchair management (*e.g.*, assessment, fitting, training), each 15 minutes	0.45	0.48	0.48	No.
97760	Orthotic(s) management and training (including assessment and fitting when not otherwise reported), upper extremity(ies), lower extremity(ies) and/or trunk, initial orthotic(s) encounter, each 15 minutes.	0.45	0.50	0.50	No.
97761	Prosthetic(s) training, upper and/or lower extremity(ies), initial prosthetic(s) encounter, each 15 minutes.	0.45	0.50	0.50	No.
977X1	Orthotic(s)/prosthetic(s) management and/or training, upper extremity(ies), lower extremity(ies), and/or trunk, subsequent orthotic(s)/prosthetic(s) encounter, each 15 minutes.	NEW	0.48	0.48	No.
97X11	Therapeutic interventions that focus on cognitive function (*e.g.*, attention, memory, reasoning, executive function, problem solving, and/or pragmatic functioning) and compensatory strategies to manage the performance of an activity (*e.g.*, managing time or schedules, initiating, organizing and sequencing tasks, direct (one-on-one) patient contact (do not report 97X11 in conjunction with 0364T, 0365T, 0368T, 0369T) (report 97X11 only once per day).	NEW	1.50	I	Yes.
993X1	Patient/caregiver training for initiation of home INR monitoring under the direction of a physician or other qualified health care professional, including face-to-face, use and care of the INR monitor, obtaining blood sample, instructions for reporting home INR test results, and documentation of patient's/caregiver's ability to perform testing and report results.	NEW	0.00	0.00	No.

TABLE 10—PROPOSED CY 2018 WORK RVUS FOR NEW, REVISED AND POTENTIALLY MISVALUED CODES—Continued

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
993X2	Anticoagulant management for a patient taking warfarin, must include review and interpretation of a new home, office, or lab International No.rmalized Ratio (INR) test result, patient instructions, dosage adjustment (as needed), and scheduling of additional test(s) when performed.	NEW	0.18	0.18	No.
994X1	Initial psychiatric collaborative care management, first 70 minutes in the first calendar month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified health care professional, with the following required elements: Outreach to and engagement in treatment of a patient directed by the treating physician or other qualified health care professional; initial assessment of the patient, including administration of validated rating scales, with the development of an individualized treatment plan; review by the psychiatric consultant with modifications of the plan if recommended; entering patient in a registry and tracking patient follow-up and progress using the registry, with appropriate documentation, and participation in weekly caseload consultation with the psychiatric consultant; and provision of brief interventions using evidence-based techniques such as behavioral activation, motivational interviewing, and other focused treatment strategies.	NEW	1.70	1.70	No.
994X2	Subsequent psychiatric collaborative care management, first 60 minutes in a subsequent month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified health care professional, with the following required elements: Tracking patient follow-up and progress using the registry, with appropriate documentation; participation in weekly caseload consultation with the psychiatric consultant; ongoing collaboration with and coordination of the patient's mental health care with the treating physician or other qualified health care professional and any other treating mental health providers; additional review of progress and recommendations for changes in treatment, as indicated, including medications, based on recommendations provided by the psychiatric consultant; provision of brief interventions using evidence-based techniques such as behavioral activation, motivational interviewing, and other focused treatment strategies; monitoring of patient outcomes using validated rating scales; and relapse prevention planning with patients as they achieve remission of symptoms and/or other treatment goals and are prepared for discharge from active treatment.	NEW	1.53	1.53	No.
994X3	Initial or subsequent psychiatric collaborative care management, each additional 30 minutes in a calendar month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified health care professional.	NEW	0.82	0.82	No.
99XX3	Assessment of and care planning for a patient with cognitive impairment, requiring an independent historian, in the office or other outpatient, home or domiciliary or rest home, with all of the following required elements: Cognition-focused evaluation including a pertinent history and examination; Medical decision making of moderate or high complexity; Functional assessment (*e.g.*, Basic and Instrumental Activities of Daily Living), including decision-making capacity; Use of standardized instruments for staging of dementia (*e.g.*, Functional Assessment Staging Test [FAST], Clinical Dementia Rating [CDR]); Medication reconciliation and review for high-risk medications; Evaluation for neuropsychiatric and behavioral symptoms, including depression, including use of standardized screening instrument(s); Evaluation of safety (*e.g.*, home), including motor vehicle operation; Identification of caregiver(s), caregiver knowledge, caregiver needs, social supports, and the willingness of caregiver to take on caregiving tasks; Development, updating or revision, or review of an Advance Care Plan; Creation of a written care plan, including initial plans to address any neuropsychiatric symptoms, neuro-cognitive symptoms, functional limitations, and referral to community resources as needed (*e.g.*, rehabilitation services, adult day programs, support groups) shared with the patient and/or caregiver with initial education and support. Typically, 50 minutes are spent face-to-face with the patient and/or family or caregiver.	NEW	3.44	3.44	No.
99XX5	Care management services for behavioral health conditions, at least 20 minutes of clinical staff time, directed by a physician or other qualified health care professional, per calendar month, with the following required elements: Initial assessment or follow-up monitoring, including the use of applicable validated rating scales; Behavioral health care planning in relation to behavioral/psychiatric health problems, including revision for patients who are not progressing or whose status changes; Facilitating and coordinating treatment such as psychotherapy, pharmacotherapy, counseling and/or psychiatric consultation; and Continuity of care with a designated member of the care team.	NEW	0.61	0.61	No.
G0283	Electrical stimulation (unattended), to one or more areas for indication(s) other than wound care, as part of a therapy plan of care.	0.18	0.18	0.18	No.
GDDD1	Insertion, non-biodegradable drug delivery implants, 4 or more	NEW		1.82	No.
GDDD2	Removal, non-biodegradable drug deliver implants, 4 or more	NEW		2.10	No.
GDDD3	Removal with reinsertion, non-biodegradable drug delivery implants, 4 or more	NEW		3.55	No.
GRRR1	Superficial radiation treatment planning and management related services, including but not limited to, when performed, clinical treatment planning (*e.g.*, 77261, 77262, 77263), therapeutic radiology simulation-aided field setting (*e.g.*, 77280, 77285, 77290, 77293), basic radiation dosimetry calculation (*e.g.*, 77300), treatment devices (*e.g.*, 77332, 77333, 77334), isodose planning (*e.g.*, 77306, 77307, 77316, 77317, 77318), radiation treatment management (*e.g.*, 77427, 77431, 77432, 77435, 77469, 77470, 77499), and associated evaluation and management per course of treatment.	NEW		7.93	No.
GXXX1	Therapeutic interventions that focus on cognitive function (*e.g.*, attention, memory, reasoning, executive function, problem solving, and/or pragmatic functioning) and compensatory strategies to manage the performance of an activity (*e.g.*, managing time or schedules, initiating, organizing and sequencing tasks, direct (one-on-one) patient contact.	NEW		0.44	No.
GYYY1	Prolonged preventive service(s), initial 30 minutes	NEW		1.17	No.
GYYY2	Prolonged preventive service(s), first 30 minutes	NEW		1.17	No.

TABLE 11—CY 2018 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS WITH REFINEMENTS

HCPCS code	HCPCS code description	Input code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
157X1	Mdfc flap w/ prsrv vasc pedcl.	ED050	Technologist PACS workstation.	NF		115	117	E15: Refined equipment time to conform to changes in clinical labor time.	$0.04
157X1	Mdfc flap w/ prsrv vasc pedcl.	EF014	light, surgical	NF		115	117	E15: Refined equipment time to conform to changes in clinical labor time.	0.02
157X1	Mdfc flap w/ prsrv vasc pedcl.	EF031	table, power	NF		115	117	E15: Refined equipment time to conform to changes in clinical labor time.	0.03
157X1	Mdfc flap w/ prsrv vasc pedcl.	EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp).	NF		115	117	E15: Refined equipment time to conform to changes in clinical labor time.	0.03
157X1	Mdfc flap w/ prsrv vasc pedcl.	EQ110	electrocautery-hyfrecator, up to 45 watts.	NF		115	117	E15: Refined equipment time to conform to changes in clinical labor time.	0.01
157X1	Mdfc flap w/ prsrv vasc pedcl.	EQ138	instrument pack, medium ($1500 and up).	NF		127	129	E15: Refined equipment time to conform to changes in clinical labor time.	0.01
157X1	Mdfc flap w/ prsrv vasc pedcl.	L038A	COMT/COT/RN/CST.	NF	Obtain vital signs.	3	5	L1: Refined time to standard for this clinical labor task.	0.76
29445	Apply rigid leg cast.	EF031	table, power	NF		69	67	E15: Refined equipment time to conform to changes in clinical labor time.	−0.03
29445	Apply rigid leg cast.	EQ080	cast cart	NF		69	67	E15: Refined equipment time to conform to changes in clinical labor time.	−0.02
29445	Apply rigid leg cast.	EQ168	light, exam	NF		69	67	E15: Refined equipment time to conform to changes in clinical labor time.	−0.01
29445	Apply rigid leg cast.	L037D	RN/LPN/MTA	NF	Check dressings & wound/home care instructions/coordinate office visits/prescriptions.	5	3	L1: Refined time to standard for this clinical labor task.	−0.74

TABLE 11—CY 2018 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
29580	Application of paste boot.	EF023	table, exam	NF		35	34	E15: Refined equipment time to conform to changes in clinical labor time.	0.00
29580	Application of paste boot.	EQ168	light, exam	NF		35	34	E15: Refined equipment time to conform to changes in clinical labor time.	0.00
29580	Application of paste boot.	L037D	RN/LPN/MTA	NF	Provide pre-service education/obtain consent.	3	2	L1: Refined time to standard for this clinical labor task.	−0.37
29581	Apply multlay comprs lwr leg.	EF023	table, exam	NF		37	36	E15: Refined equipment time to conform to changes in clinical labor time.	0.00
29581	Apply multlay comprs lwr leg.	EQ168	light, exam	NF		37	36	E15: Refined equipment time to conform to changes in clinical labor time.	0.00
29581	Apply multlay comprs lwr leg.	L037D	RN/LPN/MTA	NF	Provide pre-service education/obtain consent.	3	2	L1: Refined time to standard for this clinical labor task.	−0.37
30140	Resect inferior turbinate.	EF008	chair with headrest, exam, reclining.	NF		98	100	E15: Refined equipment time to conform to changes in clinical labor time.	0.02
30140	Resect inferior turbinate.	EQ137	instrument pack, basic ($500–$1499).	NF		102	104	E15: Refined equipment time to conform to changes in clinical labor time.	0.00
30140	Resect inferior turbinate.	EQ170	light, fiberoptic headlight w-source.	NF		98	100	E15: Refined equipment time to conform to changes in clinical labor time.	0.02
30140	Resect inferior turbinate.	EQ234	suction and pressure cabinet, ENT (SMR).	NF		98	100	E15: Refined equipment time to conform to changes in clinical labor time.	0.02
30140	Resect inferior turbinate.	EQ383	reusable shaver blade, 2mm.	NF		102	104	E15: Refined equipment time to conform to changes in clinical labor time.	0.01

TABLE 11—CY 2018 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
30140	Resect inferior turbinate.	EQ384	Microdebrider handpiece.	NF	.....	98	100	E15: Refined equipment time to conform to changes in clinical labor time.	0.03
30140	Resect inferior turbinate.	EQ385	Microdebrider console.	NF	.....	98	100	E15: Refined equipment time to conform to changes in clinical labor time.	0.06
30140	Resect inferior turbinate.	L037D	RN/LPN/MTA ...	NF	Obtain vital signs.	3	5	L1: Refined time to standard for this clinical labor task.	0.74
30901	Control of nosebleed.	EF008	chair with headrest, exam, reclining.	NF	.....	22	26	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	0.04
30901	Control of nosebleed.	EQ137	instrument pack, basic ($500–$1499).	NF	.....	29	33	E5: Refined equipment time to conform to established policies for surgical instrument packs.	0.01
30901	Control of nosebleed.	EQ170	light, fiberoptic headlight w-source.	NF	.....	22	26	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	0.03
30901	Control of nosebleed.	EQ234	suction and pressure cabinet, ENT (SMR).	NF	.....	22	26	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	0.04
30903	Control of nosebleed.	EF008	chair with headrest, exam, reclining.	NF	.....	27	31	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	0.04
30903	Control of nosebleed.	EQ110	electrocautery-hyfrecator, up to 45 watts.	NF	.....	27	31	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	0.01
30903	Control of nosebleed.	EQ137	instrument pack, basic ($500–$1499).	NF	.....	34	38	E5: Refined equipment time to conform to established policies for surgical instrument packs.	0.01

TABLE 11—CY 2018 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
30903	Control of nosebleed.	EQ170	light, fiberoptic headlight w-source.	NF	.....	27	31	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	0.03
30903	Control of nosebleed.	EQ234	suction and pressure cabinet, ENT (SMR).	NF	.....	27	31	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	0.04
30905	Control of nosebleed.	EF008	chair with headrest, exam, reclining.	NF	.....	32	62	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	0.32
30905	Control of nosebleed.	EQ110	electrocautery-hyfrecator, up to 45 watts.	NF	.....	32	62	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	0.08
30905	Control of nosebleed.	EQ137	instrument pack, basic ($500–1499).	NF	.....	39	69	E5: Refined equipment time to conform to established policies for surgical instrument packs.	0.07
30905	Control of nosebleed.	EQ170	light, fiberoptic headlight w-source.	NF	.....	32	62	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	0.24
30905	Control of nosebleed.	EQ234	suction and pressure cabinet, ENT (SMR).	NF	.....	32	62	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	0.28
30906	Repeat control of nosebleed.	EF008	chair with headrest, exam, reclining.	NF	.....	42	72	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	0.32
30906	Repeat control of nosebleed.	EQ110	electrocautery-hyfrecator, up to 45 watts.	NF	.....	42	72	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	0.08

TABLE 11—CY 2018 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
30906	Repeat control of nosebleed.	EQ137	instrument pack, basic ($500–$1499).	NF	.....	49	79	E5: Refined equipment time to conform to established policies for surgical instrument packs.	0.07
30906	Repeat control of nosebleed.	EQ170	light, fiberoptic headlight w-source.	NF	.....	42	72	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	0.24
30906	Repeat control of nosebleed.	EQ234	suction and pressure cabinet, ENT (SMR).	NF	.....	42	72	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	0.28
31254	Nsl/sins ndsc w/ prtl ethmdct.	EF008	chair with headrest, exam, reclining.	NF	.....	47	52	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	0.05
31254	Nsl/sins ndsc w/ prtl ethmdct.	EF015	mayo stand	NF	.....	47	52	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	0.01
31254	Nsl/sins ndsc w/ prtl ethmdct.	EQ138	instrument pack, medium ($1500 and up).	NF	.....	59	64	E5: Refined equipment time to conform to established policies for surgical instrument packs.	0.03
31254	Nsl/sins ndsc w/ prtl ethmdct.	EQ167	light source, xenon.	NF	.....	47	52	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	0.14
31254	Nsl/sins ndsc w/ prtl ethmdct.	EQ170	light, fiberoptic headlight w-source.	NF	.....	47	52	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	0.04
31254	Nsl/sins ndsc w/ prtl ethmdct.	EQ234	suction and pressure cabinet, ENT (SMR).	NF	.....	47	52	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	0.05

TABLE 11—CY 2018 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
31254	Nsl/sins ndsc w/ prtl ethmdct.	EQ383	reusable shaver blade, 2mm.	NF	.....	47	52	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	0.02
31254	Nsl/sins ndsc w/ prtl ethmdct.	EQ384	Microdebrider handpiece.	NF	.....	47	52	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	0.06
31254	Nsl/sins ndsc w/ prtl ethmdct.	EQ385	Microdebrider console.	NF	.....	47	52	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	0.15
31254	Nsl/sins ndsc w/ prtl ethmdct.	ES005	endoscope disinfector, rigid or fiberoptic, w-cart.	NF	.....	37	51	E4: Refined equipment time to conform to established policies for scopes.	0.85
31254	Nsl/sins ndsc w/ prtl ethmdct.	ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart).	NF	.....	47	44	E19: Refined equipment time to conform to established policies for scope accessories.	−0.39
31254	Nsl/sins ndsc w/ prtl ethmdct.	ES040	PROXY endoscope, rigid, sinoscopy (0 degrees).	NF	.....	37	51	E4: Refined equipment time to conform to established policies for scopes.	0.11
31254	Nsl/sins ndsc w/ prtl ethmdct.	L037D	RN/LPN/MTA ...	NF	Complete pre-service diagnostic and referral forms.	3	0	L1: Refined time to standard for this clinical labor task.	−1.11
31254	Nsl/sins ndsc w/ prtl ethmdct.	L037D	RN/LPN/MTA ...	NF	Obtain vital signs.	3	5	L1: Refined time to standard for this clinical labor task.	0.74
31254	Nsl/sins ndsc w/ prtl ethmdct.	L037D	RN/LPN/MTA ...	NF	Provide pre-service education/obtain consent.	3	0	L1: Refined time to standard for this clinical labor task.	−1.11
31254	Nsl/sins ndsc w/ prtl ethmdct.	L037D	RN/LPN/MTA ...	NF	Complete pre-procedure phone calls and prescription.	3	0	L1: Refined time to standard for this clinical labor task.	−1.11
31295	Sinus endo w/ balloon dil.	EF008	chair with headrest, exam, reclining.	NF	.....	37	42	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	0.05
31295	Sinus endo w/ balloon dil.	EF015	mayo stand	NF	.....	37	42	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	0.01

TABLE 11—CY 2018 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
31295	Sinus endo w/ balloon dil.	EQ138	instrument pack, medium ($1500 and up).	NF	.....	49	54	E5: Refined equipment time to conform to established policies for surgical instrument packs.	0.03
31295	Sinus endo w/ balloon dil.	EQ167	light source, xenon.	NF	.....	37	42	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	0.14
31295	Sinus endo w/ balloon dil.	EQ170	light, fiberoptic headlight w-source.	NF	.....	37	42	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	0.04
31295	Sinus endo w/ balloon dil.	EQ234	suction and pressure cabinet, ENT (SMR).	NF	.....	37	42	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	0.05
31295	Sinus endo w/ balloon dil.	EQ383	reusable shaver blade, 2mm.	NF	.....	37	42	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	0.02
31295	Sinus endo w/ balloon dil.	EQ384	Microdebrider handpiece.	NF	.....	37	42	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	0.06
31295	Sinus endo w/ balloon dil.	EQ385	Microdebrider console.	NF	.....	37	42	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	0.15
31295	Sinus endo w/ balloon dil.	ES005	endoscope disinfector, rigid or fiberoptic, w-cart.	NF	.....	27	41	E4: Refined equipment time to conform to established policies for scopes.	0.85
31295	Sinus endo w/ balloon dil.	ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart).	NF	.....	37	34	E19: Refined equipment time to conform to established policies for scope accessories.	−0.39
31295	Sinus endo w/ balloon dil.	ES040	PROXY endoscope, rigid, sinoscopy (0 degrees).	NF	.....	27	41	E4: Refined equipment time to conform to established policies for scopes.	0.11

TABLE 11—CY 2018 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
31295	Sinus endo w/ balloon dil.	L037D	RN/LPN/MTA ...	NF	Provide pre-service education/obtain consent.	3	0	L1: Refined time to standard for this clinical labor task.	−1.11
31295	Sinus endo w/ balloon dil.	L037D	RN/LPN/MTA ...	NF	Complete pre-procedure phone calls and prescription.	3	0	L1: Refined time to standard for this clinical labor task.	−1.11
31295	Sinus endo w/ balloon dil.	L037D	RN/LPN/MTA ...	NF	Obtain vital signs.	3	5	L1: Refined time to standard for this clinical labor task.	0.74
31295	Sinus endo w/ balloon dil.	L037D	RN/LPN/MTA ...	NF	Complete pre-service diagnostic and referral forms.	3	0	L1: Refined time to standard for this clinical labor task.	−1.11
31296	Sinus endo w/ balloon dil.	EF008	chair with headrest, exam, reclining.	NF	.....	40	45	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	0.05
31296	Sinus endo w/ balloon dil.	EF015	mayo stand	NF	.....	40	45	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	0.01
31296	Sinus endo w/ balloon dil.	EQ138	instrument pack, medium ($1500 and up).	NF	.....	52	57	E5: Refined equipment time to conform to established policies for surgical instrument packs.	0.03
31296	Sinus endo w/ balloon dil.	EQ167	light source, xenon.	NF	.....	40	45	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	0.14
31296	Sinus endo w/ balloon dil.	EQ170	light, fiberoptic headlight w-source.	NF	.....	40	45	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	0.04
31296	Sinus endo w/ balloon dil.	EQ234	suction and pressure cabinet, ENT (SMR).	NF	.....	40	45	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	0.05
31296	Sinus endo w/ balloon dil.	EQ383	reusable shaver blade, 2mm.	NF	.....	40	45	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	0.02

TABLE 11—CY 2018 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
31296	Sinus endo w/ balloon dil.	EQ384	Microdebrider handpiece.	NF	.....	40	45	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	0.06
31296	Sinus endo w/ balloon dil.	EQ385	Microdebrider console.	NF	.....	40	45	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	0.15
31296	Sinus endo w/ balloon dil.	ES005	endoscope disinfector, rigid or fiberoptic, w-cart.	NF	.....	32	44	E4: Refined equipment time to conform to established policies for scopes.	0.73
31296	Sinus endo w/ balloon dil.	ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart).	NF	.....	40	37	E19: Refined equipment time to conform to established policies for scope accessories.	−0.39
31296	Sinus endo w/ balloon dil.	ES040	PROXY endoscope, rigid, sinoscopy (0 degrees).	NF	.....	32	44	E4: Refined equipment time to conform to established policies for scopes.	0.09
31296	Sinus endo w/ balloon dil.	L037D	RN/LPN/MTA ...	NF	Complete pre-service diagnostic and referral forms.	3	0	L1: Refined time to standard for this clinical labor task.	−1.11
31296	Sinus endo w/ balloon dil.	L037D	RN/LPN/MTA ...	NF	Provide pre-service education/obtain consent.	3	0	L1: Refined time to standard for this clinical labor task.	−1.11
31296	Sinus endo w/ balloon dil.	L037D	RN/LPN/MTA ...	NF	Obtain vital signs.	3	5	L1: Refined time to standard for this clinical labor task.	0.74
31296	Sinus endo w/ balloon dil.	L037D	RN/LPN/MTA ...	NF	Complete pre-procedure phone calls and prescription.	3	0	L1: Refined time to standard for this clinical labor task.	−1.11
31297	Sinus endo w/ balloon dil.	EF008	chair with headrest, exam, reclining.	NF	.....	37	42	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	0.05
31297	Sinus endo w/ balloon dil.	EF015	mayo stand	NF	.....	37	42	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	0.01
31297	Sinus endo w/ balloon dil.	EQ138	instrument pack, medium ($1500 and up).	NF	.....	49	54	E5: Refined equipment time to conform to established policies for surgical instrument packs.	0.03

TABLE 11—CY 2018 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
31297	Sinus endo w/ balloon dil.	EQ167	light source, xenon.	NF	.....	37	42	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	0.14
31297	Sinus endo w/ balloon dil.	EQ170	light, fiberoptic headlight w-source.	NF	.....	37	42	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	0.04
31297	Sinus endo w/ balloon dil.	EQ234	suction and pressure cabinet, ENT (SMR).	NF	.....	37	42	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	0.05
31297	Sinus endo w/ balloon dil.	EQ383	reusable shaver blade, 2mm.	NF	.....	37	42	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	0.02
31297	Sinus endo w/ balloon dil.	EQ384	Microdebrider handpiece.	NF	.....	37	42	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	0.06
31297	Sinus endo w/ balloon dil.	EQ385	Microdebrider console.	NF	.....	37	42	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	0.15
31297	Sinus endo w/ balloon dil.	ES005	endoscope disinfector, rigid or fiberoptic, w-cart.	NF	.....	27	41	E4: Refined equipment time to conform to established policies for scopes.	0.85
31297	Sinus endo w/ balloon dil.	ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart).	NF	.....	37	34	E19: Refined equipment time to conform to established policies for scope accessories.	−0.39
31297	Sinus endo w/ balloon dil.	ES040	PROXY endoscope, rigid, sinoscopy (0 degrees).	NF	.....	27	41	E4: Refined equipment time to conform to established policies for scopes.	0.11
31297	Sinus endo w/ balloon dil.	L037D	RN/LPN/MTA ...	NF	Obtain vital signs.	3	5	L1: Refined time to standard for this clinical labor task.	0.74
31297	Sinus endo w/ balloon dil.	L037D	RN/LPN/MTA ...	NF	Complete pre-procedure phone calls and prescription.	3	0	L1: Refined time to standard for this clinical labor task.	−1.11

TABLE 11—CY 2018 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
31297	Sinus endo w/ balloon dil.	L037D	RN/LPN/MTA ...	NF	Complete pre-service diagnostic and referral forms.	3	0	L1: Refined time to standard for this clinical labor task.	−1.11
31297	Sinus endo w/ balloon dil.	L037D	RN/LPN/MTA ...	NF	Provide pre-service education/obtain consent.	3	0	L1: Refined time to standard for this clinical labor task.	−1.11
31645	Brnchsc w/ther aspir 1st.	EF027	table, instrument, mobile.	NF	.....	57	0	G1: See preamble text.	−0.08
31645	Brnchsc w/ther aspir 1st.	EF031	table, power	NF	.....	57	58	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	0.02
31645	Brnchsc w/ther aspir 1st.	EQ004	CO2 respiratory profile monitor.	NF	.....	57	0	G1: See preamble text.	−1.47
31645	Brnchsc w/ther aspir 1st.	EQ032	IV infusion pump.	NF	.....	57	0	G1: See preamble text.	−0.36
31645	Brnchsc w/ther aspir 1st.	EQ235	suction machine (Gomco).	NF	.....	57	58	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	0.00
31645	Brnchsc w/ther aspir 1st.	ES017	fiberscope, flexible, bronchoscopy.	NF	.....	72	82	E4: Refined equipment time to conform to established policies for scopes.	0.82
31645	Brnchsc w/ther aspir 1st.	ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart).	NF	.....	42	55	E19: Refined equipment time to conform to established policies for scope accessories.	1.68
31645	Brnchsc w/ther aspir 1st.	SD084	gas, oxygen	NF	.....	175	0	G1: See preamble text.	−0.53
31XX5	Nsl/sins ndsc w/ sins dilat.	EF008	chair with headrest, exam, reclining.	NF	.....	59	64	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	0.05
31XX5	Nsl/sins ndsc w/ sins dilat.	EF015	mayo stand	NF	.....	59	64	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	0.01
31XX5	Nsl/sins ndsc w/ sins dilat.	EQ138	instrument pack, medium ($1500 and up).	NF	.....	71	76	E5: Refined equipment time to conform to established policies for surgical instrument packs.	0.03
31XX5	Nsl/sins ndsc w/ sins dilat.	EQ167	light source, xenon.	NF	.....	59	64	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	0.14

TABLE 11—CY 2018 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
31XX5	Nsl/sins ndsc w/ sins dilat.	EQ170	light, fiberoptic headlight w-source.	NF	.....	59	64	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	0.04
31XX5	Nsl/sins ndsc w/ sins dilat.	EQ234	suction and pressure cabinet, ENT (SMR).	NF	.....	59	64	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	0.05
31XX5	Nsl/sins ndsc w/ sins dilat.	EQ383	reusable shaver blade, 2mm.	NF	.....	59	64	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	0.02
31XX5	Nsl/sins ndsc w/ sins dilat.	EQ384	Microdebrider handpiece.	NF	.....	59	64	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	0.06
31XX5	Nsl/sins ndsc w/ sins dilat.	EQ385	Microdebrider console.	NF	.....	59	64	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	0.15
31XX5	Nsl/sins ndsc w/ sins dilat.	ES005	endoscope disinfector, rigid or fiberoptic, w-cart.	NF	.....	57	73	E4: Refined equipment time to conform to established policies for scopes.	0.97
31XX5	Nsl/sins ndsc w/ sins dilat.	ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart).	NF	.....	59	56	E19: Refined equipment time to conform to established policies for scope accessories.	−0.39
31XX5	Nsl/sins ndsc w/ sins dilat.	ES040	PROXY endoscope, rigid, sinoscopy (0 degrees).	NF	.....	57	73	E4: Refined equipment time to conform to established policies for scopes.	0.12
31XX5	Nsl/sins ndsc w/ sins dilat.	L037D	RN/LPN/MTA ...	NF	Complete pre-service diagnostic and referral forms.	3	0	L1: Refined time to standard for this clinical labor task.	−1.11
31XX5	Nsl/sins ndsc w/ sins dilat.	L037D	RN/LPN/MTA ...	NF	Provide pre-service education/obtain consent.	3	0	L1: Refined time to standard for this clinical labor task.	−1.11
31XX5	Nsl/sins ndsc w/ sins dilat.	L037D	RN/LPN/MTA ...	NF	Complete pre-procedure phone calls and prescription.	3	0	L1: Refined time to standard for this clinical labor task.	−1.11
31XX5	Nsl/sins ndsc w/ sins dilat.	L037D	RN/LPN/MTA ...	NF	Obtain vital signs.	3	5	L1: Refined time to standard for this clinical labor task.	0.74

TABLE 11—CY 2018 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
32998	Ablate pulm tumor perq rf.	ED050	Technologist PACS workstation.	NF		133	112	E18: Refined equipment time to conform to established policies for PACS Workstations.	−0.46
32998	Ablate pulm tumor perq rf.	EL007	room, CT	NF		98	96	E2: Refined equipment time to conform to established policies for highly technical equipment.	−9.73
32998	Ablate pulm tumor perq rf.	EQ168	light, exam	NF		98	107	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	0.04
32998	Ablate pulm tumor perq rf.	EQ214	radiofrequency generator (NEURO).	NF		98	96	E2: Refined equipment time to conform to established policies for highly technical equipment.	−0.25
32X99	Ablate pulm tumor perq crybl.	ED050	Technologist PACS workstation.	NF		138	117	E18: Refined equipment time to conform to established policies for PACS Workstations.	−0.46
32X99	Ablate pulm tumor perq crybl.	EL007	room, CT	NF		103	101	E2: Refined equipment time to conform to established policies for highly technical equipment.	−9.73
32X99	Ablate pulm tumor perq crybl.	EQ168	light, exam	NF		103	112	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	0.04
32X99	Ablate pulm tumor perq crybl.	EQ302	cryosurgery system (for tumor ablation).	NF		103	101	E2: Refined equipment time to conform to established policies for highly technical equipment.	−0.19
36215	Place catheter in artery.	ED050	Technologist PACS workstation.	NF		61	59	E15: Refined equipment time to conform to changes in clinical labor time.	−0.04
36215	Place catheter in artery.	EF027	table, instrument, mobile.	NF		180	0	G1: See preamble text.	−0.25

TABLE 11—CY 2018 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
36215	Place catheter in artery.	L037D	RN/LPN/MTA ...	NF	Other Clinical Activity—specify: Post-procedure doppler evaluation (extremity).	3	1	G1: See preamble text.	−0.74
36216	Place catheter in artery.	ED050	Technologist PACS workstation.	NF	.....	76	74	E15: Refined equipment time to conform to changes in clinical labor time.	−0.04
36216	Place catheter in artery.	EF027	table, instrument, mobile.	NF	.....	180	0	G1: See preamble text.	−0.25
36216	Place catheter in artery.	L037D	RN/LPN/MTA ...	NF	Other Clinical Activity—specify: Post-procedure doppler evaluation (extremity).	3	1	G1: See preamble text.	−0.74
36217	Place catheter in artery.	ED050	Technologist PACS workstation.	NF	.....	91	89	E15: Refined equipment time to conform to changes in clinical labor time.	−0.04
36217	Place catheter in artery.	EF027	table, instrument, mobile.	NF	.....	180	0	G1: See preamble text.	−0.25
36217	Place catheter in artery.	L037D	RN/LPN/MTA ...	NF	Other Clinical Activity—specify: Post-procedure doppler evaluation (extremity).	3	1	G1: See preamble text.	−0.74
36217	Place catheter in artery.	L037D	RN/LPN/MTA ...	NF	Circulator (25%)	12	15	G1: See preamble text.	1.11
36470	Njx sclrsnt 1 incmptnt vein.	L037D	RN/LPN/MTA ...	NF	Obtain vital signs.	3	5	L1: Refined time to standard for this clinical labor task.	0.74
36470	Njx sclrsnt 1 incmptnt vein.	L037D	RN/LPN/MTA ...	NF	Check dressings, catheters, wounds.	5	3	L1: Refined time to standard for this clinical labor task.	−0.74
36470	Njx sclrsnt 1 incmptnt vein.	SG055	gauze, sterile 4in x 4in.	NF	.....	6	0	S7: Supply item replaced by another item; see preamble SG056.	−0.95
36470	Njx sclrsnt 1 incmptnt vein.	SG056	gauze, sterile 4in x 4in (10 pack uou).	NF	.....	0	1	S8: Supply item replaces another item; see preamble SG055.	0.80
36471	Njx sclrsnt mlt incmptnt vn.	L037D	RN/LPN/MTA ...	NF	Obtain vital signs.	3	5	L1: Refined time to standard for this clinical labor task.	0.74
36471	Njx sclrsnt mlt incmptnt vn.	L037D	RN/LPN/MTA ...	NF	Check dressings, catheters, wounds.	5	3	L1: Refined time to standard for this clinical labor task.	−0.74
36471	Njx sclrsnt mlt incmptnt vn.	SG055	gauze, sterile 4in x 4in.	NF	.....	6	0	S7: Supply item replaced by another item; see preamble SG056.	−0.95
36471	Njx sclrsnt mlt incmptnt vn.	SG056	gauze, sterile 4in x 4in (10 pack uou).	NF	.....	0	1	S8: Supply item replaces another item; see preamble SG055.	0.80

TABLE 11—CY 2018 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
364X3	Endoven ther chem adhes 1st.	EF014	light, surgical	NF	.....	58	53	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	−0.05
364X3	Endoven ther chem adhes 1st.	EF031	table, power	NF	.....	58	53	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	−0.08
364X3	Endoven ther chem adhes 1st.	EQ250	ultrasound unit, portable.	NF	.....	58	53	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	−0.58
364X3	Endoven ther chem adhes 1st.	L037D	RN/LPN/MTA ...	NF	Check dressings, catheters, wounds.	5	3	L1: Refined time to standard for this clinical labor task.	−0.74
364X3	Endoven ther chem adhes 1st.	L037D	RN/LPN/MTA ...	NF	Obtain vital signs.	3	5	L1: Refined time to standard for this clinical labor task.	0.74
364X3	Endoven ther chem adhes 1st.	L054A	Vascular Technologist.	NF	Prepare room, equipment and supplies.	0	2	G1: See preamble text.	1.08
364X3	Endoven ther chem adhes 1st.	L054A	Vascular Technologist.	NF	Setup scope (nonfacility setting only).	2	0	G1: See preamble text.	−1.08
364X3	Endoven ther chem adhes 1st.	SG055	gauze, sterile 4in x 4in.	NF	.....	6	0	S7: Supply item replaced by another item; see preamble SG056.	−0.95
364X3	Endoven ther chem adhes 1st.	SG056	gauze, sterile 4in x 4in (10 pack uou).	NF	.....	0	1	S8: Supply item replaces another item; see preamble SG055.	0.80
364X5	Njx noncmpnd sclrsnt 1 vein.	EF014	light, surgical	NF	.....	48	43	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	−0.05
364X5	Njx noncmpnd sclrsnt 1 vein.	EF031	table, power	NF	.....	48	43	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	−0.08
364X5	Njx noncmpnd sclrsnt 1 vein.	EQ250	ultrasound unit, portable.	NF	.....	48	43	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	−0.58
364X5	Njx noncmpnd sclrsnt 1 vein.	L037D	RN/LPN/MTA ...	NF	Check dressings, catheters, wounds.	5	3	L1: Refined time to standard for this clinical labor task.	−0.74

TABLE 11—CY 2018 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
364X5	Njx noncmpnd sclrsnt 1 vein.	L037D	RN/LPN/MTA ...	NF	Obtain vital signs.	3	5	L1: Refined time to standard for this clinical labor task.	0.74
364X5	Njx noncmpnd sclrsnt 1 vein.	L054A	Vascular Technologist.	NF	Setup scope (nonfacility setting only).	2	0	G1: See preamble text.	−1.08
364X5	Njx noncmpnd sclrsnt 1 vein.	L054A	Vascular Technologist.	NF	Prepare room, equipment and supplies.	0	2	G1: See preamble text.	1.08
364X5	Njx noncmpnd sclrsnt 1 vein.	SG055	gauze, sterile 4in x 4in.	NF	.....	6	0	S7: Supply item replaced by another item; see preamble SG056.	−0.95
364X5	Njx noncmpnd sclrsnt 1 vein.	SG056	gauze, sterile 4in x 4in (10 pack uou).	NF	.....	0	1	S8: Supply item replaces another item; see preamble SG055.	0.80
364X6	Njx noncmpnd sclrsnt mlt vn.	EF014	light, surgical	NF	.....	58	53	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	−0.05
364X6	Njx noncmpnd sclrsnt mlt vn.	EF031	table, power	NF	.....	58	53	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	−0.08
364X6	Njx noncmpnd sclrsnt mlt vn.	EQ250	ultrasound unit, portable.	NF	.....	58	53	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	−0.58
364X6	Njx noncmpnd sclrsnt mlt vn.	L037D	RN/LPN/MTA ...	NF	Obtain vital signs.	3	5	L1: Refined time to standard for this clinical labor task.	0.74
364X6	Njx noncmpnd sclrsnt mlt vn.	L037D	RN/LPN/MTA ...	NF	Check dressings, catheters, wounds.	5	3	L1: Refined time to standard for this clinical labor task.	−0.74
364X6	Njx noncmpnd sclrsnt mlt vn.	L054A	Vascular Technologist.	NF	Setup scope (nonfacility setting only).	2	0	G1: See preamble text.	−1.08
364X6	Njx noncmpnd sclrsnt mlt vn.	L054A	Vascular Technologist.	NF	Prepare room, equipment and supplies.	0	2	G1: See preamble text.	1.08
364X6	Njx noncmpnd sclrsnt mlt vn.	SG055	gauze, sterile 4in x 4in.	NF	.....	6	0	S7: Supply item replaced by another item; see preamble SG056.	−0.95
364X6	Njx noncmpnd sclrsnt mlt vn.	SG056	gauze, sterile 4in x 4in (10 pack uou).	NF	.....	0	1	S8: Supply item replaces another item; see preamble SG055.	0.80
36555	Insert non-tunnel cv cath.	EF023	table, exam	NF	.....	68	38	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	−0.09

TABLE 11—CY 2018 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
36555	Insert non-tunnel cv cath.	EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp).	NF		68	0	G1: See preamble text.	−0.95
36555	Insert non-tunnel cv cath.	EQ168	light, exam	NF		68	38	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	−0.13
36555	Insert non-tunnel cv cath.	L037D	RN/LPN/MTA	NF	Monitor pt. following procedure/check tubes, monitors, drains, multitasking 1:4.	7.5	0	L11: Removed clinical labor associated with moderate sedation; moderate sedation not typical for this procedure.	−2.78
36569	Insert picc cath	EF023	table, exam	NF		30	0	G1: See preamble text.	−0.09
36569	Insert picc cath	EQ168	light, exam	NF		30	32	E15: Refined equipment time to conform to changes in clinical labor time.	0.01
36569	Insert picc cath	L037D	RN/LPN/MTA	NF	Obtain vital signs.	3	5	L1: Refined time to standard for this clinical labor task.	0.74
38220	Dx bone marrow aspirations.	EF023	table, exam	NF		84	82	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	−0.01
38220	Dx bone marrow aspirations.	L033A	Lab Technician	NF	Other Clinical Activity—specify:Lab Tech activities.	12	9	G1: See preamble text.	−0.99
38221	Dx bone marrow biopsies.	EF023	table, exam	NF		83	82	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	0.00
38221	Dx bone marrow biopsies.	L033A	Lab Technician	NF	Other Clinical Activity—specify:Lab Tech activities.	7.5	7	G1: See preamble text.	−0.17
382X3	Dx bone marrow bx & aspir.	EF023	table, exam	NF		95	92	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	−0.01
382X3	Dx bone marrow bx & aspir.	L033A	Lab Technician	NF	Other Clinical Activity—specify:Lab Tech activities.	12.5	10	G1: See preamble text.	−0.83
55X87	Tprnl plmt biodegrdabl matrl.	EF031	table, power	NF		63	65	E15: Refined equipment time to conform to changes in clinical labor time.	0.03

TABLE 11—CY 2018 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
55X87	Tprnl plmt biodegrdabl matrl.	EQ250	ultrasound unit, portable.	NF		48	50	E15: Refined equipment time to conform to changes in clinical labor time.	0.23
55X87	Tprnl plmt biodegrdabl matrl.	EQ386	Endocavitary US probe.	NF		48	50	E15: Refined equipment time to conform to changes in clinical labor time.	0.13
55X87	Tprnl plmt biodegrdabl matrl.	ER061	stepper, stabilizer, template (for brachytherapy treatment).	NF		48	50	E15: Refined equipment time to conform to changes in clinical labor time.	0.12
55X87	Tprnl plmt biodegrdabl matrl.	ER062	stirrups (for brachytherapy table).	NF		48	50	E15: Refined equipment time to conform to changes in clinical labor time.	0.02
55X87	Tprnl plmt biodegrdabl matrl.	L037D	RN/LPN/MTA	NF	Obtain vital signs.	3	5	L1: Refined time to standard for this clinical labor task.	0.74
5857X	Laps tot hyst resj mal.	EQ168	light, exam	F		142	125	E7: Refined equipment time to conform to office visit duration.	−0.07
5857X	Laps tot hyst resj mal.	SA051	pack, pelvic exam.	F		4	3	G1: See preamble text.	−1.17
67820	Revise eyelashes.	EL006	lane, screening (oph).	NF		11	5	G1: See preamble text.	−0.54
67820	Revise eyelashes.	L038A	COMT/COT/RN/CST.	F	Coordinate presurgery services.	3	0	L1: Refined time to standard for this clinical labor task.	−1.14
67820	Revise eyelashes.	L038A	COMT/COT/RN/CST.	F	Provide preservice education/obtain consent.	3	0	L1: Refined time to standard for this clinical labor task.	−1.14
67820	Revise eyelashes.	L038A	COMT/COT/RN/CST.	F	Schedule space and equipment in facility.	3	0	L1: Refined time to standard for this clinical labor task.	−1.14
67820	Revise eyelashes.	L038A	COMT/COT/RN/CST.	F	Complete preservice diagnostic and referral forms.	3	0	L1: Refined time to standard for this clinical labor task.	−1.14
67820	Revise eyelashes.	L038A	COMT/COT/RN/CST.	F	Follow-up phone calls and prescriptions.	3	0	L1: Refined time to standard for this clinical labor task.	−1.14
70544	Mr angiography head w/o dye.	ED050	Technologist PACS workstation.	NF		72	69	E15: Refined equipment time to conform to changes in clinical labor time.	−0.07
70544	Mr angiography head w/o dye.	ED053	Professional PACS Workstation.	NF		17	15	E18: Refined equipment time to conform to established policies for PACS Workstations.	−0.12

TABLE 11—CY 2018 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
70544	Mr angiography head w/o dye.	EL008	room, MR	NF		39	38	E15: Refined equipment time to conform to changes in clinical labor time.	−3.38
70544	Mr angiography head w/o dye.	L047A	MRI Technologist.	NF	Technologist QCs images in PACS, checking all images, reformats, and dose page.	4	3	L1: Refined time to standard for this clinical labor task.	−0.47
70544	Mr angiography head w/o dye.	L047A	MRI Technologist.	NF	Provide pre-service education/obtain consent.	7	5	G1: See preamble text.	−0.94
70545	Mr angiography head w/dye.	ED050	Technologist PACS workstation.	NF		75	74	E15: Refined equipment time to conform to changes in clinical labor time.	−0.02
70545	Mr angiography head w/dye.	ED053	Professional PACS Workstation.	NF		17	15	E18: Refined equipment time to conform to established policies for PACS Workstations.	−0.12
70545	Mr angiography head w/dye.	EL008	room, MR	NF		37	36	E15: Refined equipment time to conform to changes in clinical labor time.	−3.38
70545	Mr angiography head w/dye.	L047A	MRI Technologist.	NF	Technologist QCs images in PACS, checking all images, reformats, and dose page.	4	3	L1: Refined time to standard for this clinical labor task.	−0.47
70545	Mr angiography head w/dye.	L047A	MRI Technologist.	NF	Obtain vital signs.	3	5	L1: Refined time to standard for this clinical labor task.	0.94
70545	Mr angiography head w/dye.	L047A	MRI Technologist.	NF	Provide pre-service education/obtain consent.	9	7	G1: See preamble text.	−0.94
70546	Mr angiograph head w/o&w/dye.	ED050	Technologist PACS workstation.	NF		116	115	E15: Refined equipment time to conform to changes in clinical labor time.	−0.02
70546	Mr angiograph head w/o&w/dye.	ED053	Professional PACS Workstation.	NF		20	18	E18: Refined equipment time to conform to established policies for PACS Workstations.	−0.12
70546	Mr angiograph head w/o&w/dye.	EL008	room, MR	NF		58	57	E15: Refined equipment time to conform to changes in clinical labor time.	−3.38

TABLE 11—CY 2018 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
70546	Mr angiograph head w/o&w/ dye.	L047A	MRI Technologist.	NF	Obtain vital signs.	3	5	L1: Refined time to standard for this clinical labor task.	0.94
70546	Mr angiograph head w/o&w/ dye.	L047A	MRI Technologist.	NF	Technologist QCs images in PACS, checking all images, reformats, and dose page.	4	3	L1: Refined time to standard for this clinical labor task.	−0.47
70546	Mr angiograph head w/o&w/ dye.	L047A	MRI Technologist.	NF	Provide pre-service education/obtain consent.	9	7	G1: See preamble text.	−0.94
70547	Mr angiography neck w/o dye.	ED050	Technologist PACS workstation.	NF	.....	72	69	E15: Refined equipment time to conform to changes in clinical labor time.	−0.07
70547	Mr angiography neck w/o dye.	ED053	Professional PACS Workstation.	NF	.....	17	15	E18: Refined equipment time to conform to established policies for PACS Workstations.	−0.12
70547	Mr angiography neck w/o dye.	EL008	room, MR	NF	.....	39	38	E15: Refined equipment time to conform to changes in clinical labor time.	−3.38
70547	Mr angiography neck w/o dye.	L047A	MRI Technologist.	NF	Technologist QCs images in PACS, checking all images, reformats, and dose page.	4	3	L1: Refined time to standard for this clinical labor task.	−0.47
70547	Mr angiography neck w/o dye.	L047A	MRI Technologist.	NF	Provide pre-service education/obtain consent.	7	5	G1: See preamble text.	−0.94
70548	Mr angiography neck w/dye.	ED050	Technologist PACS workstation.	NF	.....	75	74	E15: Refined equipment time to conform to changes in clinical labor time.	−0.02
70548	Mr angiography neck w/dye.	ED053	Professional PACS Workstation.	NF	.....	20	18	E18: Refined equipment time to conform to established policies for PACS Workstations.	−0.12
70548	Mr angiography neck w/dye.	EL008	room, MR	NF	.....	37	36	E15: Refined equipment time to conform to changes in clinical labor time.	−3.38
70548	Mr angiography neck w/dye.	L047A	MRI Technologist.	NF	Technologist QCs images in PACS, checking all images, reformats, and dose page.	4	3	L1: Refined time to standard for this clinical labor task.	−0.47

TABLE 11—CY 2018 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
70548	Mr angiography neck w/dye.	L047A	MRI Technologist.	NF	Provide pre-service education/obtain consent.	9	7	G1: See preamble text.	−0.94
70548	Mr angiography neck w/dye.	L047A	MRI Technologist.	NF	Obtain vital signs.	3	5	L1: Refined time to standard for this clinical labor task.	0.94
70549	Mr angiograph neck w/o&w/dye.	ED050	Technologist PACS workstation.	NF	.....	116	115	E15: Refined equipment time to conform to changes in clinical labor time.	−0.02
70549	Mr angiograph neck w/o&w/dye.	ED053	Professional PACS Workstation.	NF	.....	25	23	E18: Refined equipment time to conform to established policies for PACS Workstations.	−0.12
70549	Mr angiograph neck w/o&w/dye.	EL008	room, MR	NF	.....	58	57	E15: Refined equipment time to conform to changes in clinical labor time.	−3.38
70549	Mr angiograph neck w/o&w/dye.	L047A	MRI Technologist.	NF	Obtain vital signs.	3	5	L1: Refined time to standard for this clinical labor task.	0.94
70549	Mr angiograph neck w/o&w/dye.	L047A	MRI Technologist.	NF	Provide pre-service education/obtain consent.	9	7	G1: See preamble text.	−0.94
70549	Mr angiograph neck w/o&w/dye.	L047A	MRI Technologist.	NF	Technologist QCs images in PACS, checking all images, reformats, and dose page.	4	3	L1: Refined time to standard for this clinical labor task.	−0.47
71250	Ct thorax w/o dye.	ED053	Professional PACS Workstation.	NF	.....	20	18	E18: Refined equipment time to conform to established policies for PACS Workstations.	−0.12
71260	Ct thorax w/dye	ED053	Professional PACS Workstation.	NF	.....	21	19	E18: Refined equipment time to conform to established policies for PACS Workstations.	−0.12
71270	Ct thorax w/o & w/dye.	ED053	Professional PACS Workstation.	NF	.....	25	23	E18: Refined equipment time to conform to established policies for PACS Workstations.	−0.12
72195	Mri pelvis w/o dye.	ED053	Professional PACS Workstation.	NF	.....	25	23	E18: Refined equipment time to conform to established policies for PACS Workstations.	−0.12

TABLE 11—CY 2018 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
72196	Mri pelvis w/dye	ED050	Technologist PACS workstation.	NF		64	66	E15: Refined equipment time to conform to changes in clinical labor time.	0.04
72196	Mri pelvis w/dye	ED053	Professional PACS Workstation.	NF		30	28	E18: Refined equipment time to conform to established policies for PACS Workstations.	−0.12
72196	Mri pelvis w/dye	L047A	MRI Technologist.	NF	Obtain vital signs.	3	5	L1: Refined time to standard for this clinical labor task.	0.94
72197	Mri pelvis w/o & w/dye.	ED050	Technologist PACS workstation.	NF		79	81	E15: Refined equipment time to conform to changes in clinical labor time.	0.04
72197	Mri pelvis w/o & w/dye.	ED053	Professional PACS Workstation.	NF		32	30	E18: Refined equipment time to conform to established policies for PACS Workstations.	−0.12
72197	Mri pelvis w/o & w/dye.	L047A	MRI Technologist.	NF	Obtain vital signs.	3	5	L1: Refined time to standard for this clinical labor task.	0.94
73718	Mri lower extremity w/o dye.	ED050	Technologist PACS workstation.	NF		55	53	E15: Refined equipment time to conform to changes in clinical labor time.	−0.04
73718	Mri lower extremity w/o dye.	ED053	Professional PACS Workstation.	NF		20	18	E18: Refined equipment time to conform to established policies for PACS Workstations.	−0.12
73718	Mri lower extremity w/o dye.	EL008	room, MR	NF		44	42	E15: Refined equipment time to conform to changes in clinical labor time.	−6.76
73718	Mri lower extremity w/o dye.	L047A	MRI Technologist.	NF	Prepare room, equipment, supplies.	5	3	G1: See preamble text.	−0.94
73719	Mri lower extremity w/dye.	ED050	Technologist PACS workstation.	NF		62	64	E15: Refined equipment time to conform to changes in clinical labor time.	0.04
73719	Mri lower extremity w/dye.	ED053	Professional PACS Workstation.	NF		25	23	E18: Refined equipment time to conform to established policies for PACS Workstations.	−0.12

TABLE 11—CY 2018 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
73719	Mri lower extremity w/dye.	EL008	room, MR	NF		48	46	E15: Refined equipment time to conform to changes in clinical labor time.	−6.76
73719	Mri lower extremity w/dye.	L047A	MRI Technologist.	NF	Provide pre-service education/obtain consent.	5	7	G1: See preamble text.	0.94
73719	Mri lower extremity w/dye.	L047A	MRI Technologist.	NF	Prepare room, equipment, supplies.	7	5	G1: See preamble text.	−0.94
73719	Mri lower extremity w/dye.	L047A	MRI Technologist.	NF	Obtain vital signs.	3	5	L1: Refined time to standard for this clinical labor task.	0.94
73720	Mri lwr extremity w/o&w/dye.	ED050	Technologist PACS workstation.	NF		77	79	E15: Refined equipment time to conform to changes in clinical labor time.	0.04
73720	Mri lwr extremity w/o&w/dye.	ED053	Professional PACS Workstation.	NF		29	27	E18: Refined equipment time to conform to established policies for PACS Workstations.	−0.12
73720	Mri lwr extremity w/o&w/dye.	EL008	room, MR	NF		63	61	E15: Refined equipment time to conform to changes in clinical labor time.	−6.76
73720	Mri lwr extremity w/o&w/dye.	L047A	MRI Technologist.	NF	Prepare room, equipment, supplies.	7	5	G1: See preamble text.	−0.94
73720	Mri lwr extremity w/o&w/dye.	L047A	MRI Technologist.	NF	Provide pre-service education/obtain consent.	5	7	G1: See preamble text.	0.94
73720	Mri lwr extremity w/o&w/dye.	L047A	MRI Technologist.	NF	Obtain vital signs.	3	5	L1: Refined time to standard for this clinical labor task.	0.94
74181	Mri abdomen w/o dye.	ED053	Professional PACS Workstation.	NF		25	23	E18: Refined equipment time to conform to established policies for PACS Workstations.	−0.12
74182	Mri abdomen w/dye.	ED050	Technologist PACS workstation.	NF		74	76	E15: Refined equipment time to conform to changes in clinical labor time.	0.04
74182	Mri abdomen w/dye.	ED053	Professional PACS Workstation.	NF		30	28	E18: Refined equipment time to conform to established policies for PACS Workstations.	−0.12
74182	Mri abdomen w/dye.	L047A	MRI Technologist.	NF	Obtain vital signs.	3	5	L1: Refined time to standard for this clinical labor task.	0.94

TABLE 11—CY 2018 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
74183	Mri abdomen w/o & w/dye.	ED050	Technologist PACS workstation.	NF		79	81	E15: Refined equipment time to conform to changes in clinical labor time.	0.04
74183	Mri abdomen w/o & w/dye.	ED053	Professional PACS Workstation.	NF		35	33	E18: Refined equipment time to conform to established policies for PACS Workstations.	−0.12
74183	Mri abdomen w/o & w/dye.	L047A	MRI Technologist.	NF	Obtain vital signs.	3	5	L1: Refined time to standard for this clinical labor task.	0.94
75635	Ct angio abdominal arteries.	ED050	Technologist PACS workstation.	NF		119	124	E18: Refined equipment time to conform to established policies for PACS Workstations.	0.11
75635	Ct angio abdominal arteries.	ED053	Professional PACS Workstation.	NF		49	44	E18: Refined equipment time to conform to established policies for PACS Workstations.	−0.29
75635	Ct angio abdominal arteries.	EL007	room, CT	NF		71	70	E15: Refined equipment time to conform to changes in clinical labor time.	−2.70
75635	Ct angio abdominal arteries.	L046A	CT Technologist	NF	Technologist QCs images in PACS, checking all images, reformats, and dose page.	4	3	L1: Refined time to standard for this clinical labor task.	−0.46
75710	Artery x-rays arm/leg.	ED050	Technologist PACS workstation.	NF		52	49	E15: Refined equipment time to conform to changes in clinical labor time.	−0.07
75710	Artery x-rays arm/leg.	ED053	Professional PACS Workstation.	NF		55	48	E18: Refined equipment time to conform to established policies for PACS Workstations.	−0.41
75710	Artery x-rays arm/leg.	L041B	Radiologic Technologist.	NF	Technologist QCs images in PACS, checking all images, reformats, and dose page.	4	3	L1: Refined time to standard for this clinical labor task.	−0.41
75710	Artery x-rays arm/leg.	L041B	Radiologic Technologist.	NF	Prepare room, equipment, supplies.	2	0	G1: See preamble text.	−0.82
75716	Artery x-rays arms/legs.	ED050	Technologist PACS workstation.	NF		62	59	E15: Refined equipment time to conform to changes in clinical labor time.	−0.07

TABLE 11—CY 2018 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
75716	Artery x-rays arms/legs.	ED053	Professional PACS Workstation.	NF	.....	65	58	E18: Refined equipment time to conform to established policies for PACS Workstations.	−0.41
75716	Artery x-rays arms/legs.	L041B	Radiologic Technologist.	NF	Prepare room, equipment, supplies.	2	0	G1: See preamble text.	−0.82
75716	Artery x-rays arms/legs.	L041B	Radiologic Technologist.	NF	Technologist QCs images in PACS, checking all images, reformats, and dose page.	4	3	L1: Refined time to standard for this clinical labor task.	−0.41
76881	Us xtr non-vasc complete.	EF031	table, power	NF	.....	8	7	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	−0.02
76881	Us xtr non-vasc complete.	EQ250	ultrasound unit, portable.	NF	.....	8	7	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	−0.12
76881	Us xtr non-vasc complete.	L026A	Medical/Technical Assistant.	NF	Exam document scanned into PACS. Exam completed in RIS system to generate billing process and to populate images into Radiologist work queue.	1	0	G1: See preamble text.	−0.26
78300	Bone imaging limited area.	ED053	Professional PACS Workstation.	NF	.....	15	13	E18: Refined equipment time to conform to established policies for PACS Workstations.	−0.12
78305	Bone imaging multiple areas.	ED053	Professional PACS Workstation.	NF	.....	15	13	E18: Refined equipment time to conform to established policies for PACS Workstations.	−0.12
78306	Bone imaging whole body.	ED053	Professional PACS Workstation.	NF	.....	78	13	E18: Refined equipment time to conform to established policies for PACS Workstations.	−3.76
88333	Intraop cyto path consult 1.	L033A	Lab Technician	NF	Prepare room. Filter and replenish stains and supplies. (including OCT blocks, set up grossing station with colored stains).	10	0	G6: Indirect Practice Expense input and/or not individually allocable to a particular patient for a particular service.	−3.30

TABLE 11—CY 2018 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
88333	Intraop cyto path consult 1.	L037B	Histotechnologist.	NF	Clean room/ equipment following procedure (including any equipment maintenance that must be done after the procedure).	5	1	L1: Refined time to standard for this clinical labor task.	−1.48
88360	Tumor immunohistochem/manual.	EP112	Benchmark ULTRA automated slide preparation system.	NF	.....	18	16	G1: See preamble text.	−1.14
88360	Tumor immunohistochem/manual.	L033A	Lab Technician	NF	Recycle xylene from tissue processor and stainer.	1	0	G6: Indirect Practice Expense input and/or not individually allocable to a particular patient for a particular service.	−0.33
88360	Tumor immunohistochem/manual.	L037B	Histotechnologist.	NF	Clean room/ equipment following procedure (including any equipment maintenance that must be done after the procedure).	1	0	L2: Clinical labor task redundant with clinical labor task Clean equipment and work station in histology lab.	−0.37
88360	Tumor immunohistochem/manual.	L037B	Histotechnologist.	NF	Verify results and complete work load recording logs.	1	0	G6: Indirect Practice Expense input and/or not individually allocable to a particular patient for a particular service.	−0.37
88360	Tumor immunohistochem/manual.	L037B	Histotechnologist.	NF	Enter patient data, computational prep for antibody testing, generate and apply bar codes to slides, and enter data for automated slide stainer.	5	1	L1: Refined time to standard for this clinical labor task.	−1.48
88361	Tumor immunohistochem/comput.	EP112	Benchmark ULTRA automated slide preparation system.	NF	.....	18	16	G1: See preamble text.	−1.14
88361	Tumor immunohistochem/comput.	L033A	Lab Technician	NF	Recycle xylene from tissue processor and stainer.	1	0	G6: Indirect Practice Expense input and/or not individually allocable to a particular patient for a particular service.	−0.33

TABLE 11—CY 2018 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
88361	Tumor immunohistochem/comput.	L037B	Histotechnologist.	NF	Verify results and complete work load recording logs.	1	0	G6: Indirect Practice Expense input and/or not individually allocable to a particular patient for a particular service.	−0.37
88361	Tumor immunohistochem/comput.	L037B	Histotechnologist.	NF	Performing instrument calibration, instrument qc and start up and shutdown..	1	0	G1: See preamble text.	−0.37
88361	Tumor immunohistochem/comput.	L037B	Histotechnologist.	NF	Gate areas to be counted by the machine.	1	0	G1: See preamble text.	−0.37
88361	Tumor immunohistochem/comput.	L037B	Histotechnologist.	NF	Enter patient data, computational prep for antibody testing, generate and apply bar codes to slides, and enter data for automated slide stainer.	5	1	L1: Refined time to standard for this clinical labor task.	−1.48
88361	Tumor immunohistochem/comput.	L037B	Histotechnologist.	NF	Clean room/equipment following procedure (including any equipment maintenance that must be done after the procedure).	1	0	L2: Clinical labor task redundant with clinical labor task Clean equipment and work station in histology lab.	−0.37
93279	Pm device progr eval sngl.	EF023	table, exam	NF	.....	33	26	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	−0.02
93279	Pm device progr eval sngl.	EQ198	pacemaker follow-up system (incl software and hardware) (Paceart).	NF	.....	33	26	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	−0.53
93279	Pm device progr eval sngl.	L026A	Medical/Technical Assistant.	NF	Complete diagnostic forms, lab, X-ray requisitions.	2	0	L2: Clinical labor task redundant with clinical labor task L037D.	−0.52
93279	Pm device progr eval sngl.	L037D	RN/LPN/MTA ...	NF	Other Clinical Activity—specify: Review charts.	2	0	L1: Refined time to standard for this clinical labor task.	−0.74
93280	Pm device progr eval dual.	EF023	table, exam	NF	.....	38	31	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	−0.02

TABLE 11—CY 2018 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
93280	Pm device progr eval dual.	EQ198	pacemaker follow-up system (incl software and hardware) (Paceart).	NF	.....	38	31	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	−0.53
93280	Pm device progr eval dual.	L026A	Medical/Technical Assistant.	NF	Complete diagnostic forms, lab, X-ray requisitions.	2	0	L2: Clinical labor task redundant with clinical labor task L037D.	−0.52
93280	Pm device progr eval dual.	L037D	RN/LPN/MTA ...	NF	Other Clinical Activity—specify: Review charts.	2	0	L1: Refined time to standard for this clinical labor task.	−0.74
93281	Pm device progr eval multi.	EF023	table, exam	NF	.....	39	31	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	−0.02
93281	Pm device progr eval multi.	EQ198	pacemaker follow-up system (incl software and hardware) (Paceart).	NF	.....	39	31	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	−0.61
93281	Pm device progr eval multi.	L026A	Medical/Technical Assistant.	NF	Complete diagnostic forms, lab, X-ray requisitions.	2	0	L2: Clinical labor task redundant with clinical labor task L037D.	−0.52
93281	Pm device progr eval multi.	L037D	RN/LPN/MTA ...	NF	Other Clinical Activity—specify: Review charts.	2	0	L1: Refined time to standard for this clinical labor task.	−0.74
93281	Pm device progr eval multi.	L037D	RN/LPN/MTA ...	NF	Assist physician in performing procedure.	16	15	L15: Refined clinical labor time to match intraservice work time.	−0.37
93282	Prgrmg eval implantable dfb.	EF023	table, exam	NF	.....	35	28	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	−0.02
93282	Prgrmg eval implantable dfb.	EQ198	pacemaker follow-up system (incl software and hardware) (Paceart).	NF	.....	35	28	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	−0.53
93282	Prgrmg eval implantable dfb.	L026A	Medical/Technical Assistant.	NF	Complete diagnostic forms, lab, X-ray requisitions.	2	0	L2: Clinical labor task redundant with clinical labor task L037D.	−0.52
93282	Prgrmg eval implantable dfb.	L037D	RN/LPN/MTA ...	NF	Other Clinical Activity—specify: Review charts.	2	0	L1: Refined time to standard for this clinical labor task.	−0.74

TABLE 11—CY 2018 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
93283	Prgrmg eval implantable dfb.	EF023	table, exam	NF	.....	38	31	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	−0.02
93283	Prgrmg eval implantable dfb.	EQ198	pacemaker follow-up system (incl software and hardware) (Paceart).	NF	.....	38	31	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	−0.53
93283	Prgrmg eval implantable dfb.	L026A	Medical/Technical Assistant.	NF	Complete diagnostic forms, lab, X-ray requisitions.	2	0	L2: Clinical labor task redundant with clinical labor task L037D.	−0.52
93283	Prgrmg eval implantable dfb.	L037D	RN/LPN/MTA ...	NF	Other Clinical Activity—specify: Review charts.	2	0	L1: Refined time to standard for this clinical labor task.	−0.74
93284	Prgrmg eval implantable dfb.	EF023	table, exam	NF	.....	40.5	33.5	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	−0.02
93284	Prgrmg eval implantable dfb.	EQ198	pacemaker follow-up system (incl software and hardware) (Paceart).	NF	.....	40.5	33.5	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	−0.53
93284	Prgrmg eval implantable dfb.	L026A	Medical/Technical Assistant.	NF	Complete diagnostic forms, lab, X-ray requisitions.	2	0	L2: Clinical labor task redundant with clinical labor task L037D.	−0.52
93284	Prgrmg eval implantable dfb.	L037D	RN/LPN/MTA ...	NF	Other Clinical Activity—specify: Review charts.	2	0	L1: Refined time to standard for this clinical labor task.	−0.74
93285	Ilr device eval progr.	EF023	table, exam	NF	.....	30	25	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	−0.01
93285	Ilr device eval progr.	EQ198	pacemaker follow-up system (incl software and hardware) (Paceart).	NF	.....	30	25	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	−0.38
93285	Ilr device eval progr.	L026A	Medical/Technical Assistant.	NF	Complete diagnostic forms, lab, X-ray requisitions.	1	0	L2: Clinical labor task redundant with clinical labor task L037D.	−0.26
93285	Ilr device eval progr.	L037D	RN/LPN/MTA ...	NF	Other Clinical Activity—specify: Review charts.	2	0	L1: Refined time to standard for this clinical labor task.	−0.74

TABLE 11—CY 2018 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
93286	Peri-px pacemaker device evl.	EF023	table, exam	NF	.....	27	20	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	−0.02
93286	Peri-px pacemaker device evl.	EQ198	pacemaker follow-up system (incl software and hardware) (Paceart).	NF	.....	27	20	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	−0.53
93286	Peri-px pacemaker device evl.	L026A	Medical/Technical Assistant.	NF	Complete diagnostic forms, lab, X-ray requisitions.	2	0	L2: Clinical labor task redundant with clinical labor task L037D.	−0.52
93286	Peri-px pacemaker device evl.	L037D	RN/LPN/MTA ...	NF	Other Clinical Activity—specify: Review charts.	2	0	L1: Refined time to standard for this clinical labor task.	−0.74
93287	Peri-px device eval & prgr.	EF023	table, exam	NF	.....	27	20	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	−0.02
93287	Peri-px device eval & prgr.	EQ198	pacemaker follow-up system (incl software and hardware) (Paceart).	NF	.....	27	20	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	−0.53
93287	Peri-px device eval & prgr.	L026A	Medical/Technical Assistant.	NF	Complete diagnostic forms, lab, X-ray requisitions.	2	0	L2: Clinical labor task redundant with clinical labor task L037D.	−0.52
93287	Peri-px device eval & prgr.	L037D	RN/LPN/MTA ...	NF	Other Clinical Activity—specify: Review charts.	2	0	L1: Refined time to standard for this clinical labor task.	−0.74
93288	Pm device eval in person.	EF023	table, exam	NF	.....	33	26	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	−0.02
93288	Pm device eval in person.	EQ198	pacemaker follow-up system (incl software and hardware) (Paceart).	NF	.....	33	26	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	−0.53
93288	Pm device eval in person.	L026A	Medical/Technical Assistant.	NF	Complete diagnostic forms, lab, X-ray requisitions.	2	0	L2: Clinical labor task redundant with clinical labor task L037D.	−0.52
93288	Pm device eval in person.	L037D	RN/LPN/MTA ...	NF	Other Clinical Activity—specify: Review charts.	2	0	L1: Refined time to standard for this clinical labor task.	−0.74

TABLE 11—CY 2018 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
93289	Interrog device eval heart.	EF023	table, exam	NF	.....	33	26	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	−0.02
93289	Interrog device eval heart.	EQ198	pacemaker follow-up system (incl software and hardware) (Paceart).	NF	.....	33	26	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	−0.53
93289	Interrog device eval heart.	L026A	Medical/Technical Assistant.	NF	Complete diagnostic forms, lab, X-ray requisitions.	2	0	L2: Clinical labor task redundant with clinical labor task L037D.	−0.52
93289	Interrog device eval heart.	L037D	RN/LPN/MTA ...	NF	Other Clinical Activity—specify: Review charts.	2	0	L1: Refined time to standard for this clinical labor task.	−0.74
93290	Icm device eval	EF023	table, exam	NF	.....	28	24	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	−0.01
93290	Icm device eval	EQ198	pacemaker follow-up system (incl software and hardware) (Paceart).	NF	.....	28	24	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	−0.30
93290	Icm device eval	L026A	Medical/Technical Assistant.	NF	Complete diagnostic forms, lab, X-ray requisitions.	1	0	L2: Clinical labor task redundant with clinical labor task L037D.	−0.26
93290	Icm device eval	L037D	RN/LPN/MTA ...	NF	Other Clinical Activity—specify: Review charts.	2	0	L1: Refined time to standard for this clinical labor task.	−0.74
93291	Ilr device interrogate.	EF023	table, exam	NF	.....	27	22	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	−0.01
93291	Ilr device interrogate.	EQ198	pacemaker follow-up system (incl software and hardware) (Paceart).	NF	.....	27	22	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	−0.38
93291	Ilr device interrogate.	L026A	Medical/Technical Assistant.	NF	Complete diagnostic forms, lab, X-ray requisitions.	1	0	L2: Clinical labor task redundant with clinical labor task L037D.	−0.26
93291	Ilr device interrogate.	L037D	RN/LPN/MTA ...	NF	Other Clinical Activity—specify: Review charts.	2	0	L1: Refined time to standard for this clinical labor task.	−0.74

TABLE 11—CY 2018 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
93292	Wcd device interrogate.	EF023	table, exam	NF		30	25	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	−0.01
93292	Wcd device interrogate.	EQ198	pacemaker follow-up system (incl software and hardware) (Paceart).	NF		30	25	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	−0.38
93292	Wcd device interrogate.	L026A	Medical/Technical Assistant.	NF	Complete diagnostic forms, lab, X-ray requisitions.	1	0	L2: Clinical labor task redundant with clinical labor task L037D.	−0.26
93292	Wcd device interrogate.	L037D	RN/LPN/MTA	NF	Other Clinical Activity—specify: Review charts.	2	0	L1: Refined time to standard for this clinical labor task.	−0.74
93350	Stress tte only	ED053	Professional PACS Workstation.	NF		20	18	E18: Refined equipment time to conform to established policies for PACS Workstations.	−0.12
93351	Stress tte complete.	ED050	Technologist PACS workstation.	NF		104	114	E18: Refined equipment time to conform to established policies for PACS Workstations.	0.22
93351	Stress tte complete.	ED053	Professional PACS Workstation.	NF		30	25	E18: Refined equipment time to conform to established policies for PACS Workstations.	−0.29
93351	Stress tte complete.	EQ078	cardiac monitor w-treadmill (12-lead PC-based ECG).	NF		104	91	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	−0.49
93351	Stress tte complete.	L037D	RN/LPN/MTA	NF	Obtain vital signs.	3	5	L1: Refined time to standard for this clinical labor task.	0.74
93351	Stress tte complete.	L037D	RN/LPN/MTA	NF	Provide pre-service education/obtain consent.	3	2	L1: Refined time to standard for this clinical labor task.	−0.37
93351	Stress tte complete.	L051A	RN	NF	Setup scope (non facility setting only).	5	0	G1: See preamble text.	−2.55
94621	Cardiopulm exercise testing.	EQ042	Vmax 29c (cardio-pulm stress test equip, treadmill, computer system).	NF		127	115	E6: Refined equipment time to conform to established policies for equipment with 4x monitoring time.	−1.98

TABLE 11—CY 2018 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
94621	Cardiopulm exercise testing.	EQ211	pulse oximeter w-printer.	NF		127	115	E6: Refined equipment time to conform to established policies for equipment with 4x monitoring time.	−0.05
94621	Cardiopulm exercise testing.	L047C	RN/Respiratory Therapist.	NF	Prepare and position pt/monitor pt/set up IV.	5	3	G1: See preamble text.	−0.94
94621	Cardiopulm exercise testing.	L047C	RN/Respiratory Therapist.	NF	Provide pre-service education/obtain consent.	10	5	G1: See preamble text.	−2.35
94621	Cardiopulm exercise testing.	L047C	RN/Respiratory Therapist.	NF	Complete diagnostic forms, lab, X-ray requisitions.	5	3	L1: Refined time to standard for this clinical labor task.	−0.94
946X2	Exercise tst brncspsm.	EQ043	Vmax 29s (spirometry testing equip, computer system).	NF		87	83	E6: Refined equipment time to conform to established policies for equipment with 4x monitoring time.	−0.31
946X2	Exercise tst brncspsm.	EQ078	cardiac monitor w-treadmill (12-lead PC-based ECG).	NF		87	83	E6: Refined equipment time to conform to established policies for equipment with 4x monitoring time.	−0.15
946X2	Exercise tst brncspsm.	EQ211	pulse oximeter w-printer.	NF		87	83	E6: Refined equipment time to conform to established policies for equipment with 4x monitoring time.	−0.02
946X2	Exercise tst brncspsm.	L047C	RN/Respiratory Therapist.	NF	Complete diagnostic forms, lab, X-ray requisitions.	4	3	L1: Refined time to standard for this clinical labor task.	−0.47
946X3	Pulmonary stress testing.	EQ211	pulse oximeter w-printer.	NF		17	15	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	−0.01
946X3	Pulmonary stress testing.	L047C	RN/Respiratory Therapist.	NF	Complete diagnostic forms, lab, X-ray requisitions.	2	3	L1: Refined time to standard for this clinical labor task.	0.47
95004	Percut allergy skin tests.	EF015	mayo stand	NF		1.28	1.58	E6: Refined equipment time to conform to established policies for equipment with 4x monitoring time.	0.00
95004	Percut allergy skin tests.	EF023	table, exam	NF		1.28	1.58	E6: Refined equipment time to conform to established policies for equipment with 4x monitoring time.	0.00

TABLE 11—CY 2018 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
96160	Pt-focused hlth risk assmt.	L026A	Medical/Technical Assistant.	NF	Explain purpose of assessment to patient/caregiver and answer questions.	2	0	G1: See preamble text.	−0.52
96160	Pt-focused hlth risk assmt.	L026A	Medical/Technical Assistant.	NF	Remain in exam room with patient/caregiver exclusive to completion of assessment.	2	0	G1: See preamble text.	−0.52
96160	Pt-focused hlth risk assmt.	L026A	Medical/Technical Assistant.	NF	Collate and score data elements on assessment in advance of physician exam.	1	0	G1: See preamble text.	−0.26
96160	Pt-focused hlth risk assmt.	L026A	Medical/Technical Assistant.	NF	Scan assessment or enter data elements and total score into electronic health record.	2	0	G1: See preamble text.	−0.52
96160	Pt-focused hlth risk assmt.	L026A	Medical/Technical Assistant.	NF	Administration, scoring, and documenting results of completed standardized instrument.	0	7	G1: See preamble text.	1.82
96161	Caregiver health risk assmt.	L026A	Medical/Technical Assistant.	NF	Explain purpose of assessment to patient/caregiver and answer questions.	2	0	G1: See preamble text.	−0.52
96161	Caregiver health risk assmt.	L026A	Medical/Technical Assistant.	NF	Remain in exam room with patient/caregiver exclusive to completion of assessment.	2	0	G1: See preamble text.	−0.52
96161	Caregiver health risk assmt.	L026A	Medical/Technical Assistant.	NF	Collate and score data elements on assessment in advance of physician exam.	1	0	G1: See preamble text.	−0.26
96161	Caregiver health risk assmt.	L026A	Medical/Technical Assistant.	NF	Scan assessment or enter data elements and total score into electronic health record.	2	0	G1: See preamble text.	−0.52
96161	Caregiver health risk assmt.	L026A	Medical/Technical Assistant.	NF	Administration, scoring, and documenting results of completed standardized instrument.	0	7	G1: See preamble text.	1.82
96360	Hydration iv infusion init.	EF023	table, exam	NF	.....	16	24	E6: Refined equipment time to conform to established policies for equipment with 4x monitoring time.	0.02

TABLE 11—CY 2018 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
96360	Hydration iv infusion init.	EQ032	IV infusion pump.	NF		16	24	E6: Refined equipment time to conform to established policies for equipment with 4x monitoring time.	0.05
96360	Hydration iv infusion init.	L056A	RN/OCN	NF	Obtain vital signs.	3	5	L1: Refined time to standard for this clinical labor task.	1.58
96361	Hydrate iv infusion add-on.	EF023	table, exam	NF		7	9	E15: Refined equipment time to conform to changes in clinical labor time.	0.01
96361	Hydrate iv infusion add-on.	EQ032	IV infusion pump.	NF		7	9	E15: Refined equipment time to conform to changes in clinical labor time.	0.01
96361	Hydrate iv infusion add-on.	L056A	RN/OCN	NF	Obtain vital signs.	3	5	L1: Refined time to standard for this clinical labor task.	1.58
96372	Ther/proph/diag inj sc/im.	EF023	table, exam	NF		12	9	E15: Refined equipment time to conform to changes in clinical labor time.	−0.01
96372	Ther/proph/diag inj sc/im.	EQ189	otoscope-ophthalmoscope (wall unit).	NF		12	9	E15: Refined equipment time to conform to changes in clinical labor time.	−0.01
96372	Ther/proph/diag inj sc/im.	L037D	RN/LPN/MTA	NF	Complete medical record documentation.	1	0	G6: Indirect Practice Expense input and/or not individually allocable to a particular patient for a particular service.	−0.37
96372	Ther/proph/diag inj sc/im.	L037D	RN/LPN/MTA	NF	Document lot number and expiration date.	1	0	L3: Refined clinical labor time to conform with identical labor activity in other codes in the family.	−0.37
96372	Ther/proph/diag inj sc/im.	L037D	RN/LPN/MTA	NF	Clean room/ equipment by physician staff.	1	0	G8: Input removed; code is typically billed with an E/M or other evaluation service.	−0.37
96374	Ther/proph/diag inj iv push.	EF023	table, exam	NF		23	31	E6: Refined equipment time to conform to established policies for equipment with 4x monitoring time.	0.02

TABLE 11—CY 2018 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
96374	Ther/proph/diag inj iv push.	EQ189	otoscope-ophthalmoscope (wall unit).	NF		23	31	E6: Refined equipment time to conform to established policies for equipment with 4x monitoring time.	0.01
96374	Ther/proph/diag inj iv push.	L056A	RN/OCN	NF	Complete medical record documentation.	1	0	G6: Indirect Practice Expense input and/or not individually allocable to a particular patient for a particular service.	−0.79
96375	Tx/pro/dx inj new drug addon.	EF023	table, exam	NF		12	17	E6: Refined equipment time to conform to established policies for equipment with 4x monitoring time.	0.01
96375	Tx/pro/dx inj new drug addon.	EQ189	otoscope-ophthalmoscope (wall unit).	NF		12	17	E6: Refined equipment time to conform to established policies for equipment with 4x monitoring time.	0.01
96375	Tx/pro/dx inj new drug addon.	L056A	RN/OCN	NF	Complete medical record documentation.	1	0	G6: Indirect Practice Expense input and/or not individually allocable to a particular patient for a particular service.	−0.79
96377	Applicaton on-body injector.	EF023	table, exam	NF		12	11	E15: Refined equipment time to conform to changes in clinical labor time.	0.00
96377	Applicaton on-body injector.	EQ189	otoscope-ophthalmoscope (wall unit).	NF		12	11	E15: Refined equipment time to conform to changes in clinical labor time.	0.00
96377	Applicaton on-body injector.	L056A	RN/OCN	NF	Complete medical record documentation.	1	0	G6: Indirect Practice Expense input and/or not individually allocable to a particular patient for a particular service.	−0.79
96910	Photochemotherapy with uv-b.	EF023	table, exam	NF		67	65	E15: Refined equipment time to conform to changes in clinical labor time.	−0.01

TABLE 11—CY 2018 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
96910	Photochemotherapy with uv-b.	EQ168	light, exam	NF	.....	67	65	E15: Refined equipment time to conform to changes in clinical labor time.	−0.01
96910	Photochemotherapy with uv-b.	EQ204	phototherapy unit, hand-foot, UVA–UVB.	NF	.....	67	65	E15: Refined equipment time to conform to changes in clinical labor time.	−0.01
96910	Photochemotherapy with uv-b.	EQ205	phototherapy unit, whole body, UVA–UVB.	NF	.....	67	65	E15: Refined equipment time to conform to changes in clinical labor time.	−0.07
96910	Photochemotherapy with uv-b.	L037D	RN/LPN/MTA ...	NF	Complete diagnostic forms, lab & X-ray requisitions, and documentation.	2	0	G6: Indirect Practice Expense input and/or not individually allocable to a particular patient for a particular service.	−0.74
96910	Photochemotherapy with uv-b.	L037D	RN/LPN/MTA ...	NF	Provide pre-service education/obtain consent.	3	1	G1: See preamble text.	−0.74
96910	Photochemotherapy with uv-b.	L037D	RN/LPN/MTA ...	NF	Obtain vital signs.	3	5	L1: Refined time to standard for this clinical labor task.	0.74
96X73	Pdt dstr prmlg les phys/qhp.	EF031	table, power	NF	.....	230	52	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	−2.91
96X73	Pdt dstr prmlg les phys/qhp.	EQ169	light, external PDT, w-probe set (LumaCare).	NF	.....	20	52	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	1.12
96X73	Pdt dstr prmlg les phys/qhp.	L037D	RN/LPN/MTA ...	NF	Obtain vital signs.	3	5	L1: Refined time to standard for this clinical labor task.	0.74
96X73	Pdt dstr prmlg les phys/qhp.	SJ027	goggles, uv-blocking.	NF	.....	0	3	S8: Supply item replaces another item; see preamble.	12.30
96X74	Dbrdmt prmlg les w/pdt.	EF031	table, power	NF	.....	232	54	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	−2.91

TABLE 11—CY 2018 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
96X74	Dbrdmt prmlg les w/pdt.	EQ168	light, exam	NF		52	54	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	0.01
96X74	Dbrdmt prmlg les w/pdt.	EQ169	light, external PDT, w-probe set (LumaCare).	NF		20	54	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	1.19
96X74	Dbrdmt prmlg les w/pdt.	L037D	RN/LPN/MTA	NF	Obtain vital signs.	3	5	L1: Refined time to standard for this clinical labor task.	0.74
96X74	Dbrdmt prmlg les w/pdt.	SJ027	goggles, uv-blocking.	NF		0	3	S8: Supply item replaces another item; see preamble.	12.30
97012	Mechanical traction therapy.	EQ241	traction system (hi-low table, digital unit, accessories).	NF		13	15	G1: See preamble text.	0.03
97012	Mechanical traction therapy.	L023A	Physical Therapy Aide.	NF	Clean room/ equipment by physician staff.	1	2	G1: See preamble text.	0.23
97012	Mechanical traction therapy.	L023A	Physical Therapy Aide.	NF	Assist therapist	2	0	G1: See preamble text.	−0.46
97012	Mechanical traction therapy.	L023A	Physical Therapy Aide.	NF	Other clinical Activity—specify: post-treatment assistance.	0	1	G1: See preamble text.	0.23
97012	Mechanical traction therapy.	L023A	Physical Therapy Aide.	NF	Prepare room, equipment, supplies.	1	0	G1: See preamble text.	−0.23
97012	Mechanical traction therapy.	L023A	Physical Therapy Aide.	NF	Prepare and position patient.	1	0	G1: See preamble text.	−0.23
97012	Mechanical traction therapy.	L039B	Physical Therapy Assistant.	NF	Check dressings & wound/home care instructions/coordinate office visits/prescriptions.	0	1	G1: See preamble text.	0.39
97012	Mechanical traction therapy.	L039B	Physical Therapy Assistant.	NF	Assist therapist	0	5	G1: See preamble text.	1.95
97012	Mechanical traction therapy.	SB022	gloves, non-sterile.	NF		1	0	G1: See preamble text.	−0.08
97012	Mechanical traction therapy.	SB026	gown, patient	NF		1	0	G1: See preamble text.	−0.53
97012	Mechanical traction therapy.	SG039	dressing, 5in x 9in (ABD-Combine).	NF		0	1	G1: See preamble text.	0.27
97012	Mechanical traction therapy.	SK082	towel, paper (Bounty) (per sheet).	NF		2	0	G1: See preamble text.	−0.01
97012	Mechanical traction therapy.	SM012	disinfectant spray (Transeptic).	NF		2	0	G1: See preamble text.	−0.06
97014	Electric stimulation therapy.	EF028	table, mat, hi-lo, 6 x 8 platform.	NF		10	15	G1: See preamble text.	0.05
97014	Electric stimulation therapy.	EQ116	electrotherapy stimulator, high volt, 2 channel.	NF		10	15	G1: See preamble text.	0.03
97014	Electric stimulation therapy.	L023A	Physical Therapy Aide.	NF	Prepare room, equipment, supplies.	1	0	G1: See preamble text.	−0.23
97014	Electric stimulation therapy.	L023A	Physical Therapy Aide.	NF	Assist therapist	2	0	G1: See preamble text.	−0.46

TABLE 11—CY 2018 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
97014	Electric stimulation therapy.	L023A	Physical Therapy Aide.	NF	Clean room/ equipment by physician staff.	1	2	G1: See preamble text.	0.23
97014	Electric stimulation therapy.	L023A	Physical Therapy Aide.	NF	Other clinical Activity—specify: post-treatment assistance.	0	1	G1: See preamble text.	0.23
97014	Electric stimulation therapy.	L023A	Physical Therapy Aide.	NF	Prepare and position patient.	1	0	G1: See preamble text.	−0.23
97014	Electric stimulation therapy.	L039B	Physical Therapy Assistant.	NF	Assist therapist	0	3	G1: See preamble text.	1.17
97014	Electric stimulation therapy.	L039B	Physical Therapy Assistant.	NF	Check dressings & wound/home care instructions/coordinate office visits/prescriptions.	0	1	G1: See preamble text.	0.39
97014	Electric stimulation therapy.	SB026	gown, patient ...	NF	.....	1	0	G1: See preamble text.	−0.53
97014	Electric stimulation therapy.	SJ024	electrolyte coupling gel.	NF	.....	0	1	G1: See preamble text.	0.02
97014	Electric stimulation therapy.	SK068	razor	NF	.....	0	1	G1: See preamble text.	0.39
97014	Electric stimulation therapy.	SK082	towel, paper (Bounty) (per sheet).	NF	.....	1	0	G1: See preamble text.	−0.01
97014	Electric stimulation therapy.	SM012	disinfectant spray (Transeptic).	NF	.....	1	0	G1: See preamble text.	−0.03
97016	Vasopneumatic device therapy.	EF028	table, mat, hi-lo, 6 x 8 platform.	NF	.....	11	20	G1: See preamble text.	0.09
97016	Vasopneumatic device therapy.	EQ263	vasopneumatic compression system.	NF	.....	11	20	G1: See preamble text.	0.02
97016	Vasopneumatic device therapy.	L023A	Physical Therapy Aide.	NF	Other clinical Activity—specify: post-treatment assistance.	0	2	G1: See preamble text.	0.46
97016	Vasopneumatic device therapy.	L023A	Physical Therapy Aide.	NF	Prepare room, equipment, supplies.	1	0	G1: See preamble text.	−0.23
97016	Vasopneumatic device therapy.	L023A	Physical Therapy Aide.	NF	Clean room/ equipment by physician staff.	1	2	G1: See preamble text.	0.23
97016	Vasopneumatic device therapy.	L023A	Physical Therapy Aide.	NF	Prepare and position patient.	1	0	G1: See preamble text.	−0.23
97016	Vasopneumatic device therapy.	L023A	Physical Therapy Aide.	NF	Assist therapist	2	0	G1: See preamble text.	−0.46
97016	Vasopneumatic device therapy.	L039B	Physical Therapy Assistant.	NF	Assist therapist	0	10	G1: See preamble text.	3.90
97016	Vasopneumatic device therapy.	L039B	Physical Therapy Assistant.	NF	Check dressings & wound/home care instructions/coordinate office visits/prescriptions.	0	5	G1: See preamble text.	1.95
97016	Vasopneumatic device therapy.	L039B	Physical Therapy Assistant.	NF	Obtain vital signs.	0	2	G1: See preamble text.	0.78
97016	Vasopneumatic device therapy.	SB026	gown, patient ...	NF	.....	1	0	G1: See preamble text.	−0.53
97018	Paraffin bath therapy.	EQ200	paraffin bath, hand-foot (institutional).	NF	.....	11	15	G1: See preamble text.	0.03

TABLE 11—CY 2018 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
97018	Paraffin bath therapy.	L023A	Physical Therapy Aide.	NF	Prepare room, equipment, supplies.	1	3	G1: See preamble text.	0.46
97018	Paraffin bath therapy.	L023A	Physical Therapy Aide.	NF	Other clinical Activity—specify: post-treatment assistance.	0	1	G1: See preamble text.	0.23
97018	Paraffin bath therapy.	L023A	Physical Therapy Aide.	NF	Clean room/equipment by physician staff.	1	2	G1: See preamble text.	0.23
97018	Paraffin bath therapy.	L023A	Physical Therapy Aide.	NF	Assist therapist	2	0	G1: See preamble text.	−0.46
97018	Paraffin bath therapy.	L023A	Physical Therapy Aide.	NF	Prepare and position patient.	1	3	G1: See preamble text.	0.46
97018	Paraffin bath therapy.	L039B	Physical Therapy Assistant.	NF	Check dressings & wound/home care instructions/coordinate office visits/prescriptions.	0	1	G1: See preamble text.	0.39
97018	Paraffin bath therapy.	L039B	Physical Therapy Assistant.	NF	Assist therapist	0	5	G1: See preamble text.	1.95
97018	Paraffin bath therapy.	SA048	pack, minimum multi-specialty visit.	NF	.....	0	0.5	G1: See preamble text.	0.57
97022	Whirlpool therapy.	EF012	lift, hydraulic, chair.	NF	.....	26	4	G1: See preamble text.	−0.28
97022	Whirlpool therapy.	EF036	whirlpool, lo-boy tank (whole body).	NF	.....	26	24	G1: See preamble text.	−0.02
97022	Whirlpool therapy.	L023A	Physical Therapy Aide.	NF	Prepare and position patient.	2	3	G1: See preamble text.	0.23
97022	Whirlpool therapy.	L023A	Physical Therapy Aide.	NF	Assist therapist	2	0	G1: See preamble text.	−0.46
97022	Whirlpool therapy.	L023A	Physical Therapy Aide.	NF	Other clinical Activity—specify: post-treatment assistance.	0	3	G1: See preamble text.	0.69
97022	Whirlpool therapy.	L039B	Physical Therapy Assistant.	NF	Assist therapist	0	5	G1: See preamble text.	1.95
97022	Whirlpool therapy.	L039B	Physical Therapy Assistant.	NF	Check dressings & wound/home care instructions/coordinate office visits/prescriptions.	0	1	G1: See preamble text.	0.39
97022	Whirlpool therapy.	SB022	gloves, non-sterile.	NF	.....	1	0	G1: See preamble text.	−0.08
97022	Whirlpool therapy.	SB024	gloves, sterile ...	NF	.....	0	1	G1: See preamble text.	0.84
97022	Whirlpool therapy.	SB033	mask, surgical ..	NF	.....	0	1	G1: See preamble text.	0.20
97022	Whirlpool therapy.	SG017	bandage, Kling, non-sterile 2in.	NF	.....	0	1	G1: See preamble text.	0.36
97022	Whirlpool therapy.	SG027	cast, stockinette 4in.	NF	.....	0	1	G1: See preamble text.	0.46
97022	Whirlpool therapy.	SG055	gauze, sterile 4in x 4in.	NF	.....	0	5	G1: See preamble text.	0.80
97022	Whirlpool therapy.	SG079	tape, surgical paper 1in (Micropore).	NF	.....	0	12	G1: See preamble text.	0.02
97022	Whirlpool therapy.	SJ046	silver nitrate applicator.	NF	.....	0	1	G1: See preamble text.	0.07
97032	Electrical stimulation.	EF028	table, mat, hi-lo, 6 x 8 platform.	NF	.....	18	15	G1: See preamble text.	−0.03
97032	Electrical stimulation.	EQ116	electrotherapy stimulator, high volt, 2 channel.	NF	.....	18	15	G1: See preamble text.	−0.02

TABLE 11—CY 2018 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
97032	Electrical stimulation.	L023A	Physical Therapy Aide.	NF	Prepare room, equipment, supplies.	1	0	G1: See preamble text.	−0.23
97032	Electrical stimulation.	L023A	Physical Therapy Aide.	NF	Prepare and position patient.	1	0	G1: See preamble text.	−0.23
97032	Electrical stimulation.	L023A	Physical Therapy Aide.	NF	Other clinical Activity—specify: post-treatment assistance.	0	1	G1: See preamble text.	0.23
97032	Electrical stimulation.	L023A	Physical Therapy Aide.	NF	Clean room/equipment by physician staff.	1	2	G1: See preamble text.	0.23
97032	Electrical stimulation.	L039B	Physical Therapy Assistant.	NF	Assist therapist	0	3	G1: See preamble text.	1.17
97032	Electrical stimulation.	L039B	Physical Therapy Assistant.	NF	Check dressings & wound/home care instructions/coordinate office visits/prescriptions.	0	1	G1: See preamble text.	0.39
97032	Electrical stimulation.	SB022	gloves, non-sterile.	NF	.....	1	0	G1: See preamble text.	−0.08
97032	Electrical stimulation.	SB026	gown, patient ...	NF	.....	1	0	G1: See preamble text.	−0.53
97032	Electrical stimulation.	SD055	electrode, electrical stimulation.	NF	.....	0	2	G1: See preamble text.	2.62
97032	Electrical stimulation.	SG079	tape, surgical paper 1in (Micropore).	NF	.....	0	6	G1: See preamble text.	0.01
97032	Electrical stimulation.	SJ020	electrode conductive gel.	NF	.....	0	5	G1: See preamble text.	0.08
97032	Electrical stimulation.	SJ053	swab-pad, alcohol.	NF	.....	1	2	G1: See preamble text.	0.01
97032	Electrical stimulation.	SK068	razor	NF	.....	0	1	G1: See preamble text.	0.39
97032	Electrical stimulation.	SK082	towel, paper (Bounty) (per sheet).	NF	.....	1	0	G1: See preamble text.	−0.01
97032	Electrical stimulation.	SM012	disinfectant spray (Transeptic).	NF	.....	1	0	G1: See preamble text.	−0.03
97033	Electric current therapy.	EF028	table, mat, hi-lo, 6 x 8 platform.	NF	.....	20	15	G1: See preamble text.	−0.05
97033	Electric current therapy.	EQ141	iontophoresis machine.	NF	.....	20	15	G1: See preamble text.	−0.01
97033	Electric current therapy.	L023A	Physical Therapy Aide.	NF	Other clinical Activity—specify: post-treatment assistance.	0	1	G1: See preamble text.	0.23
97033	Electric current therapy.	L023A	Physical Therapy Aide.	NF	Prepare room, equipment, supplies.	2	3	G1: See preamble text.	0.23
97033	Electric current therapy.	L023A	Physical Therapy Aide.	NF	Clean room/equipment by physician staff.	1	3	G1: See preamble text.	0.46
97033	Electric current therapy.	L039B	Physical Therapy Assistant.	NF	Other Clinical Activity—specify: Obtain measurements.	0	1	G1: See preamble text.	0.39
97033	Electric current therapy.	SG055	gauze, sterile 4in x 4in.	NF	.....	0	1	G1: See preamble text.	0.16
97033	Electric current therapy.	SK068	razor	NF	.....	0	1	G1: See preamble text.	0.39
97034	Contrast bath therapy.	L023A	Physical Therapy Aide.	NF	Clean room/equipment by physician staff.	2	5	G1: See preamble text.	0.69
97034	Contrast bath therapy.	L023A	Physical Therapy Aide.	NF	Prepare room, equipment, supplies.	2	3	G1: See preamble text.	0.23
97034	Contrast bath therapy.	L023A	Physical Therapy Aide.	NF	Prepare and position patient.	1	2	G1: See preamble text.	0.23

TABLE 11—CY 2018 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
97034	Contrast bath therapy.	L039B	Physical Therapy Assistant.	NF	Assist therapist	0	3	G1: See preamble text.	1.17
97034	Contrast bath therapy.	L039B	Physical Therapy Assistant.	NF	Check dressings & wound/home care instructions/coordinate office visits/prescriptions.	0	3	G1: See preamble text.	1.17
97034	Contrast bath therapy.	SB022	gloves, non-sterile.	NF	.....	1	0	G1: See preamble text.	−0.08
97034	Contrast bath therapy.	SB026	gown, patient ...	NF	.....	1	0	G1: See preamble text.	−0.53
97035	Ultrasound therapy.	EF028	table, mat, hi-lo, 6 x 8 platform.	NF	.....	16	15	G1: See preamble text.	−0.01
97035	Ultrasound therapy.	EQ251	ultrasound unit, therapeutic.	NF	.....	16	8	G1: See preamble text.	−0.03
97035	Ultrasound therapy.	L023A	Physical Therapy Aide.	NF	Prepare and position patient.	1	0	G1: See preamble text.	−0.23
97035	Ultrasound therapy.	L023A	Physical Therapy Aide.	NF	Prepare room, equipment, supplies.	1	0	G1: See preamble text.	−0.23
97035	Ultrasound therapy.	L023A	Physical Therapy Aide.	NF	Other clinical Activity—specify: post-treatment assistance.	0	1	G1: See preamble text.	0.23
97035	Ultrasound therapy.	L039B	Physical Therapy Assistant.	NF	Assist therapist	0	3	G1: See preamble text.	1.17
97035	Ultrasound therapy.	SB022	gloves, non-sterile.	NF	.....	1	0	G1: See preamble text.	−0.08
97035	Ultrasound therapy.	SB026	gown, patient ...	NF	.....	1	0	G1: See preamble text.	−0.53
97035	Ultrasound therapy.	SJ024	electrolyte coupling gel.	NF	.....	0	1	G1: See preamble text.	0.02
97035	Ultrasound therapy.	SJ062	ultrasound transmission gel.	NF	.....	30	0	G1: See preamble text.	−0.39
97035	Ultrasound therapy.	SK082	towel, paper (Bounty) (per sheet).	NF	.....	1	0	G1: See preamble text.	−0.01
97035	Ultrasound therapy.	SM012	disinfectant spray (Transeptic).	NF	.....	1	0	G1: See preamble text.	−0.03
97110	Therapeutic exercises.	EF028	table, mat, hi-lo, 6 x 8 platform.	NF	.....	22	10	G1: See preamble text.	−0.12
97110	Therapeutic exercises.	EQ118	exercise equipment (treadmill, bike, stepper, UBE, pulleys, balance board).	NF	.....	22	8	G1: See preamble text.	−0.40
97110	Therapeutic exercises.	EQ129	hydrocollator, cold.	NF	.....	0	4	G1: See preamble text.	0.02
97110	Therapeutic exercises.	EQ130	hydrocollator, hot.	NF	.....	0	4	G1: See preamble text.	0.01
97110	Therapeutic exercises.	L023A	Physical Therapy Aide.	NF	Other clinical Activity—specify: post-treatment assistance.	0	1	G1: See preamble text.	0.23
97110	Therapeutic exercises.	L023A	Physical Therapy Aide.	NF	Prepare room, equipment, supplies.	1	0	G1: See preamble text.	−0.23
97110	Therapeutic exercises.	L023A	Physical Therapy Aide.	NF	Prepare and position patient.	1	0	G1: See preamble text.	−0.23
97110	Therapeutic exercises.	L023A	Physical Therapy Aide.	NF	Assist therapist	5	0	G1: See preamble text.	−1.15
97110	Therapeutic exercises.	L023A	Physical Therapy Aide.	NF	Other Clinical Activity—specify: Verify/Coordinate availability of resources/equipment.	0	1.5	G1: See preamble text.	0.35

TABLE 11—CY 2018 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
97110	Therapeutic exercises.	L039B	Physical Therapy Assistant.	NF	Check dressings & wound/home care instructions/coordinate office visits/prescriptions.	1.5	2.5	G1: See preamble text.	0.39
97110	Therapeutic exercises.	L039B	Physical Therapy Assistant.	NF	Other Clinical Activity—specify: Obtain measurements.	0	1.5	G1: See preamble text.	0.59
97110	Therapeutic exercises.	L039B	Physical Therapy Assistant.	NF	Assist therapist	2.5	7.5	G1: See preamble text.	1.95
97110	Therapeutic exercises.	L039B	Physical Therapy Assistant.	NF	Other Clinical Activity—specify: Conduct phone calls/call in prescriptions.	0	1	G1: See preamble text.	0.39
97110	Therapeutic exercises.	L039B	Physical Therapy Assistant.	NF	Other Clinical Activity—specify: Review/read documentation, plan of care, treatment goals.	0	1.5	G1: See preamble text.	0.59
97110	Therapeutic exercises.	SA048	pack, minimum multi-specialty visit.	NF	.....	0	0.5	G1: See preamble text.	0.57
97110	Therapeutic exercises.	SB022	gloves, non-sterile.	NF	.....	1	0	G1: See preamble text.	−0.08
97110	Therapeutic exercises.	SK082	towel, paper (Bounty) (per sheet).	NF	.....	4	0	G1: See preamble text.	−0.03
97110	Therapeutic exercises.	SM012	disinfectant spray (Transeptic).	NF	.....	5	0	G1: See preamble text.	−0.14
97112	Neuromuscular reeducation.	EF028	table, mat, hi-lo, 6 x 8 platform.	NF	.....	22	10	G1: See preamble text.	−0.12
97112	Neuromuscular reeducation.	EQ068	balance assessment-retraining system (Balance Master).	NF	.....	22	15	G1: See preamble text.	−0.37
97112	Neuromuscular reeducation.	EQ118	exercise equipment (treadmill, bike, stepper, UBE, pulleys, balance board).	NF	.....	22	15	G1: See preamble text.	−0.20
97112	Neuromuscular reeducation.	EQ201	parallel bars, platform mounted.	NF	.....	22	5	G1: See preamble text.	−0.06
97112	Neuromuscular reeducation.	L023A	Physical Therapy Aide.	NF	Prepare room, equipment, supplies.	1	0	G1: See preamble text.	−0.23
97112	Neuromuscular reeducation.	L023A	Physical Therapy Aide.	NF	Prepare and position patient.	1	0	G1: See preamble text.	−0.23
97112	Neuromuscular reeducation.	L023A	Physical Therapy Aide.	NF	Assist therapist	5	0	G1: See preamble text.	−1.15
97112	Neuromuscular reeducation.	L023A	Physical Therapy Aide.	NF	Other clinical Activity—specify: post-treatment assistance.	0	1	G1: See preamble text.	0.23
97112	Neuromuscular reeducation.	L023A	Physical Therapy Aide.	NF	Other Clinical Activity—specify: Verify/Coordinate availability of resources/equipment.	0	1.5	G1: See preamble text.	0.35

TABLE 11—CY 2018 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
97112	Neuromuscular reeducation.	L039B	Physical Therapy Assistant.	NF	Check dressings & wound/home care instructions/coordinate office visits/prescriptions.	1.5	2.5	G1: See preamble text.	0.39
97112	Neuromuscular reeducation.	L039B	Physical Therapy Assistant.	NF	Other Clinical Activity—specify: Review/read documentation, plan of care, treatment goals.	0	1.5	G1: See preamble text.	0.59
97112	Neuromuscular reeducation.	L039B	Physical Therapy Assistant.	NF	Assist therapist	2.5	7.5	G1: See preamble text.	1.95
97112	Neuromuscular reeducation.	L039B	Physical Therapy Assistant.	NF	Other Clinical Activity—specify: Conduct phone calls/call in prescriptions.	0	1	G1: See preamble text.	0.39
97112	Neuromuscular reeducation.	L039B	Physical Therapy Assistant.	NF	Other Clinical Activity—specify: Obtain measurements.	0	1.5	G1: See preamble text.	0.59
97112	Neuromuscular reeducation.	SA048	pack, minimum multi-specialty visit.	NF	.....	0	0.5	G1: See preamble text.	0.57
97112	Neuromuscular reeducation.	SB022	gloves, non-sterile.	NF	.....	1	0	G1: See preamble text.	−0.08
97112	Neuromuscular reeducation.	SK082	towel, paper (Bounty) (per sheet).	NF	.....	4	0	G1: See preamble text.	−0.03
97112	Neuromuscular reeducation.	SM012	disinfectant spray (Transeptic).	NF	.....	5	0	G1: See preamble text.	−0.14
97113	Aquatic therapy/ exercises.	EF012	lift, hydraulic, chair.	NF	.....	0	4	G1: See preamble text.	0.05
97113	Aquatic therapy/ exercises.	EQ050	aquatic therapy pool.	NF	.....	30	15	G1: See preamble text.	−1.15
97113	Aquatic therapy/ exercises.	EQ145	kit, aquatic exercise.	NF	.....	30	10	G1: See preamble text.	−0.03
97113	Aquatic therapy/ exercises.	EQ207	pool cleaner	NF	.....	0	15	G1: See preamble text.	0.05
97113	Aquatic therapy/ exercises.	L023A	Physical Therapy Aide.	NF	Prepare room, equipment, supplies.	2	0	G1: See preamble text.	−0.46
97113	Aquatic therapy/ exercises.	L023A	Physical Therapy Aide.	NF	Other Clinical Activity—specify: Verify/Coordinate availability of resources/ equipment.	0	1.5	G1: See preamble text.	0.35
97113	Aquatic therapy/ exercises.	L023A	Physical Therapy Aide.	NF	Other clinical Activity—specify: post-treatment assistance.	2	3	G1: See preamble text.	0.23
97113	Aquatic therapy/ exercises.	L023A	Physical Therapy Aide.	NF	Greet patient, provide gowning, ensure appropriate medical records are available.	2	1.5	G1: See preamble text.	−0.12
97113	Aquatic therapy/ exercises.	L023A	Physical Therapy Aide.	NF	Prepare and position patient.	3	1.5	G1: See preamble text.	−0.35
97113	Aquatic therapy/ exercises.	L023A	Physical Therapy Aide.	NF	Clean room/ equipment by physician staff.	2	1	G1: See preamble text.	−0.23

TABLE 11—CY 2018 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
97113	Aquatic therapy/ exercises.	L023A	Physical Therapy Aide.	NF	Assist therapist	15	0	G1: See preamble text.	−3.45
97113	Aquatic therapy/ exercises.	L039B	Physical Therapy Assistant.	NF	Check dressings & wound/home care instructions/coordinate office visits/prescriptions.	2	2.5	G1: See preamble text.	0.20
97113	Aquatic therapy/ exercises.	L039B	Physical Therapy Assistant.	NF	Obtain vital signs.	2	1	G1: See preamble text.	−0.39
97113	Aquatic therapy/ exercises.	L039B	Physical Therapy Assistant.	NF	Other Clinical Activity—specify: Review/read documentation, plan of care, treatment goals.	0	1.5	G1: See preamble text.	0.59
97113	Aquatic therapy/ exercises.	L039B	Physical Therapy Assistant.	NF	Other Clinical Activity—specify: Obtain measurements.	0	1.5	G1: See preamble text.	0.59
97113	Aquatic therapy/ exercises.	L039B	Physical Therapy Assistant.	NF	Other Clinical Activity—specify: Conduct phone calls/call in prescriptions.	0	1	G1: See preamble text.	0.39
97113	Aquatic therapy/ exercises.	L039B	Physical Therapy Assistant.	NF	Assist therapist	2	7.5	G1: See preamble text.	2.15
97113	Aquatic therapy/ exercises.	SA048	pack, minimum multi-specialty visit.	NF	.....	0	0.5	G1: See preamble text.	0.57
97113	Aquatic therapy/ exercises.	SB022	gloves, non-sterile.	NF	.....	1	0	G1: See preamble text.	−0.08
97113	Aquatic therapy/ exercises.	SB041	swimsuit, female for hydrotherapy.	NF	.....	0	1	G1: See preamble text.	6.87
97113	Aquatic therapy/ exercises.	SK082	towel, paper (Bounty) (per sheet).	NF	.....	4	0	G1: See preamble text.	−0.03
97113	Aquatic therapy/ exercises.	SL032	culture media ...	NF	.....	0	10	G1: See preamble text.	0.13
97113	Aquatic therapy/ exercises.	SL033	culture swab system (Culturette).	NF	.....	0	1	G1: See preamble text.	0.87
97113	Aquatic therapy/ exercises.	SM012	disinfectant spray (Transeptic).	NF	.....	5	0	G1: See preamble text.	−0.14
97116	Gait training therapy.	EF028	table, mat, hi-lo, 6 x 8 platform.	NF	.....	22	0	G1: See preamble text.	−0.22
97116	Gait training therapy.	EQ144	kit, ambulation ..	NF	.....	0	15	G1: See preamble text.	0.03
97116	Gait training therapy.	EQ201	parallel bars, platform mounted.	NF	.....	22	10	G1: See preamble text.	−0.04
97116	Gait training therapy.	EQ231	stairs, ambulation training.	NF	.....	22	5	G1: See preamble text.	−0.03
97116	Gait training therapy.	EQ243	treadmill	NF	.....	22	0	G1: See preamble text.	−0.29
97116	Gait training therapy.	L023A	Physical Therapy Aide.	NF	Other clinical Activity—specify: post-treatment assistance.	0	1	G1: See preamble text.	0.23
97116	Gait training therapy.	L023A	Physical Therapy Aide.	NF	Prepare room, equipment, supplies.	1	0	G1: See preamble text.	−0.23
97116	Gait training therapy.	L023A	Physical Therapy Aide.	NF	Prepare and position patient.	1	0	G1: See preamble text.	−0.23
97116	Gait training therapy.	L023A	Physical Therapy Aide.	NF	Assist therapist	5	0	G1: See preamble text.	−1.15

TABLE 11—CY 2018 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
97116	Gait training therapy.	L023A	Physical Therapy Aide.	NF	Other Clinical Activity—specify: Verify/Coordinate availability of resources/equipment.	0	1.5	G1: See preamble text.	0.35
97116	Gait training therapy.	L039B	Physical Therapy Assistant.	NF	Assist therapist	2.5	7.5	G1: See preamble text.	1.95
97116	Gait training therapy.	L039B	Physical Therapy Assistant.	NF	Check dressings & wound/home care instructions/coordinate office visits/prescriptions.	1.5	2.5	G1: See preamble text.	0.39
97116	Gait training therapy.	L039B	Physical Therapy Assistant.	NF	Other Clinical Activity—specify: Review/read documentation, plan of care, treatment goals.	0	1.5	G1: See preamble text.	0.59
97116	Gait training therapy.	L039B	Physical Therapy Assistant.	NF	Other Clinical Activity—specify: Conduct phone calls/call in prescriptions.	0	1	G1: See preamble text.	0.39
97116	Gait training therapy.	L039B	Physical Therapy Assistant.	NF	Other Clinical Activity—specify: Obtain measurements.	0	1.5	G1: See preamble text.	0.59
97116	Gait training therapy.	SA048	pack, minimum multi-specialty visit.	NF	.....	0	0.5	G1: See preamble text.	0.57
97116	Gait training therapy.	SB022	gloves, non-sterile.	NF	.....	1	0	G1: See preamble text.	−0.08
97116	Gait training therapy.	SJ056	Thera-bands (6in width).	NF	.....	1.5	0	G1: See preamble text.	−0.90
97116	Gait training therapy.	SK082	towel, paper (Bounty) (per sheet).	NF	.....	4	0	G1: See preamble text.	−0.03
97116	Gait training therapy.	SM012	disinfectant spray (Transeptic).	NF	.....	5	0	G1: See preamble text.	−0.14
97116	Gait training therapy.	SM021	sanitizing cloth-wipe (patient).	NF	.....	0	1	G1: See preamble text.	0.04
97140	Manual therapy 1/> regions.	EF029	table, mobolization-manipulation (Lloyd's).	NF	.....	22	15	G1: See preamble text.	−0.13
97140	Manual therapy 1/> regions.	L023A	Physical Therapy Aide.	NF	Prepare room, equipment, supplies.	1	0	G1: See preamble text.	−0.23
97140	Manual therapy 1/> regions.	L023A	Physical Therapy Aide.	NF	Other Clinical Activity—specify: Verify/Coordinate availability of resources/equipment.	0	1.5	G1: See preamble text.	0.35
97140	Manual therapy 1/> regions.	L023A	Physical Therapy Aide.	NF	Prepare and position patient.	1	0	G1: See preamble text.	−0.23
97140	Manual therapy 1/> regions.	L023A	Physical Therapy Aide.	NF	Other clinical Activity—specify: post-treatment assistance.	0	1	G1: See preamble text.	0.23
97140	Manual therapy 1/> regions.	L023A	Physical Therapy Aide.	NF	Assist therapist	5	0	G1: See preamble text.	−1.15

TABLE 11—CY 2018 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
97140	Manual therapy 1/> regions.	L039B	Physical Therapy Assistant.	NF	Other Clinical Activity—specify: Conduct phone calls/call in prescriptions.	0	1	G1: See preamble text.	0.39
97140	Manual therapy 1/> regions.	L039B	Physical Therapy Assistant.	NF	Other Clinical Activity—specify: Obtain measurements.	0	1.5	G1: See preamble text.	0.59
97140	Manual therapy 1/> regions.	L039B	Physical Therapy Assistant.	NF	Other Clinical Activity—specify: Review/read documentation, plan of care, treatment goals.	0	1.5	G1: See preamble text.	0.59
97140	Manual therapy 1/> regions.	L039B	Physical Therapy Assistant.	NF	Check dressings & wound/home care instructions/coordinate office visits/prescriptions.	1.5	2.5	G1: See preamble text.	0.39
97140	Manual therapy 1/> regions.	L039B	Physical Therapy Assistant.	NF	Assist therapist	2.5	7.5	G1: See preamble text.	1.95
97140	Manual therapy 1/> regions.	SA048	pack, minimum multi-specialty visit.	NF	.....	0	0.5	G1: See preamble text.	0.57
97140	Manual therapy 1/> regions.	SB022	gloves, non-sterile.	NF	.....	1	0	G1: See preamble text.	−0.08
97140	Manual therapy 1/> regions.	SK046	lotion, massage, unscented.	NF	.....	2	0.5	G1: See preamble text.	−0.24
97140	Manual therapy 1/> regions.	SK082	towel, paper (Bounty) (per sheet).	NF	.....	4	0	G1: See preamble text.	−0.03
97140	Manual therapy 1/> regions.	SM012	disinfectant spray (Transeptic).	NF	.....	5	0	G1: See preamble text.	−0.14
97530	Therapeutic activities.	EL003	environmental module—the workshop.	NF	.....	22	12	G1: See preamble text.	−0.50
97530	Therapeutic activities.	EQ219	rehab and testing system (BTE primus).	NF	.....	22	4	G1: See preamble text.	−3.20
97530	Therapeutic activities.	EQ267	work samples, small tools (Valpar 1).	NF	.....	22	12	G1: See preamble text.	−0.06
97530	Therapeutic activities.	L023A	Physical Therapy Aide.	NF	Prepare and position patient.	1	0	G1: See preamble text.	−0.23
97530	Therapeutic activities.	L023A	Physical Therapy Aide.	NF	Assist therapist	3.75	0	G1: See preamble text.	−0.86
97530	Therapeutic activities.	L023A	Physical Therapy Aide.	NF	Other Clinical Activity—specify: Verify/Coordinate availability of resources/equipment.	0	1.5	G1: See preamble text.	0.35
97530	Therapeutic activities.	L023A	Physical Therapy Aide.	NF	Other clinical Activity—specify: post-treatment assistance.	0	1	G1: See preamble text.	0.23
97530	Therapeutic activities.	L023A	Physical Therapy Aide.	NF	Prepare room, equipment, supplies.	1	1.5	G1: See preamble text.	0.12
97530	Therapeutic activities.	L039B	Physical Therapy Assistant.	NF	Assist therapist	3.75	7.5	G1: See preamble text.	1.46

TABLE 11—CY 2018 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
97530	Therapeutic activities.	L039B	Physical Therapy Assistant.	NF	Other Clinical Activity—specify: Review/read documentation, plan of care, treatment goals.	0	1.5	G1: See preamble text.	0.59
97530	Therapeutic activities.	L039B	Physical Therapy Assistant.	NF	Check dressings & wound/home care instructions/coordinate office visits/prescriptions.	1.5	2.5	G1: See preamble text.	0.39
97530	Therapeutic activities.	SB022	gloves, nonsterile.	NF	.....	1	0	G1: See preamble text.	−0.08
97530	Therapeutic activities.	SK082	towel, paper (Bounty) (per sheet).	NF	.....	4	0	G1: See preamble text.	−0.03
97530	Therapeutic activities.	SM012	disinfectant spray (Transeptic).	NF	.....	5	0	G1: See preamble text.	−0.14
97533	Sensory integration.	EQ224	sensory integration equip (eg, ball pit, glider, trampoline, ramp).	NF	.....	22	15	G1: See preamble text.	−0.06
97533	Sensory integration.	EQ225	sensory integration equipment, suspension system.	NF	.....	22	15	G1: See preamble text.	−0.05
97533	Sensory integration.	L023A	Physical Therapy Aide.	NF	Obtain vital signs.	0	1	G1: See preamble text.	0.23
97533	Sensory integration.	L023A	Physical Therapy Aide.	NF	Other Clinical Activity—specify: Verify/Coordinate availability of resources/equipment.	0	1.5	G1: See preamble text.	0.35
97533	Sensory integration.	L023A	Physical Therapy Aide.	NF	Assist therapist	0	7.5	G1: See preamble text.	1.73
97533	Sensory integration.	L023A	Physical Therapy Aide.	NF	Prepare room, equipment, supplies.	1	1.5	G1: See preamble text.	0.12
97533	Sensory integration.	L023A	Physical Therapy Aide.	NF	Prepare and position patient.	1	0	G1: See preamble text.	−0.23
97533	Sensory integration.	L023A	Physical Therapy Aide.	NF	Other clinical Activity—specify: post-treatment assistance.	0	1	G1: See preamble text.	0.23
97533	Sensory integration.	L023A	Physical Therapy Aide.	NF	Check dressings & wound/home care instructions/coordinate office visits/prescriptions.	0	2.5	G1: See preamble text.	0.58
97533	Sensory integration.	L039B	Physical Therapy Assistant.	NF	Obtain vital signs.	1	0	G1: See preamble text.	−0.39
97533	Sensory integration.	L039B	Physical Therapy Assistant.	NF	Assist therapist	7.5	0	G1: See preamble text.	−2.93
97533	Sensory integration.	L039B	Physical Therapy Assistant.	NF	Check dressings & wound/home care instructions/coordinate office visits/prescriptions.	1.5	0	G1: See preamble text.	−0.59

TABLE 11—CY 2018 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
97533	Sensory integration.	L039B	Physical Therapy Assistant.	NF	Other Clinical Activity—specify: Review/read documentation, plan of care, treatment goals.	0	1.5	G1: See preamble text.	0.59
97533	Sensory integration.	SJ053	swab-pad, alcohol.	NF		0	3	G1: See preamble text.	0.04
97533	Sensory integration.	SK082	towel, paper (Bounty) (per sheet).	NF		4	0	G1: See preamble text.	−0.03
97533	Sensory integration.	SM012	disinfectant spray (Transeptic).	NF		5	0	G1: See preamble text.	−0.14
97535	Self care mngment training.	EL002	environmental module—kitchen.	NF		22	12	G1: See preamble text.	−1.15
97535	Self care mngment training.	EQ143	kit, ADL	NF		22	16	G1: See preamble text.	−0.01
97535	Self care mngment training.	L023A	Physical Therapy Aide.	NF	Other Clinical Activity—specify: Verify/Coordinate availability of resources/equipment.	0	1.5	G1: See preamble text.	0.35
97535	Self care mngment training.	L023A	Physical Therapy Aide.	NF	Prepare room, equipment, supplies.	1	1.5	G1: See preamble text.	0.12
97535	Self care mngment training.	L023A	Physical Therapy Aide.	NF	Prepare and position patient.	1	0	G1: See preamble text.	−0.23
97535	Self care mngment training.	L023A	Physical Therapy Aide.	NF	Other clinical Activity—specify: post-treatment assistance.	0	1	G1: See preamble text.	0.23
97535	Self care mngment training.	L039B	Physical Therapy Assistant.	NF	Check dressings & wound/home care instructions/coordinate office visits/prescriptions.	1.5	2.5	G1: See preamble text.	0.39
97535	Self care mngment training.	L039B	Physical Therapy Assistant.	NF	Other Clinical Activity—specify: Review/read documentation, plan of care, treatment goals.	0	1.5	G1: See preamble text.	0.59
97535	Self care mngment training.	SB022	gloves, non-sterile.	NF		1	0	G1: See preamble text.	−0.08
97535	Self care mngment training.	SK009	bath soap (one bar uou).	NF		0	0.5	G1: See preamble text.	0.34
97535	Self care mngment training.	SK080	toothbrush	NF		0	1	G1: See preamble text.	0.81
97535	Self care mngment training.	SK081	toothpaste	NF		0	0.25	G1: See preamble text.	0.12
97535	Self care mngment training.	SK082	towel, paper (Bounty) (per sheet).	NF		4	0	G1: See preamble text.	−0.03
97535	Self care mngment training.	SM012	disinfectant spray (Transeptic).	NF		5	0	G1: See preamble text.	−0.14

TABLE 11—CY 2018 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
97535	Self care mngment training.	SM013	disinfectant, surface (Envirocide, Sanizide).	NF		0	2	G1: See preamble text.	0.33
97537	Community/ work re-integration.	EL001	environmental module—car.	NF		22	8	G1: See preamble text.	−1.01
97537	Community/ work re-integration.	EQ147	kit, ergonomic (office).	NF		22	8	G1: See preamble text.	−0.08
97537	Community/ work re-integration.	L023A	Physical Therapy Aide.	NF	Prepare room, equipment, supplies.	1	1.5	G1: See preamble text.	0.12
97537	Community/ work re-integration.	L023A	Physical Therapy Aide.	NF	Other clinical Activity—specify: post-treatment assistance.	0	1	G1: See preamble text.	0.23
97537	Community/ work re-integration.	L023A	Physical Therapy Aide.	NF	Prepare and position patient.	1	0	G1: See preamble text.	−0.23
97537	Community/ work re-integration.	L023A	Physical Therapy Aide.	NF	Other Clinical Activity—specify: Verify/Coordinate availability of resources/ equipment.	0	1.5	G1: See preamble text.	0.35
97537	Community/ work re-integration.	L039B	Physical Therapy Assistant.	NF	Check dressings & wound/home care instructions/coordinate office visits/prescriptions.	1.5	2.5	G1: See preamble text.	0.39
97537	Community/ work re-integration.	L039B	Physical Therapy Assistant.	NF	Other Clinical Activity—specify: Review/read documentation, plan of care, treatment goals.	0	1.5	G1: See preamble text.	0.59
97537	Community/ work re-integration.	SB022	gloves, non-sterile.	NF		1	0	G1: See preamble text.	−0.08
97537	Community/ work re-integration.	SK082	towel, paper (Bounty) (per sheet).	NF		4	0	G1: See preamble text.	−0.03
97537	Community/ work re-integration.	SM012	disinfectant spray (Transeptic).	NF		5	0	G1: See preamble text.	−0.14
97542	Wheelchair mngment training.	EL002	environmental module—kitchen.	NF		22	8	G1: See preamble text.	−1.61
97542	Wheelchair mngment training.	L023A	Physical Therapy Aide.	NF	Prepare room, equipment, supplies.	1	1.5	G1: See preamble text.	0.12
97542	Wheelchair mngment training.	L023A	Physical Therapy Aide.	NF	Other clinical Activity—specify: post-treatment assistance.	0	1	G1: See preamble text.	0.23
97542	Wheelchair mngment training.	L023A	Physical Therapy Aide.	NF	Prepare and position patient.	1	0	G1: See preamble text.	−0.23
97542	Wheelchair mngment training.	L023A	Physical Therapy Aide.	NF	Assist therapist	3.75	0	G1: See preamble text.	−0.86

TABLE 11—CY 2018 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
97542	Wheelchair mngment training.	L023A	Physical Therapy Aide.	NF	Other Clinical Activity—specify: Verify/Coordinate availability of resources/equipment.	0	1.5	G1: See preamble text.	0.35
97542	Wheelchair mngment training.	L039B	Physical Therapy Assistant.	NF	Check dressings & wound/home care instructions/coordinate office visits/prescriptions.	1.5	2.5	G1: See preamble text.	0.39
97542	Wheelchair mngment training.	L039B	Physical Therapy Assistant.	NF	Other Clinical Activity—specify: Review/read documentation, plan of care, treatment goals.	0	1.5	G1: See preamble text.	0.59
97542	Wheelchair mngment training.	L039B	Physical Therapy Assistant.	NF	Assist therapist	3.75	7.5	G1: See preamble text.	1.46
97542	Wheelchair mngment training.	SB022	gloves, non-sterile.	NF	.....	1	0	G1: See preamble text.	−0.08
97542	Wheelchair mngment training.	SK082	towel, paper (Bounty) (per sheet).	NF	.....	4	0	G1: See preamble text.	−0.03
97542	Wheelchair mngment training.	SM012	disinfectant spray (Transeptic).	NF	.....	5	0	G1: See preamble text.	−0.14
97760	Orthotic mgmt&trainj 1st enc.	EF005	cart-workbench, orthotic, mobile.	NF	.....	27	10	G1: See preamble text.	−0.03
97760	Orthotic mgmt&trainj 1st enc.	EF033	table, treatment, hi-lo.	NF	.....	27	10	G1: See preamble text.	−0.09
97760	Orthotic mgmt&trainj 1st enc.	EQ219	rehab and testing system (BTE primus).	NF	.....	27	5	G1: See preamble text.	−3.91
97760	Orthotic mgmt&trainj 1st enc.	ER064	water bath, thermoplastic softener (20in x 12in).	NF	.....	27	10	G1: See preamble text.	−0.04
97760	Orthotic mgmt&trainj 1st enc.	L023A	Physical Therapy Aide.	NF	Assist therapist	5	0	G1: See preamble text.	−1.15
97760	Orthotic mgmt&trainj 1st enc.	L023A	Physical Therapy Aide.	NF	Other Clinical Activity—specify: Verify/Coordinate availability of resources/equipment.	0	1.5	G1: See preamble text.	0.35
97760	Orthotic mgmt&trainj 1st enc.	L023A	Physical Therapy Aide.	NF	Other clinical Activity—specify: post-treatment assistance.	0	1	G1: See preamble text.	0.23
97760	Orthotic mgmt&trainj 1st enc.	L023A	Physical Therapy Aide.	NF	Greet patient, provide gowning, ensure appropriate medical records are available.	2	1.5	G1: See preamble text.	−0.12
97760	Orthotic mgmt&trainj 1st enc.	L023A	Physical Therapy Aide.	NF	Clean room/equipment by physician staff.	2	1	G1: See preamble text.	−0.23

TABLE 11—CY 2018 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
97760	Orthotic mgmt&trainj 1st enc.	L023A	Physical Therapy Aide.	NF	Prepare room, equipment, supplies.	2	1.5	G1: See preamble text.	−0.12
97760	Orthotic mgmt&trainj 1st enc.	L023A	Physical Therapy Aide.	NF	Prepare and position patient.	2	0	G1: See preamble text.	−0.46
97760	Orthotic mgmt&trainj 1st enc.	L039B	Physical Therapy Assistant.	NF	Assist therapist	2.5	7.5	G1: See preamble text.	1.95
97760	Orthotic mgmt&trainj 1st enc.	L039B	Physical Therapy Assistant.	NF	Obtain vital signs.	2	1	G1: See preamble text.	−0.39
97760	Orthotic mgmt&trainj 1st enc.	L039B	Physical Therapy Assistant.	NF	Other Clinical Activity—specify: Review/read documentation, plan of care, treatment goals.	0	1.5	G1: See preamble text.	0.59
97760	Orthotic mgmt&trainj 1st enc.	L039B	Physical Therapy Assistant.	NF	Check dressings & wound/home care instructions/coordinate office visits/prescriptions.	2	2.5	G1: See preamble text.	0.20
97760	Orthotic mgmt&trainj 1st enc.	L039B	Physical Therapy Assistant.	NF	Conduct phone calls/call in prescriptions.	2	0	G1: See preamble text.	−0.78
97760	Orthotic mgmt&trainj 1st enc.	SH035	fluori-methane (cold spray).	NF	.....	5	7.5	G1: See preamble text.	1.06
97760	Orthotic mgmt&trainj 1st enc.	SK082	towel, paper (Bounty) (per sheet).	NF	.....	4	0	G1: See preamble text.	−0.03
97760	Orthotic mgmt&trainj 1st enc.	SK087	water, distilled ..	NF	.....	85	128	G1: See preamble text.	0.56
97760	Orthotic mgmt&trainj 1st enc.	SM012	disinfectant spray (Transeptic).	NF	.....	5	0	G1: See preamble text.	−0.14
97761	Prosthetic trainj 1st enc.	EF028	table, mat, hi-lo, 6 x 8 platform.	NF	.....	27	5	G1: See preamble text.	−0.22
97761	Prosthetic trainj 1st enc.	EQ069	balance board ..	NF	.....	27	4	G1: See preamble text.	−0.03
97761	Prosthetic trainj 1st enc.	EQ201	parallel bars, platform mounted.	NF	.....	27	4	G1: See preamble text.	−0.09
97761	Prosthetic trainj 1st enc.	EQ231	stairs, ambulation training.	NF	.....	27	3	G1: See preamble text.	−0.04
97761	Prosthetic trainj 1st enc.	EQ243	treadmill	NF	.....	27	3	G1: See preamble text.	−0.32
97761	Prosthetic trainj 1st enc.	L023A	Physical Therapy Aide.	NF	Greet patient, provide gowning, ensure appropriate medical records are available.	2	1.5	G1: See preamble text.	−0.12
97761	Prosthetic trainj 1st enc.	L023A	Physical Therapy Aide.	NF	Prepare room, equipment, supplies.	2	0	G1: See preamble text.	−0.46
97761	Prosthetic trainj 1st enc.	L023A	Physical Therapy Aide.	NF	Prepare and position patient.	2	0	G1: See preamble text.	−0.46
97761	Prosthetic trainj 1st enc.	L023A	Physical Therapy Aide.	NF	Other Clinical Activity—specify: Verify/Coordinate availability of resources/equipment.	0	1.5	G1: See preamble text.	0.35

TABLE 11—CY 2018 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
97761	Prosthetic trainj 1st enc.	L023A	Physical Therapy Aide.	NF	Other clinical Activity—specify: post-treatment assistance.	0	1	G1: See preamble text.	0.23
97761	Prosthetic trainj 1st enc.	L023A	Physical Therapy Aide.	NF	Assist therapist	10	0	G1: See preamble text.	−2.30
97761	Prosthetic trainj 1st enc.	L023A	Physical Therapy Aide.	NF	Clean room/equipment by physician staff.	2	1	G1: See preamble text.	−0.23
97761	Prosthetic trainj 1st enc.	L039B	Physical Therapy Assistant.	NF	Other Clinical Activity—specify: Obtain measurements.	0	1.5	G1: See preamble text.	0.59
97761	Prosthetic trainj 1st enc.	L039B	Physical Therapy Assistant.	NF	Obtain vital signs.	2	1	G1: See preamble text.	−0.39
97761	Prosthetic trainj 1st enc.	L039B	Physical Therapy Assistant.	NF	Assist therapist	5	7.5	G1: See preamble text.	0.98
97761	Prosthetic trainj 1st enc.	L039B	Physical Therapy Assistant.	NF	Other Clinical Activity—specify: Review/read documentation, plan of care, treatment goals.	0	1.5	G1: See preamble text.	0.59
97761	Prosthetic trainj 1st enc.	L039B	Physical Therapy Assistant.	NF	Other Clinical Activity—specify: Conduct phone calls/call in prescriptions.	0	1	G1: See preamble text.	0.39
97761	Prosthetic trainj 1st enc.	L039B	Physical Therapy Assistant.	NF	Conduct phone calls/call in prescriptions.	2	0	G1: See preamble text.	−0.78
97761	Prosthetic trainj 1st enc.	L039B	Physical Therapy Assistant.	NF	Check dressings & wound/home care instructions/coordinate office visits/prescriptions.	2	2.5	G1: See preamble text.	0.20
97761	Prosthetic trainj 1st enc.	SB026	gown, patient ...	NF	.....	0.75	0	G1: See preamble text.	−0.40
97761	Prosthetic trainj 1st enc.	SG027	cast, stockinette 4in.	NF	.....	0.3	1	G1: See preamble text.	0.32
97761	Prosthetic trainj 1st enc.	SG058	moleskin 9in width.	NF	.....	0.2	0.33	G1: See preamble text.	0.45
97761	Prosthetic trainj 1st enc.	SK082	towel, paper (Bounty) (per sheet).	NF	.....	4	0	G1: See preamble text.	−0.03
97761	Prosthetic trainj 1st enc.	SM012	disinfectant spray (Transeptic).	NF	.....	5	0	G1: See preamble text.	−0.14
977X1	Orthc/prostc mgmt sbsq enc.	EF005	cart-workbench, orthotic, mobile.	NF	.....	27	10	G1: See preamble text.	−0.03
977X1	Orthc/prostc mgmt sbsq enc.	EF033	table, treatment, hi-lo.	NF	.....	27	16	G1: See preamble text.	−0.06
977X1	Orthc/prostc mgmt sbsq enc.	ER064	water bath, thermoplastic softener (20in x 12in).	NF	.....	27	10	G1: See preamble text.	−0.04
977X1	Orthc/prostc mgmt sbsq enc.	L023A	Physical Therapy Aide.	NF	Other clinical Activity—specify: post-treatment assistance.	0	1	G1: See preamble text.	0.23

TABLE 11—CY 2018 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
977X1	Orthc/prostc mgmt sbsq enc.	L023A	Physical Therapy Aide.	NF	Greet patient, provide gowning, ensure appropriate medical records are available.	2	1.5	G1: See preamble text.	−0.12
977X1	Orthc/prostc mgmt sbsq enc.	L023A	Physical Therapy Aide.	NF	Clean room/ equipment by physician staff.	2	1	G1: See preamble text.	−0.23
977X1	Orthc/prostc mgmt sbsq enc.	L023A	Physical Therapy Aide.	NF	Other Clinical Activity—specify: Verify/Coordinate availability of resources/ equipment.	0	1.5	G1: See preamble text.	0.35
977X1	Orthc/prostc mgmt sbsq enc.	L023A	Physical Therapy Aide.	NF	Assist therapist	5	0	G1: See preamble text.	−1.15
977X1	Orthc/prostc mgmt sbsq enc.	L023A	Physical Therapy Aide.	NF	Prepare room, equipment, supplies.	2	1.5	G1: See preamble text.	−0.12
977X1	Orthc/prostc mgmt sbsq enc.	L023A	Physical Therapy Aide.	NF	Prepare and position patient.	2	0	G1: See preamble text.	−0.46
977X1	Orthc/prostc mgmt sbsq enc.	L039B	Physical Therapy Assistant.	NF	Other Clinical Activity—specify: Review/read documentation, plan of care, treatment goals.	0	1.5	G1: See preamble text.	0.59
977X1	Orthc/prostc mgmt sbsq enc.	L039B	Physical Therapy Assistant.	NF	Obtain vital signs.	2	1	G1: See preamble text.	−0.39
977X1	Orthc/prostc mgmt sbsq enc.	L039B	Physical Therapy Assistant.	NF	Check dressings & wound/home care instructions/coordinate office visits/prescriptions.	2	2.5	G1: See preamble text.	0.20
977X1	Orthc/prostc mgmt sbsq enc.	L039B	Physical Therapy Assistant.	NF	Assist therapist	2.5	7.5	G1: See preamble text.	1.95
977X1	Orthc/prostc mgmt sbsq enc.	SA048	pack, minimum multi-specialty visit.	NF	.....	0.5	1	G1: See preamble text.	0.57
977X1	Orthc/prostc mgmt sbsq enc.	SG027	cast, stockinette 4in.	NF	.....	0.4	0.5	G1: See preamble text.	0.05
977X1	Orthc/prostc mgmt sbsq enc.	SG058	moleskin 9in width.	NF	.....	0.7	1	G1: See preamble text.	1.04
977X1	Orthc/prostc mgmt sbsq enc.	SG060	outrigger line	NF	.....	7	50	G1: See preamble text.	3.91
977X1	Orthc/prostc mgmt sbsq enc.	SG061	outrigger post ...	NF	.....	3	4	G1: See preamble text.	0.40
977X1	Orthc/prostc mgmt sbsq enc.	SH035	fluori-methane (cold spray).	NF	.....	5	7.5	G1: See preamble text.	1.06
977X1	Orthc/prostc mgmt sbsq enc.	SJ047	splint straps 1in	NF	.....	0.7	1	G1: See preamble text.	0.39
977X1	Orthc/prostc mgmt sbsq enc.	SJ048	splint straps 2in	NF	.....	1.3	2	G1: See preamble text.	1.07
977X1	Orthc/prostc mgmt sbsq enc.	SK071	rubber bands, non-sterile.	NF	.....	4	6	G1: See preamble text.	0.04

TABLE 11—CY 2018 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
977X1	Orthc/prostc mgmt sbsq enc.	SK082	towel, paper (Bounty) (per sheet).	NF	.....	4	0	G1: See preamble text.	−0.03
977X1	Orthc/prostc mgmt sbsq enc.	SK087	water, distilled ..	NF	.....	85	128	G1: See preamble text.	0.56
977X1	Orthc/prostc mgmt sbsq enc.	SM012	disinfectant spray (Transeptic).	NF	.....	5	0	G1: See preamble text.	−0.14
97X11	Ther ivntj w/ focus cog funcj.	ED038	notebook (Dell Latitute D600).	NF	.....	60	0	G1: See preamble text.	−0.52
97X11	Ther ivntj w/ focus cog funcj.	EF027	table, instrument, mobile.	NF	.....	60	5	G1: See preamble text.	−0.08
97X11	Ther ivntj w/ focus cog funcj.	L023A	Physical Therapy Aide.	NF	Assist physician in performing procedure.	0	12	G1: See preamble text.	2.76
97X11	Ther ivntj w/ focus cog funcj.	SK057	paper, laser printing (each sheet).	NF	.....	10	0	G1: See preamble text.	−0.05
994X1	1st psyc collab care mgmt.	EF042	One Couch and Two Chairs.	F	.....	38	0	G1: See preamble text.	−0.15
994X1	1st psyc collab care mgmt.	L057B	Behavioral Health Care Manager.	F	Other clinical Activity—specify: 994X1 and 994X3.	85	0	G1: See preamble text.	−48.45
994X2	Sbsq psyc collab care mgmt.	EF042	One Couch and Two Chairs.	F	.....	27	0	G1: See preamble text.	−0.11
994X2	Sbsq psyc collab care mgmt.	L057B	Behavioral Health Care Manager.	F	Other clinical Activity—specify: 994X2.	60	0	G1: See preamble text.	−34.20
994X3	1st/sbsq psyc collab care.	EF042	One Couch and Two Chairs.	F	.....	13.5	0	G1: See preamble text.	−0.05
994X3	1st/sbsq psyc collab care.	L057B	Behavioral Health Care Manager.	F	Other clinical Activity—specify: 994X1 and 994X3.	30	0	G1: See preamble text.	−17.10
99XX5	Care mgmt svc bhvl hlth cond.	L057B	Behavioral Health Care Manager.	F	Other clinical Activity—specify: G0507.	20	0	G1: See preamble text.	−11.40
G0507	Care manage serv minimum 20.	L057B	Behavioral Health Care Manager.	F	Other clinical Activity—specify: G0507.	20	0	G1: See preamble text.	−11.40

TABLE 12—CY 2018 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS WITHOUT REFINEMENT

HCPCS code	Description
007X1	Anes upr gi ndsc px nos.
007X2	Anes upr gi ndsc px ercp.
008X1	Anes lwr intst ndsc nos.
008X2	Anes lwr intst scr colsc.
008X3	Anes upr lwr gi hdsc px.
10040	Acne surgery.
15734	Muscle-skin graft trunk.
15736	Muscle-skin graft arm.
15738	Muscle-skin graft leg.
157X2	Musc myoq/fscq flp h&n pedcl.
19303	Mast simple complete.
31255	Nsl/sins ndsc w/tot ethmdct.
31256	Exploration maxillary sinus.
31267	Endoscopy maxillary sinus.

TABLE 12—CY 2018 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS WITHOUT REFINEMENT—Continued

HCPCS code	Description
31276	Nsl/sins ndsc frnt tiss rmvl.
31287	Nasal/sinus endoscopy surg.
31288	Nasal/sinus endoscopy surg.
31600	Incision of windpipe.
31601	Incision of windpipe.
31603	Incision of windpipe.
31610	Incision of windpipe.
31646	Brnchsc w/ther aspir sbsq.
31XX1	Nsl/sins ndsc w/artery lig.
31XX2	Nsl/sins ndsc total.
31XX3	Nsl/sins ndsc tot w/sphendt.
31XX4	Nsl/sins ndsc sphn tiss rmvl.
34812	Opn fem art expos.
34820	Opn ilac art expos.

TABLE 12—CY 2018 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS WITHOUT REFINEMENT—Continued

HCPCS code	Description
34833	Opn ilac art expos cndt crtj.
34834	Opn brach art expos.
34X01	Evasc rpr a-ao ndgft.
34X02	Evasc rpr a-ao ndgft rpt.
34X03	Evasc rpr a-unilac ndgft.
34X04	Evasc rpr a-unilac ndgft rpt.
34X05	Evac rpr a-biiliac ndgft.
34X06	Evasc rpr a-biiliac rpt.
34X07	Evasc rpr ilio-iliac ndgft.
34X08	Evasc rpr ilio-iliac rpt.
34X09	Plmt xtn prosth evasc rpr.
34X10	Dlyd plmt xtn prosth 1st vsl.
34X11	Dlyd plmt xtn prosth ea addl.
34X12	Tcat dlvr enhncd fixj dev.

TABLE 12—CY 2018 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS WITHOUT REFINEMENT—Continued

HCPCS code	Description
34X13	Perq access & clsr fem art.
34X15	Opn fem art expos cndt crtj.
34X19	Opn ax/subcla art expos.
34X20	Opn ax/subcla art expos cndt.
36218	Place catheter in artery.
364X4	Endoven ther chem adhes sbsq.
36514	Apheresis plasma.
36516	Apheresis immunoads slctv.
36522	Photopheresis.
36556	Insert non-tunnel cv cath.
3857X	Laps pelvic lymphadec.
43107	Removal of esophagus.
43112	Esphg tot w/thrcm.
43117	Partial removal of esophagus.
432X5	Esphg tot w/laps moblj.
432X6	Esphg dstl ⅔ w/laps moblj.
432X7	Esphg tot thrsc moblj.
51798	Us urine capacity measure.
52601	Prostatectomy (turp).
57240	Anterior colporrhaphy.
57250	Repair rectum & vagina.
57260	Cmbn ant pst colprhy.
57265	Cmbn ap colprhy w/ntrcl rpr.
64418	N block inj suprascapular.
64553	Implant neuroelectrodes.

TABLE 12—CY 2018 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS WITHOUT REFINEMENT—Continued

HCPCS code	Description
64555	Implant neuroelectrodes.
64910	Nerve repair w/allograft.
64911	Neurorraphy w/vein autograft.
64X91	Nrv rpr w/nrv algrft 1st.
70490	Ct soft tissue neck w/o dye.
70491	Ct soft tissue neck w/dye.
70492	Ct sft tsue nck w/o & w/dye.
710X1	X-ray exam chest 1 view.
710X2	X-ray exam chest 2 views.
710X3	X-ray exam chest 3 views.
710X4	X-ray exam chest 4+ views.
71100	X-ray exam ribs uni 2 views.
71101	X-ray exam unilat ribs/chest.
71110	X-ray exam ribs bil 3 views.
71111	X-ray exam ribs/chest4/> vws.
73100	X-ray exam of wrist.
73110	X-ray exam of wrist.
73120	X-ray exam of hand.
73130	X-ray exam of hand.
73140	X-ray exam of finger(s).
74022	X-ray exam series abdomen.
740X1	X-ray exam abdomen 1 view.
740X2	X-ray exam abdomen 2 views.
740X3	X-ray exam abdomen 3+ views.
76510	Ophth us b & quant a.

TABLE 12—CY 2018 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS WITHOUT REFINEMENT—Continued

HCPCS code	Description
76511	Ophth us quant a only.
76512	Ophth us b w/non-quant a.
76516	Echo exam of eye.
76519	Echo exam of eye.
76882	Us xtr non-vasc lmtd.
88334	Intraop cyto path consult 2.
92136	Ophthalmic biometry.
93293	Pm phone r-strip device eval.
93296	Pm/icd remote tech serv.
93299	Icm/ilr remote tech serv.
93306	Tte w/doppler complete.
93307	Tte w/o doppler complete.
93308	Tte f-up or lmtd.
95250	Glucose monitoring cont.
95930	Visual ep test cns w/i&r.
96401	Chemo anti-neopl sq/im.
96402	Chemo hormon antineopl sq/im.
96409	Chemo iv push sngl drug.
96411	Chemo iv push addl drug.
96567	Pdt dstr prmlg les skn.
993X1	Pt/caregiver trainj home inr.
993X2	Anticoag mgmt pt warfarin.
99XX3	Assmt & care pln pt cog imp.
GXXX1	Cognitive skills development.

TABLE 13—CY 2018 PROPOSED RULE—INVOICES RECEIVED FOR NEW DIRECT PE INPUTS

CMS code	Average price	Number of invoices	Estimated non-facility allowed services for HCPCS codes using this item
EQ383	790.00	1	39,006
SD322	25.00	1	3,435
EQ384	4,760.00	1	39,006
EQ385	9,034.00	1	39,006
SD323	1,495.00	1	387
SD324	3,195.00	2	1550
SA125	40.00	2	1550
SD328	353.64	1	41
SD325	39.90	1	4
SA126	2,850.00	3	4
EQ386	16,146.00	1	4
SA124	2.35	2	421,539
SJ092	8.44	209	9,931,981
SJ093	0.19	5	9,931,981
SB054	9.99	1	387,359

TABLE 14—CY 2018 PROPOSED RULE—INVOICES RECEIVED FOR EXISTING DIRECT PE INPUTS

CPT/HCPCS codes	Item name	CMS code	Current price	Updated price	Percent change	Number of invoices	Estimated non-facility allowed services for HCPCS codes using this item
17000, 17003, 17004, 46607, 96567, 96X73, 96X74.	LMX 4% anesthetic cream.	SH092	1.60	0.78	−51	1	23,584,412
20982, 32998, 50592	probe, radio-frequency, 3 array (StarBurstSDE).	SD109	353.64	2233.00	531	1	2,972

TABLE 14—CY 2018 PROPOSED RULE—INVOICES RECEIVED FOR EXISTING DIRECT PE INPUTS—Continued

CPT/HCPCS codes	Item name	CMS code	Current price	Updated price	Percent change	Number of invoices	Estimated non-facility allowed services for HCPCS codes using this item
30140, 30901, 30903, 30905, 30906, 31231, 31237, 31238, 43197, 43198.	Atomizer tips (disposable).	SL464	0.00	2.66	.....	1	625,876
36514	tubing set, plasma exchange.	SC085	173.33	273.66	58	1	1,237
36514, 36516	ACD–A anticoagulant	SJ071	6.58	7.10	8	1	2,517
none (formerly in deleted code 36515).	kit, apheresis treatment.	SA072	140.00	243.33	74	1	22
36522	kit, photopheresis procedure.	SA024	858.00	1598.00	86	1	25
36522, 96567, 96910, 96912, 96913, 96920, 96921, 96922, 96X73, 96X74.	goggles, uv-blocking	SJ027	2.30	4.1	78	1	697,047
88360, 88361	Antibody Estrogen Receptor monoclonal.	SL493	14.00	14.47	3	3	209,384
95004, 95017, 95018	negative control, allergy test.	SH101	5.08	5.17	2	2	10,036,050
95004, 95017, 95018	positive control, allergy test.	SH102	17.28	26.12	51	6	10,036,050
95250	sensor, glucose monitoring (interstitial).	SD114	29.50	53.08	80	19	26,205
95250	glucose continuous monitoring system.	EQ125	2465.00	1170.54	−53	5	26,205
993X1, G0249	test strip, INR	SJ055	21.88	5.66	−74	2	1,265,540

I. Evaluation & Management (E/M) Guidelines and Care Management Services

In recent years, we have sought to recognize significant changes in health care practice, especially innovations in the active management and ongoing care of chronically ill patients. We have been engaged in an ongoing incremental effort to identify gaps in appropriate coding and payment for care management/coordination, cognitive services and primary care within the PFS. This has included working with the CPT Editorial Panel (CPT) to develop and value (or revalue) the following service codes:

- Transitional care management (TCM) services (2013).
- Chronic care management services (CCM) (2015, 2017).
- Behavioral health integration (BHI) services (2017).
- Assessment/care planning services for cognitive impairment (2017).
- Prolonged E/M services without direct patient contact (2017).

In response to public feedback regarding the initial implementation of TCM and CCM, in the CY 2017 PFS final rule (81 FR 80225 through 80256), we finalized significant administrative burden reduction for CCM and focused on limiting as much as possible the ways in which Medicare's rules differed from the CPT guidance that generally applies for all payers. We also worked with the CPT Editorial Panel and other stakeholders to develop coding and improve payment accuracy for BHI, cognitive impairment assessment/management, and prolonged services. In the CY 2017 PFS final rule (81 FR 80255), we also reiterated our commitment to addressing disparities for individuals with disabilities and advancing health equity, and noted that we will continue to explore improvements in payment accuracy for services furnished to individuals with disabilities. We look forward to continued work with stakeholders to ensure that the coding and valuation of these services accurately reflects the resource costs involved in furnishing these services. We are soliciting public comments on ways we might further reduce administrative burden for these and similar services under the PFS.

1. E/M Guidelines

a. Background

Most physicians and other billing practitioners bill patient visits to the PFS under a relatively generic set of codes that distinguish level of complexity, site of care, and in some cases between new or established patients. These codes are called Evaluation and Management (E/M) visit codes. For example, there are generally three levels of hospital and nursing facility inpatient E/M visit codes, and five levels of office or hospital outpatient E/M visit codes, that vary based on complexity. The latter also distinguish whether or not the patient is new to the billing practitioner.

Billing practitioners must maintain information in the medical record to document that they have reported the appropriate level of E/M visit code. CMS maintains guidelines that specify the kind of information that is required to support Medicare payment for each level. According to these documentation guidelines, there are three key components to selecting the appropriate level:

- History of Present Illness (HPI or History);
- Physical Examination (Exam); and
- Medical Decision Making (MDM).

There are two versions of the documentation guidelines, commonly referenced based on the year of their

release (the ''1995'' and ''1997'' guidelines), available under downloads on the CMS Web site at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html.* The most substantial differences between the two sets of guidelines pertain to requirements for the physical exam. The two versions have a slight difference in requirements for documenting the history, and no difference in requirements for MDM. In documenting a given E/M service, practitioners must use one version of the guidelines or the other, with one exception related to extended histories (see the Evaluation and Management Services guide available on the CMS Web site at *https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/eval-mgmt-serv-guide-ICN006764.pdf*). These guidelines are very similar to guidelines within the CPT codebook for E/M visits. We provide an example of how the guidelines distinguish between level 2 and level 3 visits in Table 15.

Stakeholders have long maintained that both the 1995 and 1997 guidelines are administratively burdensome and outdated with respect to the practice of medicine, stating that they are too complex, ambiguous, and that they fail to distinguish meaningful differences among code levels. In general, we agree that there may be unnecessary burden with these guidelines and that they are potentially outdated, and believe this is especially true for the requirements for the history and the physical exam. The guidelines have not been updated to account for significant changes in technology, especially electronic health record (EHR) use, which presents challenges for data and program integrity and potential upcoding given the frequently automated selection of code level.

While CMS conducts few audits on E/M visits relative to the volume of PFS services they comprise, we have repeatedly heard from practitioners that compliance with the guidelines is a source of significant audit vulnerability and administrative burden. Our prior attempts to revise the guidelines met with a lack of stakeholder consensus and support, which contributed to the current policy that allows practitioners to use either the 1995 guidelines or 1997 guidelines, resulting in further complexity in determining or selecting the applicable requirements.

b. E/M Guidelines Public Comment Solicitation

We continue to agree with stakeholders that the E/M documentation guidelines should be substantially revised. We believe that a comprehensive reform of E/M documentation guidelines would require a multi-year, collaborative effort among stakeholders. We believe that revised guidelines could both reduce clinical burden and improve documentation in a way that would be more effective in clinical workflows and care coordination. We also think updated E/M guidelines coupled with technological advancements in voice recognition, natural language processing and user-centered design of EHRs could improve documentation for patient care while also meeting requirements for billing and population health management. We recognize that achieving the goal of reduced clinician burden and improved, meaningful documentation for patient care will require both updated E/M guidelines, as well as changes in technology, clinician documentation practices and workflow. We are seeking input from a broad array of stakeholders, including patient advocates, on the specific changes we should undertake to reform the guidelines, reduce the associated burden, and better align E/M coding and documentation with the current practice of medicine. We are specifically seeking comment on how we might focus on initial changes to the guidelines for the history and physical exam because we believe documentation for these elements may be more significantly outdated, and that differences in MDM are likely the most important factors in distinctions between visits of different levels. We are also specifically seeking comment on whether it would be appropriate to remove our documentation requirements for the history and physical exam for all E/M visits at all levels. We believe medical decision-making and time are the more significant factors in distinguishing visit levels, and that the need for extended histories and exams is being replaced by population-based screening and intervention, at least for some specialties. In addition, an increase in the utilization of EHRs, and to some extent, shared health information via EHRs, may have changed the character of extended patient histories since the guidelines were established. As long as a history and physical exam are documented and generally consistent with complexity of MDM, there may no longer be a need for us to maintain such detailed specifications for what must be performed and documented for the history and physical exam (for example, which and how many body systems are involved). We are seeking comment on whether clinicians and other stakeholders believe removing the documentation requirements for the history and physical exam would be a good approach.

While we believe MDM guidelines may also need to be updated, we believe in the nearer term it may be possible to eliminate the current focus on details of history and physical exam, and allow MDM and/or time to serve as the key determinant of E/M visit level. We are seeking public comment on this approach. We are also seeking comment on how such reforms may differentially affect physicians and practitioners of different specialties, including primary care clinicians, and how we could or should account for such effects as we examine this issue. We note, however, that there may still be clinical or legal reasons for individual practitioners to document an extended history or physical exam (for example, where there are negative findings for certain body systems in support of differential diagnosis). We are additionally seeking comment on whether CMS should leave it largely to the discretion of individual practitioners to what degree they should perform and document the history and physical exam. We also welcome comments on specific ideas that stakeholders may have on how to update MDM guidelines to foster appropriate documentation for patient care commensurate with the level of patient complexity, while avoiding burdensome documentation requirements and/or inappropriate upcoding.

We note that through letters, meetings, public comment letters in past rulemaking cycles, and other avenues, we have heard from many stakeholders that the E/M code set itself is outdated and needs to be revised. For example, some stakeholders recommend an extensive research effort to revise and revalue E/M services, especially physician work inputs (see 81 FR 46200). In prior rulemaking cycles, we acknowledged the limitations of the current E/M code set and agree that the structure of the underlying code set and its valuation relative to other PFS services are also important issues that we expect to continue to explore, though we are immediately focused on revision of the current E/M guidelines in order to reduce unnecessary administrative burden.

2. Care Management Public Comment Solicitation

We continue to be interested in the ongoing work of the medical community and other stakeholders to refine the set of codes used to describe care

management services. In section II.H., we are proposing to adopt CPT codes for CY 2018 to replace the G-codes we established for several of the care management services finalized last year. We are committed to continued work with stakeholders on necessary refinements to the code set, especially describing the professional work involved in caring for complex patients in other clinical contexts. We are seeking comment on ways we might further reduce burden on reporting practitioners for care management services, including through stronger alignment between CMS requirements and CPT guidance for existing and potential new codes.

TABLE 15—KEY COMPONENT DOCUMENTATION REQUIREMENTS FOR LEVEL 2 VS 3 EVALUATION & MANAGEMENT (E/M) VISIT

Key component †	Level 2 (1995)	Level 3 (1995)	Level 2 (1997)	Level 3 (1997)
History (History of Present Illness or HPI).	Review of Systems (ROS) n/a.	Problem Pertinent ROS: inquires about the system directly related to the problem(s) identified in the HPI.	No change from 1995	No change from 1995.
Physical Examination (Exam).	A limited examination of the affected body area or organ system.	A limited examination of the affected body area or organ system and other symptomatic or related organ system(s).	General multi-system exam: Performance and documentation of one to five elements in one or more organ system(s) or body area(s). Single organ system exam: Performance and documentation of one to five elements.	General multi-system exam: Performance and documentation of at least six elements in one or more organ system(s) or body area(s). Single organ system exam: Performance and documentation of at least six elements.
Medical Decision Making (MDM)	Straightforward: 1. Minimal 2. Minimal or no data review 3. Minimal risk	Low complexity: 1. Limited 2. Limited data review 3. Low risk	No change from 1995.	
Measured by: * 1. Problem—Number of diagnoses/treatment options 2. Data—Amount and/or complexity of data to be reviewed 3. Risk—Risk of complications and/or morbidity or mortality				

* Two of three met or exceeded.

† For certain settings and patient types, each of these three key components must be met or exceeded (for example, new patients; initial hospital visits). For others, only two of the three key components must be met or exceeded (for example, established patients, subsequent hospital or other visits).

III. Other Provisions of the Proposed Rule

A. New Care Coordination Services and Payment for Rural Health Clinics (RHCs) and Federally-Qualified Health Centers (FQHCs)

1. Overview

We have been engaged in a multi-year examination of coordinated and collaborative care services in professional settings, and as a result established codes and separate payment in the Physician Fee Schedule (PFS) to separately recognize and pay for these important services. As part of this initiative, the CY 2016 PFS proposed rule (80 FR 41708) solicited public comments on (1) improving payment for the professional work of care management services; (2) establishing separate payment for collaborative care, particularly inter-professional consultation between primary care physicians, psychiatrists, and other practitioners; and (3) assessing whether current PFS payment for Chronic Care Management (CCM) services is adequate and whether the administrative burden associated with furnishing and billing these services should be reduced.

As a result of the comments we received in response to our request, we established in the PFS separate payment for complex CCM services, and temporary codes to make separate payment for general behavioral health integration (BHI) services and a psychiatric collaborative care model (CoCM). We established four G codes to describe BHI and psychiatric CoCM services and stated that we would consider whether to adopt and establish values for any associated new CPT codes being developed under our standard process once those codes are active. The separate payment for complex CCM services, general BHI, and psychiatric CoCM services were finalized in the CY 2017 PFS final rule (81 FR 80225) beginning January 1, 2017, for practitioners billing under the PFS. Based on these payments and codes, we are proposing revisions to the CCM payment for RHCs and FQHCs, and proposing requirements and payment for general BHI and psychiatric CoCM services furnished in RHCs and FQHCs, beginning on January 1, 2018.

2. Background

a. RHC and FQHC Payment Methodologies

RHC and FQHC visits are face-to-face encounters between a patient and one or more RHC or FQHC practitioners during which time one or more RHC or FQHC qualifying services are furnished. RHC and FQHC practitioners are physicians, nurse practitioners (NPs), physician assistants (PA), certified nurse midwives (CNMs), clinical psychologists, and clinical social workers, and under certain conditions, a registered nurse or licensed practical nurse furnishing care to a homebound RHC or FQHC patient. A Transitional Care Management (TCM) service can also be an RHC or FQHC visit, and a Diabetes Self-Management Training (DSMT) service or a Medical Nutrition Therapy (MNT) service furnished by a certified DSMT or MNT provider may also be an FQHC visit. Only medically-necessary medical, mental health, or qualified preventive health services that require the skill level of an RHC or FQHC practitioner are RHC or FQHC billable visits. Services furnished by auxiliary personnel (for example, nurses, medical assistants, or other clinical personnel acting under the supervision of the RHC or FQHC practitioner) are considered incident to the visit and are included in the per-visit payment.

RHCs are paid an all-inclusive rate (AIR) for medically necessary medical and mental health services and qualified preventive health services furnished on the same day (with some exceptions). In general, the A/B Medicare Administrative Contractor (MAC) calculates the AIR for each RHC by dividing total allowable costs by the total number of visits for all patients. Productivity, payment limits, and other factors are also considered in the calculation. Allowable costs must be reasonable and necessary and may include practitioner compensation, overhead, equipment, space, supplies, personnel, and other costs incident to the delivery of RHC services. The AIR is subject to a payment limit, except for certain provider-based RHCs that have an exception to the payment limit.

FQHCs were paid under the same AIR methodology until October 1, 2014, when, in accordance with section 1834(o) of the Act (as added by section 10501(i)(3) of the Affordable Care Act), they began to transition to an FQHC PPS system in which they are paid based on the lesser of the FQHC PPS rate or their actual charges. The FQHC PPS rate is adjusted for geographic differences in the cost of services by the FQHC PPS geographic adjustment factor (GAF). The rate is increased by 34 percent when an FQHC furnishes care to a patient that is new to the FQHC, or to a beneficiary receiving an Initial Preventive Physical Examination (IPPE) or has an Annual Wellness Visit (AWV).

Both the RHC AIR and FQHC PPS payment rates were designed to reflect the cost of all services and supplies that an RHC or FQHC furnishes to a patient in a single day. The rates are not adjusted for the complexity of the patient health care needs, the length of the visit, or the number or type of practitioners involved in the patient's care.

b. Current CCM Requirements and Payment for RHCs and FQHCs

In the CY 2016 PFS final rule with comment period (80 FR 71080), we finalized policies for payment of CCM services in RHCs and FQHCs. Payment for CCM services in RHCs and FQHCs was effective beginning on January 1, 2016, for RHCs and FQHCs that furnish a minimum of 20 minutes of qualifying CCM services during a calendar month to patients with multiple (two or more) chronic conditions that are expected to last at least 12 months or until the death of the patient, and that would place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline. The requirement that RHC or FQHC services be furnished face-to-face was waived for CCM services.

In the CY 2017 PFS final rule (81 FR 80256), we finalized revisions to the CCM requirements for RHCs and FQHCs. Specifically, we revised § 405.2413(a)(5) and § 405.2415(a)(5) to state that services and supplies furnished incident to CCM and TCM services can be furnished under general supervision of an RHC or FQHC practitioner, consistent with § 410.26(b)(5), which allows CCM and TCM services and supplies to be furnished by clinical staff under general supervision when billed under the PFS. We also revised requirements pertaining to the provision of CCM services, consistent with the same revisions for practitioners billing under the PFS to reduce the burden of furnishing these services and promote beneficiary access to these services. These revisions were effective beginning on January 1, 2017, and included:

- Revising the requirement that CCM be initiated during a comprehensive evaluation and management (E/M), AWV, or IPPE visit, to require a separately billable initiating visit only for new patients or patients that have not had an E/M, AWV, or IPPE visit within the previous year;
- Revising the requirement that CCM services be available 24/7 with an RHC or FQHC practitioner who has access to the patient's electronic care plan, to allow 24/7 access to auxiliary personnel with a means to make contact with an RHC or FQHC practitioner;
- Removing the restriction on faxing information, and no longer requiring that care plan information be available on a 24/7 basis;
- Removing the requirement that clinical summaries must be formatted according to certified EHR technology, and instead requiring that the RHC or FQHC create, exchange, and transmit continuity of care document(s) in a timely manner with other practitioners and providers;
- Removing the description of the format of the care plan that is given to the patient or caregiver; and
- Revising the requirement that RHCs and FQHCs obtain a written agreement that the elements of CCM were discussed, to allowing this information to be documented in the medical record.

In the CY 2017 PFS final rule, we stated that although CCM is typically associated with primary care conditions, patient eligibility is determined by the RHC or FQHC practitioner, and mental health conditions are not excluded. We invited comments on whether an additional code specifically for mental health conditions is necessary for RHCs and FQHCs that want to include beneficiaries with mental health conditions in their CCM services. We received a few comments regarding mental health services in RHCs and FQHCs and appreciate the information that was provided.

The CCM payment rate for RHCs and FQHCs is set annually based on the PFS national non-facility payment rate, and is paid when CPT code 99490 is billed alone or with other payable services on an RHC or FQHC claim. The 2017 rate for RHCs and FQHCs is $42.71 for 20 minutes or more of CCM services. This is the only RHC and FQHC service that is paid in this manner, and RHCs and FQHCs are not currently authorized to be paid for any other CCM or other care management codes. Also, RHCs and FQHCs cannot bill for CCM services for a beneficiary during the same service period as billing for TCM or any other program that provides additional payment for care management services (outside of the RHC AIR or FQHC PPS payment) for the same beneficiary.

Additional information on CCM requirements is available on the CMS Care Management Web page at *https://www.cms.gov/Medicare/Medicare-Fee-*

for-Service-Payment/PhysicianFeeSched/Care-Management.html and on the CMS RHC and FQHC Web pages at *https://www.cms.gov/Center/Provider-Type/Rural-Health-Clinics-Center.html* and *https://www.cms.gov/Center/Provider-Type/Federally-Qualified-Health-Centers-FQHC-Center.html.*

c. Payment for Care Management Codes under the PFS

CCM Services (CPT Code 99487 and CPT Code 99489)

As we stated in the CY 2017 PFS final rule (81 FR 80244), the initial claims data for CCM services billed under the PFS showed that although utilization was increasing steadily, use of CPT code 99490 was still relatively low, and interviews with practitioners indicated that many believed that they were exceeding the 20-minute time threshold for billing this code. To pay as accurately as possible and to encourage access to CCM services, the CY 2017 PFS final rule established separate payment for two additional CCM codes, CPT code 99487 and CPT code 99489, effective beginning on January 1, 2017, for practitioners billing under the PFS. These codes are for complex CCM services that reflect additional clinical staff time, more extensive care planning, and higher complexity of the patient.

CPT code 99487 is for complex CCM services. It requires multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient; chronic conditions that place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline; establishment or substantial revision of a comprehensive care plan; moderate or high complexity medical decision making; and 60 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month.

CPT code 99489 is for each additional 30 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month.

Practitioners paid under the PFS can bill either complex (CPT code 99487 and CPT code 99489) or non-complex (CPT code 99490) CCM services during a given service period, and can submit only one professional claim for CCM services for that service period.

General BHI Services (HCPCS Code G0507)

The types of chronic conditions that are eligible for CCM services are not specified and could include chronic mental health or behavioral health conditions or chronic cognitive disorders as long as the CCM requirements are met. However, because not all behavioral health issues fit into the CCM model, and Medicare beneficiaries with behavioral health conditions often require extensive care management discussions, information-sharing, and planning between a primary care practitioner and a behavioral health specialist, the CY 2017 PFS final rule established HCPCS code G0507 for 20 minutes or more of general BHI services. Payment for this code was effective beginning on January 1, 2017, for practitioners billing under the PFS.

BHI is a team-based, collaborative approach to care that focuses on integrative treatment of patients with primary care and mental or behavioral health conditions. As finalized in the CY 2017 PFS final rule, requirements for this code include an initial assessment or follow-up monitoring (including the use of applicable validated rating scales); behavioral health care planning in relation to behavioral/psychiatric health problems (including revision for patients who are not progressing or whose status changes); facilitating and coordinating treatment such as psychotherapy, pharmacotherapy, counseling and/or psychiatric consultation; and continuity of care with a designated member of the care team.

Psychiatric CoCM Services (HCPCS codes G0502, G0503, and G0504)

Psychiatric CoCM is a specific model of care provided by a primary care team consisting of a primary care provider and a health care manager who works in collaboration with a psychiatric consultant. As finalized in the CY 2017 PFS final rule, we provide Medicare payment for psychiatric CoCM services to practitioners billing under the PFS when these services are directed by a treating physician or other qualified health care professional. We also finalized that the treating physician or other qualified health care professional directs the behavioral health care manager, who must be an individual with formal education or specialized training in behavioral health, including social work, nursing, or psychology, working under the oversight and direction of the physician or qualified health care professional. We finalized that a psychiatric consultant must be a medical professional trained in psychiatry and qualified to prescribe the full range of medications. Finally, psychiatric CoCM services may be furnished to beneficiaries with any psychiatric or behavioral health condition(s) and may include substance use disorders. The three psychiatric CoCM codes established in the CY 2017 PFS final rule were G0502, G0503, and G0504.

HCPCS code G0502 is for 70 minutes or more of initial psychiatric CoCM services in the first calendar month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified health care professional. Required elements include: outreach to and treatment of a patient as directed by the treating physician or other qualified health care professional; initial assessment of the patient, including administration of validated rating scales, with the development of an individualized treatment plan; review by the psychiatric consultant with modifications of the plan, if recommended; entering of the patient into a registry and tracking patient follow-up and progress using the registry (with appropriate documentation), participation in weekly caseload consultation with the psychiatric consultant; and provision of brief interventions using evidence-based techniques such as behavioral activation, motivational interviewing, and other focused treatment strategies.

HCPCS code G0503 is for 60 minutes of subsequent psychiatric CoCM services in a subsequent month and includes: tracking patient follow-up and progress using the registry (with appropriate documentation); participation in weekly caseload consultation with the psychiatric consultant; ongoing collaboration with and coordination of the patient's mental health care with the treating physician or other qualified health care professional and any other treating mental health providers; additional review of progress and recommendations for changes in treatment, as indicated, including medications, based on recommendations provided by the psychiatric consultant; provision of brief interventions using evidence-based techniques (such as behavioral activation, motivational interviewing, and other focused treatment strategies); monitoring of patient outcomes using validated rating scales; and relapse prevention planning with patients as they achieve remission of symptoms and/or other treatment goals and are prepared for discharge from active treatment.

HCPCS code G0504 is for each additional 30 minutes of initial or subsequent psychiatric CoCM services in a calendar month.

3. Proposed Care Management Requirements and Payment for RHCs and FQHCs

To ensure that RHC and FQHC patients have access to new care management services in a manner consistent with the RHC and FQHC per diem payment methodologies, we are proposing the establishment of two new G codes for use by RHCs and FQHCs. The first new G code, GCCC1, would be a General Care Management code for RHCs and FQHCs, with the payment amount set at the average of the national non-facility PFS payment rates for CCM codes 99490 and 99487 and general BHI code G0507. The second new G code for RHCs and FQHCs, GCCC2, would be a Psychiatric CoCM code,with the payment amount set at the average of the national non-facility PFS payment rates for psychiatric CoCM codes G0502 and G0503. The following is a detailed discussion of our proposal, as well as alternatives that we considered.

a. Proposed Establishment of a General Care Management Code for RHCs and FQHCs

The RHC AIR and the FQHC PPS rate, which include all costs associated with an RHC or FQHC visit, are based on the RHC's and FQHC's costs. Although many RHCs and FQHCs have always provided some coordination of care within and outside their facilities, the type of structured care management services that are now billable under the PFS are generally not included in the RHC AIR or the FQHC PPS rate. Because CCM services are not required to be face-to-face encounters, and do not require the skill level of an RHC or FQHC practitioner, they do not meet the requirements for an RHC or FQHC billable visit. In addition, RHC and FQHC services cannot be separately billed to the PFS. Therefore, in the CY 2016 PFS final rule with comment period, we established payment for CCM services at the PFS national non-facility rate when CPT code 99490 is billed alone or with other payable services on an RHC or FQHC claim to pay for the costs of CCM services that are not already captured in the RHC AIR or the FQHC PPS payment.

When CCM services were first established for RHCs and FQHCs, CPT code 99490 was the only CCM code that was billable under the PFS. Now that there are additional codes for more complex CCM services and for general BHI and psychiatric CoCM services, we believe it is necessary to revise our payment approach for payment of care management services.

RHCs and FQHCs are paid per-visit rates that are not adjusted based on the complexity of a service or the time spent furnishing services, and the payment rate is not designed to be equal to the payment under the PFS for a specific service. We sought to develop a methodology for payment of care management services that is consistent with the RHC and FQHC payment principles of bundling services and not paying for services based on time increments. We also sought to develop a methodology that would support the provision of care management services without creating additional reporting burdens, while promoting beneficiary access to comprehensive CCM and BHI services furnished by RHCs and FQHCs.

Therefore, effective for services furnished on or after January 1, 2018, we are proposing to create General Care Management code GCCC1 for RHCs and FQHCs, with the payment amount set at the average of the 3 national non-facility PFS payment rates for the CCM and general BHI codes and updated annually based on the PFS amounts. The 3 codes are:

- CPT 99490—20 minutes or more of CCM services
- CPT 99487—at least 60 minutes of complex CCM services
- HCPCS G0507—20 minutes or more of BHI services

RHCs and FQHCs could bill the new General Care Management code when the requirements for any of these 3 codes (CPT codes 99490, 99487, or HCPCS code G0507) are met. The General Care Management code would be billed alone or in addition to other services furnished during the RHC or FQHC visit. This code could only be billed once per month per beneficiary, and could not be billed if other care management services (such as TCM or home health care supervision) are billed for the same time period. We note that CPT 99489 is an add-on code when CPT 99487 is furnished, and is therefore not included as RHCs and FQHCs are not paid for additional time once the minimum requirements have been met.

As previously noted, the program requirements for RHCs and FQHCs furnishing CCM services were established in the CY 2016 PFS final rule with comment period (80 FR 71080) and revised in the CY 2017 PFS final rule (81 FR 80256). We are not proposing any changes to these requirements at this time.

BHI refers to care management services that integrate behavioral health services with primary care and other clinical services. To bill for this service using the proposed General Care Management Code for RHCs and FQHCs, 20 minutes or more of clinical staff time, directed by an RHC or FQHC practitioner, must be furnished per calendar month. We are proposing the following requirements for RHCs and FQHCs furnishing BHI services:

- Initiating Visit: An E/M, AWV, or IPPE visit with an RHC or FQHC primary care practitioner (physician, NP, PA, or CNM) occurring no more than one-year prior to commencing BHI services. This could be the same initiating visit that is used for initiating CCM services, and would be billed separately as an RHC or FQHC visit (if the RHC or FQHC has not already billed for this visit).
- Beneficiary Consent: Documentation in the medical record that the beneficiary has consented to receive BHI services, given permission to consult with relevant specialists as needed, and been informed that there may be beneficiary cost-sharing, including deductible and coinsurance amounts as applicable, for both in-person and non-face-to-face services that are provided. The beneficiary consent process would also include informing the patient that only one practitioner/facility can furnish and be paid for these services during a calendar month, and that the patient can stop care coordination services at any time (effective at the end of the calendar month). This could be obtained at the same time that beneficiary consent is obtained for CCM services.
- Billing Requirements: At least 20 minutes of care management services per calendar month, furnished under the direction of the RHC or FQHC primary care physician, NP, PA, or CNM, and furnished by an RHC or FQHC practitioner, or by clinical personnel under general supervision. These are the same billing requirements as for CCM services. If both CCM and BHI services are furnished in the same month, the time would be combined and billed as one under the new care coordination code.
- Patient Eligibility: One or more new or pre-existing behavioral health or psychiatric conditions being treated by the RHC or FQHC primary care practitioner, including substance use disorders, that, in the clinical judgment of the RHC or FQHC primary care practitioner, warrants BHI services.
- Required Service Elements: An initial assessment or follow-up monitoring, including the use of applicable validated rating scales; behavioral health care planning in relation to behavioral/psychiatric health problems, including revision for patients who are not progressing or whose status changes; facilitating and

coordinating treatment such as psychotherapy, pharmacotherapy, counseling and/or psychiatric consultation; and continuity of care with a designated member of the care team.

Both CCM and general BHI services are intended to provide a structured and coordinated approach to care management that is not typically included in the RHC's AIR or the FQHC PPS payment methodology. Care management services are directed by the RHC or FQHC primary care practitioner, who remains involved through ongoing oversight, management, collaboration and reassessment, while care management services are typically furnished in a non-face-to-face setting primarily by a non-RHC or FQHC practitioner working under general supervision requirements. Time spent by administrative or clerical staff cannot be counted towards the time required to bill these services.

Table 16 compares the requirements for CCM and general BHI services. We believe that even though there are some differences in the requirements of CCM and general BHI, bundling them together will help to promote integrated care management services for Medicare beneficiaries who have either or both primary care and behavioral health needs. It will also result in the least amount of reporting burden for RHCs and FQHCs because once the 20-minute threshold is met for either CCM or general BHI, reporting and tracking of additional time increments is not required.

If this policy had been adopted for CY 2017, the payment amount for General Care Management for RHCs and FQHCs would have been approximately $61 (CPT 99490 at $42.71, + CPT 99487 at $93.67, + G0507 at $47.73 = $184.11/3 = $61.37). This is more than is the CY 2017 PFS national non-facility rates for CPT code 99490 and HCPCS code G0507, and less than the PFS national non-facility rate for CPT code 99487. We believe that this bundling methodology is consistent with the RHC and FQHC payment methodology of averaging costs to determine a payment rate rather than paying for each individual service.

TABLE 16—COMPARISON OF PROPOSED CCM AND GENERAL BHI REQUIREMENTS FOR RHCS AND FQHCS

Requirements	CCM (CPT codes 99490 and 99487)	General BHI (proposed) (HCPCS code G0507)
Initiating Visit	An E/M, AWV, or IPPE visit occurring no more than one-year prior to commencing care coordination services.	Same.
	Furnished by a primary care physician, NP, PA, or CNM.	Same.
	Billed as an RHC/FQHC visit	Same.
Beneficiary Consent	Obtained during or after initiating visit and before provision of care coordination services by RHC or FQHC practitioner or clinical staff.	Same.
	Written or verbal, documented in the medical record	Same.
	Includes information: • On the availability of care coordination services and applicable cost-sharing; • That only one practitioner can furnish and be paid for care coordination services during a calendar month; • That the patient has right to stop care coordination services at any time (effective at the end of the calendar month); and • That the patient has given permission to consult with relevant specialists.	Same.
Billing Requirements	At least 20 minutes of care coordination services per calendar month that is: • Furnished under the direction of the RHC or FQHC primary care physician, NP, PA, or CNM; and • Furnished by an RHC or FQHC practitioner, or by clinical personnel under general supervision.	Same.
Patient Eligibility	Multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient, and place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline.	Any behavioral health or psychiatric condition being treated by the RHC or FQHC primary care practitioner, including substance use disorders, that, in the clinical judgment of the RHC or FQHC practitioner, warrants BHI services.

TABLE 16—COMPARISON OF PROPOSED CCM AND GENERAL BHI REQUIREMENTS FOR RHCS AND FQHCS—Continued

Requirements	CCM (CPT codes 99490 and 99487)	General BHI (proposed) (HCPCS code G0507)
Requirement Service Elements.	Includes: • Structured recording of patient health information using Certified EHR Technology and includes demographics, problems, medications, and medication allergies that inform the care plan, care coordination, and ongoing clinical care; • 24/7 access to physicians or other qualified health care professionals or clinical staff including providing patients/caregivers with a means to make contact with health care professionals in the practice to address urgent needs regardless of the time of day or day of week, and continuity of care with a designated member of the care team with whom the patient is able to schedule successive routine appointments; • Comprehensive care management including systematic assessment of the patient's medical, functional, and psychosocial needs; system-based approaches to ensure timely receipt of all recommended preventive care services; medication reconciliation with review of adherence and potential interactions; and oversight of patient self-management of medications; • Comprehensive care plan including the creation, revision, and/or monitoring of an electronic care plan based on a physical, mental, cognitive, psychosocial, functional, and environmental (re)assessment and an inventory of resources and supports; a comprehensive care plan for all health issues with particular focus on the chronic conditions being managed; • Care plan information made available electronically (including fax) in a timely manner within and outside the RHC or FQHC as appropriate and a copy of the plan of care given to the patient and/or caregiver; • Management of care transitions between and among health care providers and settings, including referrals to other clinicians; follow-up after an emergency department visit; and follow-up after discharges from hospitals, skilled nursing facilities, or other health care facilities; timely creation and exchange/transmit continuity of care document(s) with other practitioners and providers; • Coordination with home- and community-based clinical service providers, and documentation of communication to and from home- and community-based providers regarding the patient's psychosocial needs and functional deficits in the patient's medical record; and • Enhanced opportunities for the patient and any caregiver to communicate with the practitioner regarding the patient's care through not only telephone access, but also through the use of secure messaging, Internet, or other asynchronous non-face-to-face consultation methods.	Includes: • Initial assessment or follow-up monitoring, including the use of applicable validated rating scales; • Behavioral health care planning in relation to behavioral/psychiatric health problems, including revision for patients who are not progressing or whose status changes; • Facilitating and coordinating treatment (such as psychotherapy, pharmacotherapy, counseling and/or psychiatric consultation); and • Continuity of care with a designated member of the care team.
CY 2017 PFS Non-Facility Payment.	CPT 99490—$42.71 ..... CPT 99487—$93.67	G0507—$47.73.
RHC/FQHC Payment for new General Care Management G code.	Current: $42.71 ..... Proposed: Average of CPT codes 99490, 99487 and G0507 (If using the 2017 payment amounts, this would be $61.37).	Current: N/A Proposed: Average of CPT codes 99490, 99487 and G0507 (If using the 2017 payment amounts, this would be $61.37).

We expect that utilization of care coordination services will continue to increase as more health care practices, including RHCs and FQHCs, implement these services. Because the separate payments for the complex CCM codes have only been implemented this year for practitioners billing under the PFS, we do not have adequate data to determine the frequency of billing for CCM codes CPT codes 99487 by practitioners billing under the PFS compared with CPT code 99490. Although billing practices may vary between physician offices and RHCs and FQHCs (and within and between RHCs and FQHCs), we believe that utilization patterns under the PFS can provide a reasonable proxy for utilization practices in RHCs and FQHCs of care coordination utilization. If the PFS data starts to show definitive trends in billing certain CCM and BHI codes, or if data becomes available that provides information on the extent of these services in RHCs and FQHCs, we may consider using a weighted average

in determining the payment rate in the future. Similarly, if the proposal to create a new care management code for RHCs and FQHCs is finalized, and any additional care management codes become available on the PFS, we would review the new codes to determine if they should also be factored into the RHC and FQHC General Care Management Code. Any changes would be undertaken through future rulemaking.

b. Proposed Establishment of a Psychiatric CoCM Code for RHCs and FQHCs

Psychiatric CoCM is a defined model of care that integrates primary health care services with care management support for patients receiving behavioral health treatment, and includes regular psychiatric inter-specialty consultation with the primary care team, particularly regarding patients whose conditions are not improving. We recognize that the requirements of this model may be challenging for some RHCs and FQHCs, especially those who have difficulty maintaining adequate primary care and mental health staffing in rural and or underserved areas. For those RHCs and FQHCs that choose to offer these services, we believe this model may be particularly helpful, especially for patients with primary care and mental health conditions who have not benefited from standard treatment.

Effective for services furnished on or after January 1, 2018, we are proposing to create a psychiatric CoCM code for RHCs and FQHCs, GCCC2, with the payment amount set at the average of the 2 national non-facility PFS payment rates for CoCM codes, to be updated annually based on the PFS amounts. The 2 codes are:

- G0502—70 minutes or more of initial psychiatric CoCM services
- G0503—60 minutes or more of subsequent psychiatric CoCM services

RHCs and FQHCs could bill the new psychiatric CoCM code when the requirements for any of these 2 codes (G0502 or G0503) are met. The psychiatric CoCM code would be billed alone or in addition to other services furnished during the RHC or FQHC visit. To prevent duplication of payment, this code could only be billed once per month per beneficiary, and could not be billed if other care management services, including the proposed General Care Management code, are billed for the same time period. We note that G0504 is an add-on code when G0503 is furnished and is therefore not included as RHCs and FQHCs are not paid for additional time once the minimum requirements have been met.

If this policy had been adopted for CY 2017, the payment amount for psychiatric CoCM for RHCs and FQHCs would have been approximately $134.58 (G0502 at $142.84 + G0503 at $126.33 = $269.17/2 = $134.58).

All care management services, including psychiatric CoCM, require a separately billable initiating visit (E/M, AWV, or IPPE) for new patients or beneficiaries not seen within 1 year prior to commencement of care management services. Prior to commencement of psychiatric CoCM services, the beneficiary must provide consent for this service, including permission to consult with a psychiatric consultant and relevant specialists. Advance consent must also include information on cost sharing for both face-to-face and non-face-to-face services, and acceptance of these requirements must be documented in the medical record.

Patients with mental health, behavioral health, or psychiatric conditions, including substance use disorders, who are being treated by an RHC or FQHC practitioner, may be eligible for psychiatric CoCM services, as determined by the RHC or FQHC practitioner. Psychiatric CoCM services, like CCM and general BHI services, are intended to provide a structured and coordinated approach to care management that is not typically included in the RHC's AIR or the FQHC PPS payment methodology.

The psychiatric CoCM team must include the RHC or FQHC practitioner, a behavioral health manager, and a psychiatric consultant. Proposed specific requirements of the psychiatric CoCM team are as follows:

Psychiatric CoCM Team—RHC or FQHC Practitioner

For psychiatric CoCM, the RHC or FQHC practitioner may be a primary care physician, NP, PA, or CNM. The psychiatric CoCM requirements of the RHC or FQHC practitioner are to:

- Direct the behavioral health care manager and any other clinical staff;
- Oversee the beneficiary's care, including prescribing medications, providing treatments for medical conditions, and making referrals to specialty care when needed; and
- Remain involved through ongoing oversight, management, collaboration and reassessment.

Psychiatric CoCM Team—Behavioral Health Care Manager

For psychiatric CoCM, the behavioral health care manager is a designated individual with formal education or specialized training in behavioral health such as social work, nursing, or psychology. A behavioral health care manager in an RHC or FQHC would be expected to have a minimum of a bachelor's degree in a behavioral health field (such as in clinical social work or psychology), or be a clinician with behavioral health training, including RNs and LPNs. The behavioral health care manager furnishes both face-to-face and non-face-to-face services under the general supervision of the RHC or FQHC practitioner and may be employed by or working under contract to the RHC or FQHC. The psychiatric CoCM requirements of the behavioral health care manager are:

- Providing assessment and care management services, including the administration of validated rating scales; behavioral health care planning in relation to behavioral/psychiatric health problems, including revision for patients who are not progressing or whose status changes; provision of brief psychosocial interventions; ongoing collaboration with the RHC or FQHC practitioner; maintenance of the registry; acting in consultation with the psychiatric consultant;
- Being available to provide services face-to-face with the beneficiary; having a continuous relationship with the patient and a collaborative, integrated relationship with the rest of the care team; and
- Being available to contact the patient outside of regular RHC or FQHC hours as necessary to conduct the behavioral health care manager's duties.

Psychiatric CoCM Team—Psychiatric Consultant

For CoCM, a psychiatric consultant is a medical professional trained in psychiatry and qualified to prescribe the full range of medications. The psychiatric consultant is not required to be on site or to have direct contact with the patient and does not prescribe medications or furnish treatment to the beneficiary directly. The CoCM requirements of the psychiatric consultant are:

- Participating in regular reviews of the clinical status of patients receiving psychiatric CoCM services;
- Advising the RHC or FQHC practitioner regarding diagnosis and options for resolving issues with beneficiary adherence and tolerance of behavioral health treatment; making adjustments to behavioral health treatment for beneficiaries who are not progressing; managing any negative interactions between beneficiaries'

behavioral health and medical treatments; and

- Facilitating referral for direct provision of psychiatric care when clinically indicated.

RHCs and FQHCs could bill the new psychiatric CoCM code, GCCC2, when the requirements for HCPCS code G0502 or G0503 are met. This code could only be billed once per month per beneficiary, and could not be billed if other care management services, including the General Care Management code GCCC1, are billed for the same time period.

As with the proposed General Care Management code GCCC1, we would monitor PFS data to determine if a weighted average would be more appropriate in determining the psychiatric CoCM payment rate for RHCs and FQHCs, and whether any additional codes that may be added to the PFS in the future should also be factored into the RHC and FQHC psychiatric CoCM code. Any changes would be done through future rulemaking.

Table 17 compares the requirements for general BHI, which would be billed using the proposed General Care Management code GCCC1, and psychiatric CoCM services, which would be billed using the proposed psychiatric CoCM code, GCCC2.

TABLE 17—COMPARISON OF PROPOSED GENERAL BHI AND PSYCHIATRIC COCM REQUIREMENTS FOR RHCS AND FQHCS

Requirements	General BHI (proposed) (HCPCS code G0507)	Psychiatric CoCM (proposed) (HCPCS code G0502 and G0503)
Initiating Visit	An E/M, AWV, or IPPE visit occurring no more than one-year prior to commencing care coordination services.	Same.
	Furnished by a primary care physician, NP, PA, or CNM.	Same.
	Billed as an RHC or FQHC visit	Same.
Beneficiary Consent	Obtained during or after initiating visit and before provision of care coordination services by RHC or FQHC practitioner or clinical staff.	Same.
	Written or verbal, documented in the medical record	Same.
	Includes information: • On the availability of care coordination services and applicable cost-sharing; • That only one entity can furnish and be paid for care coordination services during a calendar month; • That the patient has the right to stop care coordination services at any time (effective at the end of the calendar month); and • That the patient has given permission to consult with relevant specialists.	Same.
Billing Requirements	At least 20 minutes of care management services per calendar month that is: • Furnished under the direction of the RHC or FQHC primary care physician, NP, PA, or CNM; and • Furnished by an RHC or FQHC practitioner, or by clinical personnel under general supervision.	At least 70 minutes in the first calendar month, and at least 60 minutes in subsequent calendar months of psychiatric CoCM services that is: • Furnished under the direction of the RHC or FQHC primary care practitioner; and • Furnished by an RHC or FQHC practitioner or behavioral health care manager under general supervision.
Patient Eligibility	Any mental, behavioral health, or psychiatric condition being treated by the RHC or FQHC primary care practitioner, including substance use disorders, that, in the clinical judgment of the RHC or FQHC practitioner, warrants BHI services.	Same.
Requirement Elements	Includes: • Initial assessment or follow-up monitoring, including the use of applicable validated rating scales • Behavioral health care planning in relation to behavioral/psychiatric health problems, including revision for patients who are not progressing or whose status changes • Facilitating and coordinating treatment (such as psychotherapy, pharmacotherapy, counseling and/or psychiatric consultation) Continuity of care with a designated member of the care team	Includes: RHC or FQHC primary care practitioner: • Direct the behavioral health care manager or clinical staff; • Oversee the beneficiary's care, including prescribing medications, providing treatments for medical conditions, and making referrals to specialty care when needed; and • Remain involved through ongoing oversight, management, collaboration and reassessment Behavioral Health Care Manager: • Provide assessment and care management services, including the administration of validated rating scales; behavioral health care planning in relation to behavioral/psychiatric health problems, including revision for patients who are not progressing or whose status changes; provision of brief psychosocial interventions; ongoing collaboration with the RHC or FQHC practitioner; maintenance of the registry; acting in consultation with the psychiatric consultant;

TABLE 17—COMPARISON OF PROPOSED GENERAL BHI AND PSYCHIATRIC COCM REQUIREMENTS FOR RHCS AND FQHCS—Continued

Requirements	General BHI (proposed) (HCPCS code G0507)	Psychiatric CoCM (proposed) (HCPCS code G0502 and G0503)
		• Be available to provide services face-to-face with the beneficiary; having a continuous relationship with the patient and a collaborative, integrated relationship with the rest of the care team; and • Be available to contact the patient outside of regular RHC or FQHC hours as necessary to conduct the behavioral health care manager's duties. Psychiatric Consultant: • Participate in regular reviews of the clinical status of patients receiving CoCM services; • Advise the RHC or FQHC practitioner regarding diagnosis, options for resolving issues with beneficiary adherence and tolerance of behavioral health treatment; making adjustments to behavioral health treatment for beneficiaries who are not progressing; managing any negative interactions between beneficiaries' behavioral health and medical treatments; and • Facilitate referral for direct provision of psychiatric care when clinically indicated.
Cy 2017 PFS Non-Facility Payment.	G0507—$47.73	G0502—$142.84. G0503—$126.33.
RHC/FQHC Payment for New Psychiatric CoCM G Code.	Current: N/A Proposed: Average of CPT codes 99490, 99487, and G0507. (If using the 2017 payment amounts, this would be $61.37)	Current: N/A Proposed: Average of HCPCS codes G0502 and G0503. (If using the 2017 payment amounts, this would be $134.58).

c. Other Options Considered

We considered allowing RHCs and FQHCs to bill for the complex CCM codes, the BHI code, and the psychiatric CoCM codes by allowing the individual CPT or HCPCS codes to be added to an RHC or FQHC claim, in the same manner as we currently allow CPT code 99490 to be added to a claim. We do not believe this approach is in the best interest of RHCs and FQHCs. There are now 5 separate care management codes that are applicable to RHCs and FQHCs, and more codes could be added in the future as we learn more about the benefits of non-face-to-face care management services. Each of these codes has specific time increments that must be tracked and reported for payment under the PFS. We believe that bundling the CCM and BHI codes and the psychiatric CoCM codes into 2 G codes is more consistent with the RHC and FQHC payment methodology of averaging actual costs to determine a payment rate and not paying for services based on time increments. It also requires less record keeping, monitoring, and coding expertise, while maintaining the same quality of care standards.

We also considered bundling all 5 codes together into one G code, or developing 3 G codes—one for the CCM codes, one for the BHI code, and one for the psychiatric CoCM codes. We did not choose either of these approaches because CCM and BHI are similar services that complement each other, and bundling them together is consistent with an integrated approach to care with reduced reporting requirements. We also believe that psychiatric CoCM is different enough from both CCM and BHI in its requirements, particularly in staffing and required services, that it warrants a separate G code. We believe that our proposal of creating 2 new G codes to encompass the 5 care management codes is the best option for RHCs and FQHCs now and in the future if new care management codes are developed. We welcome comments on the proposal.

4. Implementation

RHCs and FQHCs are familiar with billing G codes. If this proposal is finalized as proposed, RHCs and FQHCs would continue to receive payment for CCM when CPT code 99490 is billed alone or with other payable services on an RHC or FQHC claim until December 31, 2017. Beginning on January 1, 2018, we propose that RHCs and FQHCs would use the new General Care Management G code GCCC1 when billing for CCM or general BHI services, and the new psychiatric CoCM G code GCCC2 when billing for psychiatric CoCM services, either alone or with other payable services on an RHC or FQHC claim. Claims submitted using CPT 99490 on January 1, 2018, or after, will not be paid.

Both the current RHC and FQHC payment rate for CCM, and the proposed RHC and FQHC payment rates for General Care Management and Psychiatric CoCM codes, are based on the PFS national non-facility rates. The PFS rates are updated annually, and the new G codes for RHCs and FQHCs would be updated accordingly and finalized when the PFS rates are finalized for the year. No geographic adjustment would be applied to the General Care Management or Psychiatric CoCM G codes. RHCs and FQHCs are required to submit claims for RHC and FQHC services on an institutional claim (electronically per the HIPAA compliant ANSI X12 837I or the Form CMS 1450, also known as the UB–04,) and are not authorized to bill RHC or FQHC services separately to the PFS. Specific information on billing and claims processing for the new G codes will be provided when the policy is finalized.

We note that in section X of this proposed rule, G0502, G0503, and G0507 are proposed to be replaced by new CPT codes. Corresponding changes would be made for RHCs and FQHCs when the new CPT codes become available.

5. Regulatory Changes

As previously noted, § 405.2413(a)(5) and § 405.2415(a)(5) was revised

effective January 1, 2017, to state that services and supplies furnished incident to CCM and TCM services can be furnished under general supervision of an RHC or FQHC practitioner, consistent with § 410.26(b)(5), which allows CCM and TCM services and supplies to be furnished by clinical staff under general supervision when billed under the PFS. We propose to further revise § 405.2413(a)(5) and § 405.2415(a)(5) to state that services and supplies incident to the services of a physician, NP, PA, or CNM are furnished under the direct supervision of a physician, NP, PA, or CNM, except for TCM, General Care Management, and Psychiatric CoCM services, which can be furnished under general supervision of a physician, NP, PA, or CNM when these services or supplies are furnished by auxiliary personnel, as defined in § 410.26(a)(1).

B. Part B Drug Payment: Infusion Drugs Furnished Through an Item of Durable Medical Equipment (DME)

Section 303(c) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173, enacted on December 8, 2003) revised the payment methodology for most Medicare-covered Part B drugs and biologicals by adding section 1847A to the Act, which established a new average sales price (ASP) drug payment methodology beginning January 1, 2005. However, section 303(b) of the MMA specified payments for certain drugs using methodologies other than the ASP pricing methodology. Specifically, section 303(b) of the MMA added section 1842(o)(1)(D)(i) of the Act that required that an infusion drug furnished through an item of DME covered under section 1861(n) of the Act be paid 95 percent of the average wholesale price (AWP) for that drug in effect on October 1, 2003.

Section 5004(a) of the 21st Century Cures Act (Cures Act) (Pub. L. 114–255, enacted on December 13, 2016) revised sections 1842(o)(1)(C) and (D) of the Act, changing the payment methodology for DME infusion drugs from being based on AWP to the methodologies in sections 1847, 1847A, 1847B, or 1881(b)(13) of the Act, as the case may be for the drug or biological. To implement the pricing changes required by section 5004(a) of Cures Act, which modifies the payment for DME infusion drugs to the amount under section 1847A of the Act (ASP payment methodology), by the statutorily mandated effective date of January 1, 2017, we incorporated the ASP-based infusion drug payment amounts into the January 2017 quarterly ASP drug pricing files and instructed claims processing contractors to use the updated payment limits for DME infusion drugs.

To conform regulations with the new payment requirements in section 5004(a) of the Cures Act as they pertain to section 1847A of the Act, we propose revising § 414.904(e)(2). Currently, this describes an exception to ASP-based payments and requires pricing DME infusion drugs at 95 percent of the 2003 AWP. Consistent with section 5004(a) of the Cures Act, the proposed revision limits the exception to infusion drugs furnished before January 1, 2017. In addition, we propose at § 414.904(e)(2) to delete the phrase ''and is not updated in 2006.'' We believe this language is not relevant since there was no update for pricing DME infusion drugs in 2006, and the proposed revision will serve to simplify the language. Effective January 1, 2017, payment limits for these drugs are determined under section 1847A of the Act.

C. Solicitation of Public Comments on Initial Data Collection and Reporting Periods for Clinical Laboratory Fee Schedule

1. Background on Medicare Clinical Diagnostic Laboratory Tests Payment System Final Rule

In the final rule published in the June 23, 2016 **Federal Register** (81 FR 41036) entitled, ''Medicare Program; Medicare Clinical Diagnostic Laboratory Tests Payment System,'' we implemented the requirements of section 1834A of the Act, which requires extensive revisions to the Medicare payment, coding, and coverage for clinical diagnostic laboratory tests (CDLTs) paid under the Clinical Laboratory Fee Schedule (CLFS).

Under the CLFS final rule, reporting entities are required to report to CMS certain applicable information for their component applicable laboratories. The applicable information includes, for each CDLT furnished during a data collection period, the specific HCPCS code associated with the test, each private payor rate for which final payment has been made, and the associated volume of tests performed corresponding to each private payor rate. In general, the payment amount for a test on the CLFS furnished on or after January 1, 2018, will be equal to the weighted median of private payor rates determined for the test, based on the applicable information that is collected during a data collection period and reported to us during a data reporting period.

In the CLFS final rule, we established a data collection period that is the 6 months from January 1 through June 30 during which applicable information is collected and that precedes the data collection period. We established a data reporting period that is the 3-month period, January 1 through March 31, during which a reporting entity reports applicable information to CMS and that follows the preceding data collection period. The first data collection period was January 1, 2016 through June 30, 2016. The first data reporting period was January 1, 2017 through March 31, 2017. This 6-month data collection period and 3-month data reporting period schedule will be repeated every 3 years for CDLTs that are not advanced diagnostic laboratory tests (ADLTs), and every year for ADLTS that are not new ADLTs.

For the first data reporting period, industry feedback suggested that many reporting entities would not be able to submit a complete set of applicable information to us by the March 31, 2017 deadline, and that entities required additional time to review collected data, address any issues identified during such review, and compile the data into our required reporting format. As a result, on March 30, 2017, we announced that we would exercise enforcement discretion until May 30, 2017, with respect to the data reporting period for reporting applicable information under the Medicare CLFS and the application of the Secretary's potential assessment of civil monetary penalties for failure to report applicable information.[1] The enforcement discretion applied to entities that were subject to the data reporting requirements adopted in the CLFS final rule (81 FR 41036). We noted in the announcement that the 60-day enforcement discretion period was the maximum amount of time we could permit to still have sufficient time to calculate the CLFS payment rates scheduled to go into effect on January 1, 2018.

The announcement stated that the enforcement discretion period would not prevent reporting entities prepared to report applicable information from doing so before May 30, 2017. We explained in the announcement that we were committed to the successful implementation of the new private payor rate-based CLFS and looked forward to working with the laboratory industry to ensure accurate payment rates. Over the coming months, we will be analyzing the applicable information we received, holding our Annual

[1] *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/2017-March-Announcement.pdf.*

Laboratory Public Meeting, meeting with the Advisory Panel for Clinical Diagnostic Laboratory tests, and posting preliminary payment rates.

2. Solicitation of Public Comments on Medicare Clinical Diagnostic Laboratory Tests Payment System Initial Data Collection and Reporting Periods

To better understand the applicable laboratories' experiences with the data reporting, data collection, and other compliance requirements for the first data collection and reporting periods, we are interested in public comments from applicable laboratories and reporting entities on the following questions:

- Was the CMS data reporting system easy to use? Please describe your overall experience with navigating the CMS data reporting system. For example, describe the aspects of the CMS data reporting system that worked well for your reporting entity and/or any problems the reporting entity experienced with submitting applicable information to us.
- Did the applicable laboratory (or its reporting entity) request and receive assistance from our Help Desk regarding the CMS data reporting system? Please describe your experience with receiving assistance.
- Did the applicable laboratory (or its reporting entity) request and receive assistance from the CMS CLFS Inquiries Mailbox regarding policy questions? Please describe your experience with receiving assistance.
- Did the applicable laboratory (or its reporting entity) use the subregulatory guidance on data reporting provided on the CMS CLFS Web site? [2] If so, was the information presented useful?
- Was the information that the applicable laboratory was required to report readily available in the applicable laboratory's record systems?
- Did the reporting entity have a manual, automated, or semi-automated remittance process for data reporting?
- If the reporting entity used a manual or semi-automated remittance process for data reporting, what percentage of the process was manual?
- How much time (hours) was required to assemble and report applicable information to CMS?
- Is there any other information that will inform us regarding the reporting, recordkeeping, and other compliance requirements from the first data collection and reporting periods?

We believe that industry feedback on these issues will help inform us regarding potential refinements to the private payor rate-based CLFS for future data collection and reporting periods. We welcome comments on these questions from the public.

D. Payment for Biosimilar Biological Products Under Section 1847A of the Act

In the CY 2016 Physician Fee Schedule (PFS) final rule with comment period, we finalized a proposal to amend the regulation text at § 414.904(j) to make clear that the payment amount for a biosimilar biological product is based on the ASP of all NDCs assigned to the biosimilar biological products included within the same billing and payment code (80 FR 71096 through 71101, November 16, 2015 **Federal Register**). In general, this means that products that rely on a common reference product's biologics license application are grouped into the same payment calculation for determining a single ASP payment limit and that a single HCPCS code is used for such biosimilar products. The regulation went into effect on January 1, 2016.

The comments received on the rule revealed that stakeholders had varying opinions about payment for biosimilar biological products under Part B. The commenters included individuals, pharmaceutical manufacturers, patient advocate groups, providers, insurers, and members of Congress. A number of commenters opposed a single payment amount for all biosimilars that rely on a common reference product. Most of these commenters believed that the proposed regulation would decrease incentives for biosimilar development and that grouping payment for biosimilar biological products is inconsistent with the statute. Some commenters also expressed concerns that prescribers' choices will be limited, that tracking or pharmacovigilance activities will be impaired, and that innovation and product development will be harmed, leading to market consolidation and increased costs for biosimilar biological products. Many commenters who opposed our proposal suggested that we determine a payment amount for each biosimilar biological product. These stakeholders have expressed concerns that the finalized policy restricts and threatens the viability of their business models and expressed support for a market-based solution. Some of these stakeholders believe that determining a payment for each biosimilar product by using individual HCPCS codes, would drive and reward innovators producing potential cost savings, of at least 10–15 percent compared to the reference biologic ASP, necessary for biosimilar products to compete with the reference biological.

However, some commenters supported our proposed regulation, stating that the potential marketplace for biosimilar biological products is large and it is less risky than the marketplace for reference biologicals. Commenters also expressed concern that separate payment for each biosimilar biological product would result in less competition among manufacturers, which in turn could lead to higher payment amounts for Medicare and beneficiaries. Some commenters stated that separate billing codes could be perceived as a type of price protection and could artificially increase prices for biosimilars. Commenters who supported the proposed regulation suggested that we remain mindful of our policy as the biosimilar biological product marketplace evolves. Several commenters requested that policy decisions be delayed while issues such as naming conventions and interchangeability standards are finalized by the FDA.

As CMS expected, since the regulation was finalized, the biosimilar product marketplace has continued to grow, and several biosimilar biological products that are paid under Part B have been licensed, including one product that we expect will share a HCPCS code with another biosimilar biological product. Over the next year or so, we anticipate that several more biosimilar biological products will be licensed for use in the United States and that during the following years, the marketplace will continue to grow steadily. We also anticipate that biological products will continue to be heavily utilized in Part B. At the same time, we are aware of concerns that current policy may discourage development of new biosimilars and other innovation in this area potentially resulting in higher costs over time due to a lack of competition in the market place.

In the 2016 PFS final rule, we stated that it is desirable to have fair reimbursement in a healthy marketplace that encourages product development (80 FR 71101). CMS seeks to promote innovation, to provide more options to patients and physicians, and competition to drive prices down, recognizing that even though these two goals may be difficult to achieve concurrently, to delink them would be counterproductive.

Although we believe that the United States biosimilar biological product marketplace is still in an early phase (because only a few products are on the market), we are interested in assessing

[2] *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/PAMA-Regulations.html.*

the effects of Medicare payment policy on this important portion of the Part B drug marketplace at this time, particularly for fostering a robust, and competitive marketplace and encouraging the innovation that is necessary to bring these products to the marketplace. It is essential to take a measured approach that considers all options given the significant federal spending by Medicare on Part B drugs, the effect of payment policies on program sustainability for taxpayers, health care affordability and access for beneficiaries, and the considerable investment the biosimilar industry is making in the nascent market. Failure to do so could potentially restrict innovation in the marketplace, increase costs to the American taxpayer, and limit treatment options. With that in mind, it is CMS's goal to further investigate a solution that allows market forces to provide a robust and comprehensive selection of choices for patients at a fair price. Additionally, we are interested in better understanding if and how the innate differences in biological products and their current regulatory environment should be reflected in Medicare payment policy for biosimilars, particularly as it relates to biosimilars that are licensed for fewer than all indications for which the reference product is licensed or situations where different biosimilars may be licensed for different subsets of indications for which the reference product is licensed.

Thus, we are requesting comments regarding our Medicare Part B biosimilar biological product payment policy. This comment solicitation is seeking new or updated information on the effects of the current biosimilar payment policy that is based on experience with the United States marketplace. We are particularly interested in obtaining material, such as market analyses or research articles that provide data and insight into the current economics of the biosimilar market place. This includes patient, plan, and manufacturer data both domestic and, where applicable, from European markets that may be more established than, and provide insight for, the current United States' market.

We also seek data to demonstrate how individual HCPCS codes could impact the biosimilar market, including innovation, the number of biosimilar products introduced to the market, patient access, and drug spending. Finally, we also seek comment regarding other novel payment policies that would foster competition, increase access, and drive cost savings in the biological product marketplace. These solutions may include legislation, demonstrations, and administrative options. Please note that this is a solicitation for comments on this issue for future consideration. We are not making a proposal to change the existing payment policy in this proposed rule.

E. Appropriate Use Criteria for Advanced Diagnostic Imaging Services

Section 218(b) of the Protecting Access to Medicare Act (PAMA) amended Title XVIII of the Act to add section 1834(q) of the Act directing us to establish a program to promote the use of appropriate use criteria (AUC) for advanced diagnostic imaging services. The CY 2016 PFS final rule with comment period addressed the initial component of the new Medicare AUC program, specifying applicable AUC. In that rule (80 FR 70886), we established an evidence-based process and transparency requirements for the development of AUC, defined provider-led entities (PLEs) and established the process by which PLEs may become qualified to develop, modify or endorse AUC. The first list of qualified PLEs was posted on the CMS Web site at the end of June 2016 at which time their AUC libraries became specified applicable AUC for purposes of section 1834(q)(2)(A) of the Act. The CY 2017 PFS final rule addressed the second component of this program, specification of qualified clinical decision support mechanisms (CDSMs). In that rule (81 FR 80170), we defined CDSM, identified the requirements CDSMs must meet for qualification including an opportunity for preliminary qualification for mechanisms still working toward full adherence, and established a process by which CDSMs may become qualified. We also defined applicable payment systems under this program, specified the first list of priority clinical areas and identified exceptions to the requirements that ordering professionals consult specified applicable AUC when ordering applicable imaging services. The first list of qualified CDSMs will be posted on the CMS Web site in conjunction with this proposed rule.

This rule proposes the start date of the Medicare AUC program for advanced diagnostic imaging services. It is on and after this date that ordering professionals must consult specified applicable AUC using a qualified CDSM when ordering applicable imaging services and furnishing professionals must report consultation information on the Medicare claim. This rule also proposes to modify the policy related to significant hardship exceptions and requests public feedback on details regarding how AUC consultation information must be included on the Medicare claim. To further this iterative process of implementation, we also discuss briefly the potential for alignment with other Medicare quality programs.

1. Background

AUC present information in a manner that links: a specific clinical condition or presentation, one or more services and, an assessment of the appropriateness of the service(s). For purposes of this program AUC is a set or library of individual appropriate use criteria. Each individual criterion is an evidence-based guideline for a particular clinical scenario. Each scenario in turn starts with a patient's presenting symptoms or condition. Evidence-based AUC for imaging can assist clinicians in selecting the imaging study that is most likely to improve health outcomes for patients based on their individual clinical presentation.

AUC need to be integrated as seamlessly as possible into the clinical workflow. CDSMs are the electronic portals through which clinicians access the AUC during the patient workup. While CDSMs can be standalone applications that require direct entry of patient information, they may be more effective when they automatically incorporate information such as specific patient characteristics, laboratory results, and lists of co-morbid diseases from Electronic Health Records (EHRs) and other sources. Ideally, practitioners would interact directly with the CDSM through their primary user interface, thus minimizing interruption to the clinical workflow.

Consistent with descriptions of clinical decision support by the Agency for Healthcare Research and Quality (AHRQ) (*http://www.ahrq.gov/professionals/prevention-chronic-care/decision/clinical/index.html*), and the Office of the National Coordinator for Health Information Technology (ONC) (*https://www.healthit.gov/policy-researchers-implementers/clinical-decision-support-cds*), within health IT applications, a CDSM is a functionality that provides persons involved in care processes with general and person-specific information, intelligently filtered and organized, at appropriate times, to enhance health and health care.

2. Statutory Authority

Section 218(b) of the PAMA added a new section 1834(q) of the Act entitled, ''Recognizing Appropriate Use Criteria for Certain Imaging Services,'' which

directs the Secretary to establish a new program to promote the use of AUC. Section 1834(q)(4) of the Act requires ordering professionals to consult with a qualified CDSM for applicable imaging services furnished in an applicable setting and paid for under an applicable payment system; and for the furnishing professional to include on the Medicare claim information about the ordering professional's consultation with a qualified CDSM.

3. Discussion of Statutory Requirements

There are four major components of the AUC program under section 1834(q) of the Act, and each component has its own implementation date: (1) Establishment of AUC by November 15, 2015 (section 1834(q)(2) of the Act); (2) identification of mechanisms for consultation with AUC by April 1, 2016 (section 1834(q)(3) of the Act); (3) AUC consultation by ordering professionals, and reporting on AUC consultation by furnishing professionals by January 1, 2017 (section 1834(q)(4) of the Act); and (4) annual identification of outlier ordering professionals for services furnished after January 1, 2017 (section 1834(q)(5) of the Act). As we will discuss later in this preamble and in prior PFS rules, we did not identify mechanisms for consultation by April 1, 2016. Therefore, we did not require ordering professionals to consult CDSMs or furnishing professionals to report information on the consultation by the January 1, 2017 date.

a. Establishment of AUC

In the CY 2016 PFS final rule with comment period, we addressed the first component of the Medicare AUC program under section 1834(q)(2) of the Act—the requirements and process for establishment and specification of applicable AUC, along with relevant aspects of the definitions under section 1834(q)(1) of the Act. This included defining the term PLE and finalizing requirements for the rigorous, evidence-based process by which a PLE would develop AUC, upon which qualification is based, as provided in section 1834(q)(2)(B) of the Act and in the CY 2016 PFS final rule with comment period. Using this process, once a PLE is qualified by CMS, the AUC that are developed, modified or endorsed by the qualified PLE are considered to be specified applicable AUC under section 1834(q)(2)(A) of the Act. We defined the term PLE to include national professional medical societies, health systems, hospitals, clinical practices and collaborations of such entities such as the High Value Healthcare Collaborative or the National Comprehensive Cancer Network. Qualified PLEs may collaborate with third parties that they believe add value to their development of AUC, provided such collaboration is transparent. We expect qualified PLEs to have sufficient infrastructure, resources, and the relevant experience to develop and maintain AUC according to the rigorous, transparent, and evidence-based processes detailed in the CY 2016 PFS final rule with comment period.

In the same rule we established a timeline and process under § 414.94(c)(2) for PLEs to apply to become qualified. Consistent with this timeline the first list of qualified PLEs was published at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Appropriate-Use-Criteria-Program/PLE.html* (OMB Control Number 0938–1288).

b. Mechanism for AUC Consultation

In the CY 2017 PFS final rule, we addressed the second major component of the Medicare AUC program—the specification of qualified CDSMs for use by ordering professionals for consultation with specified applicable AUC under section 1834(q)(3) of the Act, along with relevant aspects of the definitions under section 1834(q)(1) of the Act. This included defining the term CDSM and finalizing functionality requirements of mechanisms, upon which qualification is based, as provided in section 1834(q)(3)(B) of the Act and in the CY 2017 PFS final rule. We included an opportunity for mechanisms still working toward full adherence to these requirements to receive preliminary qualification during the preliminary qualification period that begins June 30, 2017, and ends when the AUC consulting and reporting requirements become effective. The preliminarily qualified CDSMs must meet all requirements by that time. We defined CDSM as an interactive, electronic tool for use by clinicians that communicates AUC information to the user and assists them in making the most appropriate treatment decision for a patient's specific clinical condition. Tools may be modules within or available through certified EHR technology (as defined in section 1848(o)(4) of the Act) or private sector mechanisms independent from certified EHR technology or established by the Secretary.

In the CY 2017 PFS final rule we established a timeline and process in § 414.94(g)(2) for CDSM developers to apply to have their CDSMs qualified. Consistent with this timeline, the first list of qualified CDSMs will be posted on the CMS Web site *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Appropriate-Use-Criteria-Program/CDSM.html* in conjunction with this proposed rule (OMB Control Number 0938–1315).

c. AUC Consultation and Reporting

The third major component of the Medicare AUC program is in section 1834(q)(4) of the Act, Consultation with Applicable Appropriate Use Criteria. This section establishes, beginning January 1, 2017, the requirement for an ordering professional to consult with a qualified CDSM when ordering an applicable imaging service that would be furnished in an applicable setting and paid for under an applicable payment system; and for the furnishing professional to include on the Medicare claim information about the ordering professional's consultation with a qualified CDSM. The statute distinguishes between the ordering and furnishing professional, recognizing that the professional who orders an applicable imaging service is usually not the same professional who bills Medicare for that service when furnished. Since a list of qualified CDSMs was not available by January 1, 2017, we did not require ordering professionals to meet the consultation requirement by that date.

Section 1834(q)(4)(C) of the Act provides for certain exceptions to the AUC consultation and reporting requirements including in the case of certain emergency services, inpatient services paid under Medicare Part A, and ordering professionals who obtain an exception due to a significant hardship. In the CY 2017 PFS final rule, we identified the circumstances specific to ordering professionals under which consulting and reporting requirements are not required. These include orders for applicable imaging services: (1) For emergency services when provided to individuals with emergency medical conditions as defined in section 1867(e)(1) of the Act; (2) for an inpatient and for which payment is made under Medicare Part A; and (3) by ordering professionals who are granted a significant hardship exception to the Medicare EHR Incentive Program payment adjustment for that year under 42 CFR 495.102(d)(4), except for those granted such an exception under § 495.102(d)(4)(iv)(C). We propose changes to the significant hardship exception later in this preamble.

Section 1834(q)(4)(D) of the Act specifies that the applicable payment systems for the AUC consultation and reporting requirements, and, in the CY 2017 PFS final rule we defined them as:

(1) The physician fee schedule established under section 1848(b) of the Act; (2) the prospective payment system for hospital outpatient department services under section 1833(t) of the Act; and (3) the ambulatory surgical center payment system under section 1833(i) of the Act.

d. Identification of Outliers

The fourth component of the Medicare AUC program is in section 1834(q)(5) of the Act, Identification of Outlier Ordering Professionals. The identification of outlier ordering professionals under this paragraph facilitates a prior authorization requirement for outlier professionals beginning January 1, 2020, as specified under section 1834(q)(6) of the Act. Given that we are proposing a program start date of January 1, 2019, we anticipate that implementation of the prior authorization component would be delayed. We expect to discuss details around outlier calculations and prior authorization in the CY 2019 PFS proposed rule. However, we did finalize in the CY 2017 PFS final rule the first list of priority clinical areas to guide identification of outlier ordering professionals as follows:

- Coronary artery disease (suspected or diagnosed).
- Suspected pulmonary embolism.
- Headache (traumatic and non-traumatic).
- Hip pain.
- Low back pain.
- Shoulder pain (to include suspected rotator cuff injury).
- Cancer of the lung (primary or metastatic, suspected or diagnosed).
- Cervical or neck pain.

As established in § 414.94(e)(4) of our regulations, priority clinical areas may be used in the identification of outlier ordering professionals. By starting to identify these areas now, we believe ordering professionals will have the opportunity to become familiar with AUC within identified priority clinical areas prior to Medicare claims for those services being part of the input for calculating outlier ordering professionals.

We are not including proposals to expand or modify the list of priority clinical areas in this rule.

4. Proposals for Continuing Implementation

We propose to amend § 414.94 of our regulations, ''Appropriate Use Criteria for Certain Imaging Services,'' to reflect the following proposals.

a. Consultation by Ordering Professional and Reporting by Furnishing Professional

We are proposing that ordering professionals must consult specified applicable AUC through qualified CDSMs for applicable imaging services furnished in an applicable setting, paid for under an applicable payment system and ordered on or after January 1, 2019. This proposed effective date for the consulting and reporting requirements is necessary to allow time for ordering practitioners who are not already aligned with a qualified CDSM to research and evaluate the qualified CDSMs so they may make an informed decision. Although there will be another rulemaking cycle next year before the consulting and reporting requirement is effective as proposed on January 1, 2019, we are establishing this date through rulemaking this year because the agency expects practitioners and other stakeholders to begin preparing themselves to report on that date and, in response to public comment and stakeholder feedback, we want to ensure all impacted parties have sufficient time to prepare to meet the requirements of this program.

After proposing the timeline and process for qualification of CDSMs in the CY 2017 PFS proposed rule (81 FR 46392), we anticipated that furnishing professionals may begin reporting as early as January 1, 2018. However, we received comments that these timelines did not allow enough time to address the needs of different stakeholder groups. Some commenters requested that CMS delay the timeline and process to give practitioners sufficient time to obtain a qualified CDSM. Other commenters cited insufficient time for CDSMs to incorporate requirements between the release of the final CDSM requirements and January 1, 2018, and requested that CMS fully implement the program at a later date. Additionally, in the CY 2017 PFS final rule (81 FR 80411) we discussed commenters' recommendations that CMS develop and launch an educational campaign, including a Town Hall meeting. Some commenters requesting additional time suggested that, for purposes of both CDSM vendor readiness and practitioner readiness, consulting and reporting requirements should not go into effect for an additional 12–18 months after the initial list of CMS qualified CDSMs is posted.

By proposing the consulting and reporting requirements begin on January 1, 2019 we believe that we are allowing needed time for education and outreach efforts, time for practitioners and stakeholders to prepare, and time for CDSMs to continue current strides in being more user-friendly and less burdensome. We note that the statute required publication of qualified CDSMs by April 1, 2016, and required AUC consultation and reporting by January 1, 2017; therefore, our proposal substantially lags the statutory requirements. As noted above and in previous rulemaking, a delay in the statutory timeline is necessary to maximize the opportunity for public comment and stakeholder engagement, also a statutory requirement, and allows for adequate advance notice to practitioners, beneficiaries, AUC developers, and CDSM developers.

Consistent with section 1834(q)(4)(B) of the Act, we are also proposing that furnishing professionals report the following information on Medicare claims for applicable imaging services, furnished in an applicable setting, paid for under an applicable payment system as defined in § 414.94(b), and ordered on or after January 1, 2019: (1) Which qualified CDSM was consulted by the ordering professional; (2) whether the service ordered would adhere to specified applicable AUC, would not adhere to specified applicable AUC, or whether specified applicable AUC were not applicable to the service ordered; and (3) the NPI of the ordering professional (if different from the furnishing professional).

We believe that, unless a statutory exception applies, an AUC consultation must take place for every order for an applicable imaging service furnished in an applicable setting and under an applicable payment system. We further believe that section 1834(q)(4)(B) of the Act accounts for the possibility that AUC may not be available in a particular qualified CDSM to address every applicable imaging service that might be ordered; and thus, the furnishing professional can meet the requirement to report information on the ordering professional's AUC consultation by indicating that AUC is not applicable to the service ordered. We remind readers as required under § 414.94(g)(1)(iii) that qualified CDSMs must make available, at a minimum, AUC that reasonably address common and important clinical scenarios within all priority clinical areas. As discussed in the CY 2017 PFS final rule (81 FR 80170), the current list of priority clinical areas represents about 40 percent of advanced diagnostic imaging services paid for by Medicare in 2014. We also remind readers that consistent with section 1834(q)(4)(A) of the Act, ordering professionals must consult AUC for every advanced diagnostic

imaging service ordered. While section 218(b) of the PAMA allows qualified CDSMs to return a response of ''not applicable'' if a qualified CDSM does not contain specified applicable AUC for the service ordered, we expect these situations to be limited in scope and number, and to decrease over time. The ''not applicable'' responses should decrease as qualified PLEs continue to build out their AUC libraries and qualified CDSMs update their content and potentially collaborate with more qualified PLEs so as to make available highly comprehensive tools.

Section 1834(q)(4)(B) requires that payment may only be made if the claim for the service includes the specific information discussed in this proposed rule. This information, to the extent feasible, is required across claim types (including both the furnishing professional and facility claims) and across all three applicable payment systems (PFS, hospital outpatient prospective payment system and ambulatory surgical center payment system). In other words, we would expect this information to be included on the practitioner claim that includes the professional component of the imaging service and on the hospital outpatient claim for the technical component of the imaging service. Claims for services for which payment is not made under the three identified payment systems would not be required to include consultation related information.

To implement this requirement we propose to establish a series of HCPCS level 3 codes. These G-codes would describe the specific CDSM that was used by the ordering professional. Ultimately there would be one G-code for every qualified CDSM with the code description including the name of the CDSM. However, because the claims processing system can only recognize new codes quarterly, we may not be able to update the G-code descriptors simultaneously with the announcement of any new qualified CDSMs which is expected to occur in June of each year. To ensure that there is a code available to immediately describe newly qualified CDSMs, we propose to establish a generic G-code that would be used to report that a qualified CDSM was consulted, but would not identify a specific qualified CDSM; clinicians would only be permitted to use this code if a more specific named code did not yet exist for that clinician's CDSM. Furnishing professionals would report this code temporarily until a specific G-code describing the newly qualified CDSM by name becomes available. We also propose to establish a G-code to identify circumstances where there was no AUC consultation through a qualified CDSM. The description of this code would indicate that a qualified CDSM was not consulted by the ordering professional.

G-codes would be a line-item on both practitioner claims and facility claims. We would expect that one AUC consulatation G-code would be reported for every advanced diagnostic imaging service on the claim. If there are two codes billed for advanced imaging services on the claim then we would expect two G-codes. Each G-code would be expected, on the same claim line, to contain at least one new HCPCS modifier. We propose to develop a series of modifiers to provide necessary information as to whether, when a CDSM is used to consult AUC: (1) The imaging service would adhere to the applicable appropriate use criteria; (2) the imaging service would not adhere to such criteria; or (3) such criteria were not applicable to the imaging service ordered. We propose to create additional modifiers to describe situations where an exception applies and a qualified CDSM was not used to consult AUC: (1) The imaging service was ordered for a patient with an emergency medical condition or (2) the ordering professional has a significant hardship exception. Based on this proposal we specifically seek comments on any additional HCPCS modifiers that might be needed to separately identify allowable scenarios for which a qualified CDSM was not consulted by the ordering professional.

The proposed AUC consultation and reporting start date of January 1, 2019 is expected to allow adequate time for us to operationalize the claims-based procedures and systems changes needed to accomplish the processing of Medicare claims with AUC consultation information.

There are aspects of the AUC program that are novel and complex for the CMS claims processing system and for ordering and furnishing professionals. An AUC consultation by an ordering professional has never before been required by fee-for-service Medicare with such a broad application (all professionals ordering advanced diagnostic tests). Additional considerations for the complex communication of AUC consultation information from the ordering professional to the furnishing professional and facility that must include that information when billing for the service are warranted. Their billing systems will need to translate the AUC consultation information onto Medicare claims in the form of G-codes and HCPCS modifiers. These processes are new for many professionals, and there are many areas for potential error. For these reasons an educational and operations testing period is needed. During this period, ordering professionals would consult AUC and furnishing professionals would report AUC consultation information on the claim, but we would continue to pay claims whether or not they correctly include such information. This educational period allows professionals to actively participate in the program while avoiding claims denials during the learning curve. It also gives us an opportunity to make any needed claims processing adjustments before payments are impacted.

We believe it is preferable to begin implementation using a single year educational and operations testing period, rather than possibly further delaying the start-date of the program. We do not expect to continue this educational and operations testing period beyond the first year of the AUC program.

We look forward to receiving public comments on all aspects of our proposal, and specifically, comments related to whether the program should be delayed beyond the proposed start date of January 1, 2019. Although our proposal is based in part on comments received in prior rulemaking cycles, it is important to receive comments that help us understand the current readiness of stakeholders. In addition, we have proposed that the program begin with an educational and operations testing period and are interested in comments regarding how long, if longer than one year, such a period should be available.

We expect a voluntary reporting period to be available ahead of January 1, 2019 and anticipate such a period will begin July 2018. The timing for this opportunity for voluntary reporting is dependent on the readiness of the Medicare claims system to accept and process claims that include AUC consultation information. When the voluntary period becomes available we will make announcements through our educational channels such as the CMS Web site and listservs. It is important to note that the proposed educational and operations testing period beginning January 1, 2019, is separate from the anticipated voluntary reporting period that we expect to allow before January 1, 2019. During the voluntary reporting period, AUC consultation and reporting are not required. However, for applicable imaging services ordered on and after January 1, 2019, consulting specified applicable AUC and reporting consultation information on the

Medicare claim would be required for all ordering and furnishing professionals, respectively.

b. Alignment With Other Medicare Quality Programs

The CY 2017 Merit-based Incentive Payment System and Alternative Payment Model final rule with comment period (Quality Payment Program final rule) (81 FR 77008) finalized policies to improve physician and other clinician payments by changing the way Medicare incorporates quality measurement into payments and developing new policies to address and incentivize participation in Advanced Alternative Payment Models (APMs). We expect the Quality Payment Program to evolve over multiple years and to continue iterating on these policies. To this end, the AUC program has the potential to provide new opportunities to improve care delivery by supporting and rewarding clinicians as they find new ways to engage patients, families and caregivers as well as improving care coordination and patient health management.

Therefore, we have proposed in the CY 2018 Quality Payment Program proposed rule to develop a direct tie between MIPS and the AUC program (See CY 2018 Quality Payment Program Proposed Rule (82 FR 30010) published in the June 30, 2017 **Federal Register**). In that rule, we proposed to give MIPS credit to ordering professionals for consulting AUC using a qualified CDSM as a high-weight improvement activity for the performance period beginning January 1, 2018 (82 FR 30484). We believe this will incentivize early use of qualified CDSMs to consult AUC by motivated eligible clinicians looking to improve patient care and to better prepare themselves for the AUC program. Although the AUC program would not officially begin until January 1, 2019, we are able to support this proposed improvement activity because the first qualified CDSMs will be announced in conjunction with this proposed rule; therefore, ordering professionals will be able to begin consulting AUC using those tools.

We are also considering how the AUC program could serve to support a quality measure under the MIPS quality performance category and seek feedback from the public regarding feasibility and value of pursuing this idea further.

c. Significant Hardship Exceptions to Consulting and Reporting Requirements

We are proposing to modify § 414.94(i)(3) of our regulations to reflect the sunsetting of the payment adjustments under the Medicare EHR Incentive Program and to substitute an alignment with the advancing care information performance category of MIPS. The categories that we included in the CY 2017 PFS final rule for purposes of the AUC program significant hardship exceptions were the following from § 495.102(d)(4):

- Insufficient Internet Connectivity (as specified in § 495.102(d)(4)(i)).
- Practicing for less than 2 years (as specified in § 495.102(d)(4)(ii)).
- Extreme and Uncontrollable Circumstances (as specified in § 495.102(d)(4)(iii)).
- Lack of Control over the Availability of CEHRT (as specified in § 495.102(d)(4)(iv)(A)).
- Lack of Face-to-Face Patient Interaction (as specified in § 495.102(d)(4)(iv)(B)).

In addition, in the CY 2017 Quality Payment Program final rule, we finalized a policy (81 FR 77240–77243) to reweight the advancing care information performance category to zero in the MIPS final score for the year for MIPS eligible clinicians who meet the criteria in one of the above listed categories of § 495.102(d)(4), with the exception of the category for clinicians practicing for less than 2 years. Under section 1848(q)(1)(C)(v) of the Act, eligible clinicians who first enroll in Medicare during the performance period for a year and have not previously submitted claims under Medicare are not considered MIPS eligible clinicians, and thus are excluded from MIPS. We believe it is likely that many clinicians who have been practicing for less than 2 years would be excluded from MIPS on the basis that they are new Medicare-enrolled MIPS eligible clinicians as defined in § 414.1305. Because these clinicians are not MIPS eligible clinicians, they would never meet the criteria for re-weighting of their MIPS advancing care information performance category for the year. Therefore, to implement a hardship exception for purposes of the AUC program that is both operationally consistent and administratively efficient, we propose to remove as a criterion for a significant hardship exception for the AUC program the criterion specified in § 495.102(d)(4)(ii) of our regulations for those practicing for less than 2 years. We propose to keep the remaining listed categories including insufficient internet connectivity, extreme and uncontrollable circumstances, lack of control over availability of CEHRT and lack of face-to-face patient interaction. We note that section 1843(q)(4)(C)(iii) of the Act only allows the ordering professional to seek a significant hardship exception, not the furnishing professional.

As such, we propose to amend the AUC significant hardship exception regulation to specify that ordering professionals who are granted re-weighting of the advancing care information performance category to zero percent of the final score for the year under MIPS per § 414.1380(c)(2) due to circumstances that include the criteria listed in § 495.102(d)(4)(i), (iii), (iv)(A) and (iv)(B) would be excepted from the AUC consultation requirement during the same year that the re-weighting applies for purposes of the MIPS payment adjustment.

There will be scenarios when a clinician's experience of a significant hardship or extraordinary circumstance does not align with the prospective identification of these ordering professionals with reference to MIPS criteria and processes. However, we believe the prospective identification process allows us to apply exceptions in real-time for claims submitted for advanced imaging services. There are timing differences between the MIPS and the AUC program (the MIPS payment adjustment year is based on performance in a prior year while the Medicare AUC program requires real-time AUC consultation and claims-based reporting). In addition to the timing, there will be instances when a clinician who is not a MIPS eligible clinician will need to seek a significant hardship exception to the Medicare AUC program. To accommodate these two separate scenarios, we propose to establish a process to identify ordering professionals in need of a significant hardship exception to the Medicare AUC program requirements that is outside the MIPS re-weighting process. For purposes of these scenarios, we propose to use the criteria for clinicians seeking an AUC significant hardship exception described under § 495.102(d)(4) to include (i), (iii), (iv)(A) and (iv)(B) of our regulations. We propose these criteria to align with the criteria used under MIPS for re-weighting under the advancing care information performance category, and to provide predictability and consistency to the determination of significant hardship. We further propose that a significant hardship exception from the Medicare AUC program requirements would be granted for no longer than 12 months, and that we could establish an exception for a shorter period where warranted by the circumstances.

Therefore we propose that ordering professionals who have not received a re-weighting to zero for the MIPS

advancing care information performance category for the year, but experience one of the circumstances described in § 495.102(d)(4) to include (i), (iii), (iv)(A) and (iv)(B), may be granted an AUC significant hardship exception for no longer than one year. We expect to provide further information on this execption process in future rulemaking.

In addition to the proposals above, we invite the public to comment on additional circumstances for which it may be appropriate for an ordering professional to be granted a significant hardship exception under the AUC program.

5. Summary

Section 1834(q) of the Act includes rapid timelines for establishing a Medicare AUC program for advanced diagnostic imaging services. The impact of this program is extensive as it will apply to every physician or other practitioner who orders or furnishes advanced diagnostic imaging services (for example, magnetic resonance imaging (MRI), computer tomography (CT) or positron emission tomography (PET)). This crosses almost every medical specialty and could have a particular impact on primary care physicians since their scope of practice can be quite broad. Stakeholders have expressed concern that program requirements may inadvertently encourage physicians to order imaging services that they do not believe are right for their patients. The goal of evidence-based AUC is to assist clinicians in ordering the most appropriate imaging service for their patients' specific clinical scenarios. However, to ensure we are implementing the program effectively, we are asking for public comment on such potential unintended consequences. Additionally, as we continue to develop the AUC program, we continue to engage a variety of stakeholders interested in participating in the development of AUC. We seek comment about how we can continue to engage interested participants, consistent with statutory requirements at section 1834(q) of the Act, in developing AUC in a transparent and scientifically robust manner. We are particularly interested in how qualified PLEs develop or modify AUC in collaboration with non-PLE entities and what additional challenges such entities might face.

We continue to believe the best implementation approach is one that is diligent, maximizes the opportunity for public comment and stakeholder engagement, and allows for adequate advance notice to physicians and practitioners, beneficiaries, AUC developers, and CDSM developers. It is for these reasons we propose to continue a stepwise approach, adopted through notice and comment rulemaking. We propose policies to implement the third component of the AUC program—the consulting and reporting requirements and the effective date on which these requirements would begin. Under this proposal, ordering professionals must begin consulting specified applicable AUC through qualified CDSMs for applicable imaging services ordered on and after January 1, 2019, and furnishing professionals must begin reporting AUC consultation information on Medicare claims for advanced diagnostic imaging services for which payment is made under an applicable payment system as defined in § 414.94(b) and ordered on or after January 1, 2019.

We also propose modifications to the significant hardship exception to better align these exceptions under the AUC program with those under existing quality programs.

In summary, we are proposing requirements necessary to implement the third component of the AUC program. We invite the public to submit comments on these proposals.

F. Physician Quality Reporting System (PQRS) Criteria for Satisfactory Reporting for Individual EPs and Group Practices for the 2018 PQRS Payment Adjustment

1. Background

Section 1848(a)(8) of the Act provides that for covered professional services furnished by an EP during each of 2015 through 2018, if the EP does not satisfactorily report data on quality measures for covered professional services for the reporting period for the year, the PFS amount for services furnished by such professional during the year (including the PFS amount for purposes of determining a payment based on such amount) shall be equal to the applicable percent of the PFS amount that would otherwise apply to such services. For 2016 through 2018, the applicable percent is 98.0 percent. Thus, individual EPs and group practices who did not satisfactorily report data on quality measures for the CY 2016 reporting period are subject to a downward payment adjustment of 2.0 percent to the PFS payment amount for covered professional services they furnish in 2018.

2. Previously Finalized Satisfactory Reporting Criteria for Individual EPs and Group Practices for the 2018 PQRS Payment Adjustment

We previously finalized the satisfactory reporting criteria for individual EPs and group practices for the CY 2016 reporting period to avoid the 2018 PQRS payment adjustment in the CY 2016 PFS final rule (80 FR 71140 through 71250) at § 414.90(j)(8) and (9) and § 414.90(k)(5).

Table 18 summarizes the previously finalized satisfactory reporting criteria for individual EPs at § 414.90(j)(8) and § 414.90(k)(5).

TABLE 18—SUMMARY OF REQUIREMENTS FOR THE 2018 PQRS PAYMENT ADJUSTMENT: INDIVIDUAL REPORTING CRITERIA FOR THE SATISFACTORY REPORTING OF QUALITY MEASURES DATA VIA CLAIMS, QUALIFIED REGISTRY, AND ELECTRONIC HEALTH RECORDS (EHRS) AND SATISFACTORY PARTICIPATION CRITERIA IN QUALIFIED CLINICAL DATA REGISTRIES (QCDRS)

Reporting period	Measure type	Reporting mechanism	Satisfactory reporting/satisfactory participation criteria
12-month (Jan 1–Dec 31, 2016).	Individual Measures	Claims	Report at least 9 measures, covering at least 3 of the National Quality Strategy (NQS) domains AND report each measure for at least 50 percent of the EP's Medicare Part B Fee-for-Service (FFS) patients seen during the reporting period to which the measure applies. Of the measures reported, if the EP sees at least 1 Medicare patient in a face-to-face encounter, the EP will report on at least 1 measure contained in the PQRS cross-cutting measure set. If less than 9 measures apply to the EP, the EP would report on each measure that is applicable), AND report each measure for at least 50 percent of the Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate would not be counted.
12-month (Jan 1–Dec 31, 2016).	Individual Measures	Qualified Registry	Report at least 9 measures, covering at least 3 of the NQS domains AND report each measure for at least 50 percent of the EP's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Of the measures reported, if the EP sees at least 1 Medicare patient in a face-to-face encounter, the EP will report on at least 1 measure contained in the PQRS cross-cutting measure set. If less than 9 measures apply to the EP, the EP would report on each measure that is applicable, AND report each measure for at least 50 percent of the Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate would not be counted.
12-month (Jan 1–Dec 31, 2016).	Individual Measures	Direct EHR Product or EHR Data Submission Vendor Product.	Report 9 measures covering at least 3 of the NQS domains. If an EP's direct EHR product or EHR data submission vendor product does not contain patient data for at least 9 measures covering at least 3 domains, then the EP would be required to report all of the measures for which there is Medicare patient data. An EP would be required to report on at least 1 measure for which there is Medicare patient data.
12-month (Jan 1–Dec 31, 2016).	Measures Groups	Qualified Registry	Report at least 1 measures group AND report each measures group for at least 20 patients, the majority (11 patients) of which are required to be Medicare Part B FFS patients. Measures groups containing a measure with a 0 percent performance rate will not be counted.
12-month (Jan 1–Dec 31, 2016).	Individual PQRS measures and/or non-PQRS measures reportable via a QCDR.	QCDR	Report at least 9 measures available for reporting under a QCDR covering at least 3 of the NQS domains, AND report each measure for at least 50 percent of the EP's patients. Of these measures, the EP would report on at least 2 outcome measures, OR, if 2 outcomes measures are not available, report on at least 1 outcome measures and at least 1 of the following types of measures—resource use, patient experience of care, efficiency/appropriate use, or patient safety.

Table 19 summarizes the previously finalized satisfactory reporting criteria for group practices via the group practice reporting option (GPRO) at § 414.90(j)(9) and § 414.90(k)(5).

TABLE 19—SUMMARY OF REQUIREMENTS FOR THE 2018 PQRS PAYMENT ADJUSTMENT: GROUP PRACTICE REPORTING CRITERIA FOR SATISFACTORY REPORTING OF QUALITY MEASURES DATA VIA THE GPRO

Reporting period	Group practice size	Measure type	Reporting mechanism	Satisfactory reporting criteria
12-month (Jan 1–Dec 1, 2016).	25–99 EPs; 100+ EPs (if Consumer Assessment of Healthcare Providers and Systems (CAHPS) for PQRS does not apply).	Individual GPRO Measures in the Web Interface.	Web Interface	Report on all measures included in the web interface; AND populate data fields for the first 248 consecutively ranked and assigned beneficiaries in the order in which they appear in the group's sample for each module or preventive care measure. If the pool of eligible assigned beneficiaries is less than 248, then the group practice must report on 100 percent of assigned beneficiaries. In other words, we understand that, in some instances, the sampling methodology we provide will not be able to assign at least 248 patients on which a group practice may report, particularly those group practices on the smaller end of the range of 25–99 EPs. If the group practice is assigned less than 248 Medicare beneficiaries, then the group practice must report on 100 percent of its assigned beneficiaries. A group practice must report on at least 1 measure for which there is Medicare patient data.
12-month (Jan 1–Dec 31, 2016).	25–99 EPs that elect CAHPS for PQRS; 100+ EPs (if CAHPS for PQRS applies).	Individual GPRO Measures in the Web Interface + CAHPS for PQRS.	Web Interface + CMS-Certified Survey Vendor.	The group practice must have all CAHPS for PQRS survey measures reported on its behalf via a CMS-certified survey vendor. In addition, the group practice must report on all measures included in the Web Interface; AND populate data fields for the first 248 consecutively ranked and assigned beneficiaries in the order in which they appear in the group's sample for each module or preventive care measure. If the pool of eligible assigned beneficiaries is less than 248, then the group practice must report on 100 percent of assigned beneficiaries. A group practice will be required to report on at least 1 measure for which there is Medicare patient data. Please note that, if the CAHPS for PQRS survey is applicable to a group practice who reports quality measures via the Web Interface, the group practice must administer the CAHPS for PQRS survey in addition to reporting the Web Interface measures.
12-month (Jan 1–Dec 31, 2016).	2–99 EPs; 100+ EPs (if CAHPS for PQRS does not apply).	Individual Measures.	Qualified Registry.	Report at least 9 measures, covering at least 3 of the NQS domains. Of these measures, if a group practice sees at least 1 Medicare patient in a face-to-face encounter, the group practice would report on at least 1 measure in the PQRS cross-cutting measure set. If less than 9 measures covering at least 3 NQS domains apply to the group practice, the group practice would report on each measure that is applicable to the group practice, AND report each measure for at least 50 percent of the group's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate would not be counted.
12-month (Jan 1–Dec 31, 2016).	2–99 EPs that elect CAHPS for PQRS; 100+ EPs (if CAHPS for PQRS applies).	Individual Measures + CAHPS for PQRS.	Qualified Registry + CMS-Certified Survey Vendor.	The group practice must have all CAHPS for PQRS survey measures reported on its behalf via a CMS-certified survey vendor, and report at least 6 additional measures, outside of the CAHPS for PQRS survey, covering at least 2 of the NQS domains using the qualified registry. If less than 6 measures apply to the group practice, the group practice must report on each measure that is applicable to the group practice. Of the additional measures that must be reported in conjunction with reporting the CAHPS for PQRS survey measures, if any EP in the group practice sees at least 1 Medicare patient in a face-to-face encounter, the group practice must report on at least 1 measure in the PQRS cross-cutting measure set.
12-month (Jan 1–Dec 31, 2016).	2–99 EPs; 100+ EPs (if CAHPS for PQRS does not apply).	Individual Measures.	Direct EHR Product or EHR Data Submission Vendor Product.	Report 9 measures covering at least 3 domains. If the group practice's direct EHR product or EHR data submission vendor product does not contain patient data for at least 9 measures covering at least 3 domains, then the group practice must report all of the measures for which there is Medicare patient data. A group practice must report on at least 1 measure for which there is Medicare patient data.

TABLE 19—SUMMARY OF REQUIREMENTS FOR THE 2018 PQRS PAYMENT ADJUSTMENT: GROUP PRACTICE REPORTING CRITERIA FOR SATISFACTORY REPORTING OF QUALITY MEASURES DATA VIA THE GPRO—Continued

Reporting period	Group practice size	Measure type	Reporting mechanism	Satisfactory reporting criteria
12-month (Jan 1–Dec 31, 2016).	2–99 EPs that elect CAHPS for PQRS; 100+ EPs (if CAHPS for PQRS applies).	Individual Measures + CAHPS for PQRS.	Direct EHR Product or EHR Data Submission Vendor Product + CMS-Certified Survey Vendor.	The group practice must have all CAHPS for PQRS survey measures reported on its behalf via a CMS-certified survey vendor, and report at least 6 additional measures, outside of CAHPS for PQRS, covering at least 2 of the NQS domains using the direct EHR product or EHR data submission vendor product. If less than 6 measures apply to the group practice, the group practice must report all of the measures for which there is Medicare patient data. Of the additional 6 measures that must be reported in conjunction with reporting the CAHPS for PQRS survey measures, a group practice would be required to report on at least 1 measure for which there is Medicare patient data.
12-month (Jan 1–Dec 31, 2016).	2+ EPs	Individual PQRS measures and/or non-PQRS measures reportable via a QCDR.	QCDR	Report at least 9 measures available for reporting under a QCDR covering at least 3 of the NQS domains, AND report each measure for at least 50 percent of the group practice's patients. Of these measures, the group practice would report on at least 2 outcome measures, OR, if 2 outcomes measures are not available, report on at least 1 outcome measures and at least 1 of the following types of measures—resource use, patient experience of care, efficiency/appropriate use, or patient safety.

3. Proposed Modifications to the Satisfactory Reporting Criteria for Individual EPs and Group Practices for the 2018 PQRS Payment Adjustment

Since we finalized these requirements, we have heard from stakeholders that EPs have had difficulty with the previously finalized satisfactory reporting criteria for the CY 2016 reporting period, which is the final reporting period for the PQRS. Specifically, we have heard from stakeholders through written communications to CMS that EPs have found the requirements complex, and had difficulty in understanding the requirements to be a satisfactory reporter for PQRS. Stakeholders have also requested that the requirements for the CY 2016 reporting period be aligned with those of the Quality Payment Program, specifically the Merit-based Incentive Payment System (MIPS). In particular, we have heard requests to lower the previously finalized requirement from 9 measures across 3 NQS domains, where applicable, to only 6 measures with no domain requirement associated with these measures. While the PQRS and the MIPS are separate programs, we understand that stakeholders would like to see greater continuity between the final year of the PQRS and the beginning of the MIPS.

The final reporting period for the PQRS was CY 2016. The Quality Payment Program, authorized by the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), consolidates and replaces three existing programs (the Medicare EHR Incentive Program for EPs, the PQRS, and the Value-Based Payment Modifier (VM)). There are two ways eligible clinicians can participate in this program: (1) Through the MIPS; and (2) through Advanced Alternative Payment Models (APMs). The initial performance period for the MIPS began on January 1, 2017. Under MIPS, there are four connected pillars that affect how MIPS eligible clinicians will be paid by Medicare: Quality; Improvement Activities; Advancing Care Information; and Cost. For more information on the Quality Payment Program, see *https://qpp.cms.gov/.*

While we understand that the data submission period for the CY 2016 reporting period has already ended and that all data that has been submitted to CMS is based on the previously finalized satisfactory reporting criteria for the CY 2016 reporting period, we are revisiting our previously finalized policy because we want individual EPs and groups to be assessed for purposes of the 2018 PQRS payment adjustment based on satisfactory reporting criteria that are simpler, more understandable, and more consistent with the beginning of MIPS. We believe that such criteria will help clinicians more accurately gauge their readiness for the beginning of MIPS and transition into the Quality Payment Program successfully. Additionally, we want to be responsive to the concerns of the clinician community. Therefore, while we are not proposing to collect any additional data for the CY 2016 reporting period, we are proposing to modify the criteria we would apply to the data already submitted for the CY 2016 reporting period to determine whether an individual EP or group practice has satisfactorily reported for purposes of avoiding the 2018 PQRS payment adjustment. Specifically, we are proposing to revise the previously finalized satisfactory reporting criteria for the CY 2016 reporting period to lower the requirement from 9 measures across 3 NQS domains, where applicable, to only 6 measures with no domain or cross-cutting measure requirement. For individual EPs, this would apply to the following reporting mechanisms: claims, qualified registry (except for measures groups), QCDR, direct EHR product and EHR data submissions vendor product. This proposal would not affect the criteria used to determine whether an individual EP or group practice has satisfactorily reported for purposes of avoiding the 2017 PQRS payment adjustment, with the exception of the criteria applicable to individual EPs and group practices reporting using the secondary reporting period established under § 414.90(j)(1)(ii) for the 2017 PQRS payment adjustment (hereinafter referred to as the ''ACO Secondary Reporting Period''), as discussed in section III.F.4. of this proposed rule.

Table 20 summarizes our proposed modifications to the previously finalized satisfactory reporting criteria for individual EPs to avoid the 2018

PQRS payment adjustment, based on data previously submitted for the CY 2016 reporting period. We are not proposing to collect any additional data for the CY 2016 reporting period, as the data submission period for the CY 2016 reporting period has already ended. As summarized in Table 20, the NQS domain requirement would no longer apply. No changes are being proposed for the measures groups criteria.

Additionally, we are also proposing that individual EPs and group practices reporting via claims or qualified registry, as applicable, would no longer be required to report a cross-cutting measure and that individual EPs and group practices reporting via QCDR would no longer be required to report an outcome or ''high priority'' measure (that is, for purposes of PQRS, a resource use, patient experience of care, efficiency/appropriate use, or patient safety measure). We note that what is considered to be a ''high-priority'' measure in PQRS is different from what is considered a ''high-priority'' measure in MIPS, and we are not proposing to align this requirement with MIPS for the last year of PQRS as this could cause confusion. While certain MIPS eligible clinicians are required to report at least one outcome or other high-priority measure (see § 414.1335(a)(1)(i)), we are also not aligning with that requirement because, while we agree that outcome and high-priority measures are valuable for reporting, we want to revise the satisfactory reporting criteria for the last year of PQRS to be less complex for individual EPs and groups to understand.

Lastly, where we are proposing to lower the requirement to only 6 measures, if less than 6 measures apply to the individual EP or group practice, each measure that is applicable would need to have been reported. We define ''applicable'' to mean measures relevant to a particular individual EP's or group practice's services or care rendered. As previously finalized, individual EPs and group practices would continue to be subject to the measure application validity (MAV) process (80 FR 71140 through 71145). The MAV process seeks to identify clinically similar measures and creates clusters of measures that can be reported if one of the measures in the cluster is reported. We would maintain the requirement that each required measure be reported for at least 50 percent of the individual EP's or group practice's patients to which the measure applies.

TABLE 20—SUMMARY OF PROPOSED MODIFICATIONS TO THE REQUIREMENTS FOR THE 2018 PQRS PAYMENT ADJUSTMENT: INDIVIDUAL REPORTING CRITERIA FOR THE SATISFACTORY REPORTING OF QUALITY MEASURES DATA VIA CLAIMS, QUALIFIED REGISTRY, AND EHRS AND SATISFACTORY PARTICIPATION CRITERION IN QCDRS

Reporting period	Measure type	Reporting mechanism	Proposed satisfactory reporting criteria
12-month (Jan 1– Dec 31, 2016)	Individual Measures	Claims	Report at least 6 measures, AND report each measure for at least 50 percent of the EP's Medicare Part B FFS patients seen during the reporting period to which the measure applies. If less than 6 measures apply to the EP, the EP must report on each measure that is applicable, AND report each measure for at least 50 percent of the Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate will not be counted (unless they are inverse measures where a lower rate reflects better performance).
12-month (Jan 1– Dec 31, 2016)	Individual Measures	Qualified Registry	Report at least 6 measures, AND report each measure for at least 50 percent of the EP's Medicare Part B FFS patients seen during the reporting period to which the measure applies. If less than 6 measures apply to the EP, the EP must report on each measure that is applicable, AND report each measure for at least 50 percent of the Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate will not be counted (unless they are inverse measures where a lower rate reflects better performance).
12-month (Jan 1– Dec 31, 2016)	Individual Measures	Direct EHR Product or EHR Data Submission Vendor Product.	Report at least 6 measures. If an EP's direct EHR product or EHR data submission vendor product does not contain patient data for at least 6 measures, then the EP must report all of the measures for which there is Medicare patient data. An EP must report on at least 1 measure for which there is Medicare patient data.
12-month (Jan 1– Dec 31, 2016)	Measures Groups	Qualified Registry	No proposed changes.
12-month (Jan 1– Dec 31, 2016)	Individual PQRS measures and/or non-PQRS measures reportable via a QCDR.	QCDR	Report at least 6 measures available for reporting under a QCDR AND report each measure for at least 50 percent of the EP's patients seen during the reporting period to which the measure applies. If less than 6 measures apply to the EP, the EP must report on each measure that is applicable, AND report each measure for at least 50 percent of the EP's patients.

Accordingly, we are proposing to revise § 414.90(j)(8) and (k)(5) consistent with our proposals above. We believe these proposals will result in fewer individual EPs being subject to the 2018 PQRS payment adjustment, and will impose no additional burden on individual EPs because this data has already been submitted to CMS. We request comment on these proposals.

As discussed above, while we are not proposing to collect any additional data for the CY 2016 reporting period, we are proposing to modify the satisfactory reporting criteria for the CY 2016 reporting period for purposes of the 2018 PQRS payment adjustment. Specifically, we are proposing to lower the requirement from 9 measures across 3 NQS domains, where applicable, to only 6 measures with no domain or cross-cutting measure requirement. For group practices, this would apply to the following reporting mechanisms: Qualified registry; QCDR; direct EHR product; and EHR data submissions vendor product. This proposal would not affect the criteria used to determine whether an individual EP or group practice has satisfactorily reported for purposes of avoiding the 2017 PQRS payment adjustment, with the exception of the criteria applicable to individual EPs and group practices reporting using the ACO Secondary Reporting Period, as discussed in section III.F.4. of this proposed rule.

Table 21 summarizes our proposed modifications to the previously finalized satisfactory reporting criteria for group practices to avoid the 2018 PQRS payment adjustment, based on data previously submitted for the CY 2016 reporting period. We are not proposing to collect any additional data for the CY 2016 reporting period, as the data submission period for the CY 2016 reporting period has already ended. As summarized in Table 21, the NQS domain requirement would no longer apply. No changes are being proposed for the Web Interface criteria.

Additionally, as discussed above, we are proposing that individual EPs and group practices reporting via claims and qualified registry, as applicable, would no longer be required to report a cross-cutting measure and that individual EPs and group practices reporting via QCDR would no longer be required to report an outcome or high priority measure. We note that what is considered to be a ''high-priority'' measure in PQRS is different from what is considered a ''high-priority'' measure in MIPS, and are not proposing to align this requirement with MIPS for the last year of PQRS as this could cause confusion. While certain MIPS eligible clinicians are required to report at least one outcome or other high-priority measure (see § 414.1335(a)(1)(i)), we are also not aligning with that requirement because, while we agree that outcome and high-priority measures are valuable for reporting, we want to revise the satisfactory reporting criteria for the last year of PQRS to be less complex for individual EPs and groups.

Where we are proposing to lower the requirement to only 6 measures, if less than 6 measures apply to the individual EP or group practice, each measure that is applicable would need to have been reported. We define ''applicable'' to mean measures relevant to a particular individual EP's or group practice's services or care rendered. As previously finalized, individual EPs and group practices would continue to be subject to the MAV process (80 FR 71140 through 71145). The MAV process seeks to identify clinically similar measures and creates clusters of measures that can be reported if one of the measures in the cluster is reported. We would maintain the requirement that each required measure be reported for at least 50 percent of the individual EP's or group practice's patients to which the measure applies.

Lastly, for purposes of the 2018 PQRS payment adjustment, § 414.90(j)(9)(viii) currently provides that if the CAHPS for PQRS survey is applicable to the practice, group practices comprised of 100 or more eligible professionals that register to participate in the GPRO must administer the CAHPS for PQRS survey, regardless of the GPRO reporting mechanism selected. For the reasons discussed above, we are proposing to revise § 414.90(j)(9)(viii) to provide that such group practices may administer the CAHPS for PQRS survey, regardless of the GPRO reporting mechanism selected, but are not required to do so. This change would be consistent with the data submission criteria for the MIPS quality performance category, under which groups may voluntarily elect to participate in the CAHPS for MIPS survey (see § 414.1335(a)(3)(i)). As summarized in Table 21, the previously finalized satisfactory reporting criteria for group practices administering the CAHPS for PQRS survey would continue to apply to group practices that elected to administer the survey.

TABLE 21—SUMMARY OF PROPOSED MODIFICATIONS TO THE REQUIREMENTS FOR THE 2018 PQRS PAYMENT ADJUSTMENT: GROUP PRACTICE REPORTING CRITERIA FOR SATISFACTORY REPORTING OF QUALITY MEASURES DATA VIA THE GPRO

Reporting period	Group practice size [3]	Measure type	Reporting mechanism	Proposed satisfactory reporting criteria
12-month (Jan 1–Dec 31,2016).	25+ EPs	Individual GPRO Measures in the Web Interface.	Web Interface	No proposed changes.
12-month (Jan 1–Dec 31,2016).	25+ EPs that elect CAHPS for PQRS.	Individual GPRO Measures in the Web Interface+ CAHPS for PQRS.	Web Interface + CMS-Certified Survey Vendor..	No proposed changes.
12-month (Jan 1–Dec 31,2016).	2+ EPs	Individual Measures	Qualified Registry	Report at least 6 measures AND report each measure for at least 50 percent of the group's Medicare Part B FFS patients seen during the reporting period to which the measure applies. If less than 6 measures apply to the group, the group practice must report on each measure that is applicable, AND report each measure for at least 50 percent of the Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate will not be counted (unless they are inverse measures where a lower rate reflects better performance).

TABLE 21—SUMMARY OF PROPOSED MODIFICATIONS TO THE REQUIREMENTS FOR THE 2018 PQRS PAYMENT ADJUSTMENT: GROUP PRACTICE REPORTING CRITERIA FOR SATISFACTORY REPORTING OF QUALITY MEASURES DATA VIA THE GPRO—Continued

Reporting period	Group practice size [3]	Measure type	Reporting mechanism	Proposed satisfactory reporting criteria
12-month (Jan 1–Dec 31,2016).	2+ EPs that elect CAHPS for PQRS.	Individual Measures+CAHPS for PQRS.	Qualified Registry+CMS-Certified Survey Vendor.	The group practice must have all CAHPS for PQRS survey measures reported on its behalf via a CMS-certified survey vendor. In addition, the group practice must report at least 3 additional measures using the qualified registry AND report each measure for at least 50 percent of the group's Medicare Part B FFS patients seen during the reporting period to which the measure applies. If less than 3 measures apply to the group practice, the group practice must report on each measure that is applicable, AND report each measure for at least 50 percent of the Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate will not be counted (unless they are inverse measures where a lower rate reflects better performance).
12-month (Jan 1–Dec 31,2016)..	2+ EPs	Individual Measures	Direct EHR Product or EHR Data Submission Vendor Product.	Report 6 measures. If the group practice's direct EHR product or EHR data submission vendor product does not contain patient data for at least 6 measures, then the group practice must report all of the measures for which there is Medicare patient data. A group practice must report on at least 1 measure for which there is Medicare patient data.
12-month (Jan 1–Dec 31,2016)..	2+ EPs that elect CAHPS for PQRS.	Individual Measures+CAHPS for PQRS.	Direct EHR Productor EHR Data Submission Vendor Product+CMS-Certified Survey Vendor.	The group practice must have all CAHPS for PQRS survey measures reported on its behalf via a CMS-certified survey vendor. In addition, the group practice must report at least 3 additional measures using the direct EHR product or EHR data submission vendor product. If less than 3 measures apply to the group practice, the group practice must report all of the measures for which there is patient data. Of the additional 3 measures that must be reported in conjunction with reporting the CAHPS for PQRS survey measures, a group practice must report on at least 1 measure for which there is Medicare patient data.
12-month (Jan 1–Dec 31,2016).	2+ EPs	Individual PQRS measures and/or non-PQRS measures reportable via a QCDR.	QCDR	Report at least 6 measures available for reporting under a QCDR AND report each measure for at least 50 percent of the group practice's patients seen during the reporting period to which the measure applies. If less than 6 measures apply to the group practice, the group practice must report on each measure that is applicable, AND report each measure for at least 50 percent of the group practice's patients.

[3] Please note that the group practice size descriptions have been revised for greater consistency with our proposal to make the CAHPS for PQRS survey voluntary.

Accordingly, we are proposing to revise § 414.90(j)(9) and (k)(5) consistent with our proposals above. We believe these proposals will result in fewer group practices being subject to the 2018 PQRS payment adjustment, and will impose no additional burden on group practices because this data has already been submitted to CMS. We request comment on these proposals.

4. Accountable Care Organization (ACO) Participants Who Report PQRS Quality Measures Separately During the Secondary Reporting Period

As discussed in the CY 2017 PFS final rule (81 FR 80441 through 80445), individual EPs and group practices who bill under the TIN of an ACO participant may report separately from the ACO, if the ACO failed to report on behalf of such individual EPs or group practices for the applicable reporting period, during the CY 2016 reporting period for purposes of the 2017 and 2018 PQRS payment adjustments, as applicable. Please note that, in accordance with our previously established policies for the ACO Secondary Reporting Period, our proposed modifications to the satisfactory reporting criteria for individual EPs and group practices for the CY 2016 reporting period would apply to such individual EPs and group practices for purposes of the 2017 PQRS payment adjustment. This proposal would not affect the 2017 PQRS payment adjustment for any other individual EP or group practice.

5. Physician Compare Downloadable Database—Addition of Value Modifier (VM) Data

We previously finalized in the CY 2016 PFS final rule (80 FR 71129 through 71130) a decision to publicly report three data points for the 2018 VM based on 2016 data in the Physician Compare downloadable file in late 2017:

- 2018 VM quality tiers for cost and quality, based on the 2016 data, noting if the EP or group is high, low, or average on cost and quality per the VM.
- A notation of the payment adjustment received based on the cost and quality tiers—upward, downward, or neutral—for each EP or group.
- An indication if the EP or group was eligible to but did not report quality measures to CMS for CY 2016 under PQRS.

In light of the proposals to change the 2016 reporting criteria to avoid the 2018 payment adjustment for PQRS (see section III.F. of this proposed rule) and subsequent VM proposed policies to hold all physician groups and solo practitioners who met minimum quality reporting requirements harmless from downward payment adjustments for performance under quality-tiering for the last year of the program (see section III.I. of this proposed rule), and because the proposed policies for PQRS and VM in this rule would change the nature of how the PQRS data will be used under the VM, we are now proposing not to report this data specific to the VM. Given the fact that VM data would be available for posting in the Physician Compare downloadable database for only one year and the VM data may not reflect an EP or group's actual performance or payment adjustment given they could have chosen to report fewer measures, we believe that proceeding with the posting of this data could be confusing for the public.

Additionally, we have created other VM data files intended to promote transparency. For each VM performance year, we will publish a Public Use File (PUF) that contains VM performance results of de-identified practices. Supporting documentation for each PUF that contains the field name, length, type, label, description, and notes for each variable included in the PUF. The Value Modifier program years 2015 and 2016 (performance year 2013 and 2014) are currently available at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/VMPUF/Value-Modifier-PUF.html.* In addition, three Research Identifiable Files (RIFs) for Value Modifier program years 2015 and 2016 (performance year 2013 and 2014) are available through the Research Data Assistance Center (ResDAC) and will be made available for each program year. These files include a practice-level, an NPI-practice level, and a beneficiary-level file, as described at: *https://www.resdac.org/news/cms-creates-set-rif-data-files-support-value-based-payment-modifier-program/2017/06*.

All other previously finalized policies related to 2016 PQRS data available for public reporting on Physician Compare in late 2017 remain unchanged (80 FR 71116 through 71132). Appreciating this, we believe the best course of action is to not move forward with publicly reporting this VM data for 2016. All data required to be reported by law will remain available for public reporting as previously finalized (80 FR 71116 through 71132). For more information on the public reporting policies previously finalized and proposed for MIPS, we refer readers to the Medicare Program; Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive Under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models (81 FR 77390 through 77399) and Medicare Program; CY 2018 Updates to the Quality Payment Program (82 FR 30163 through 30170), respectively. We request comment on this proposal and specifically, if we were to release this data, how it could be used by the public.

G. Clinical Quality Measurement for Eligible Professionals Participating in the Electronic Health Record (EHR) Incentive Program for 2016

1. Background

Sections 1848(o), 1853(l) and (m), 1886(n), and 1814(l) of the Act provide the statutory basis for the Medicare incentive payments made to eligible professionals (EPs), Medicare Advantage (MA) organizations (for certain qualifying EPs and hospitals), subsection (d) hospitals, and critical access hospitals (CAHs) that demonstrate meaningful use of certified electronic health record (EHR) technology (CEHRT). Sections 1848(a)(7), 1853(l) and (m), 1886(b)(3)(B), and 1814(l) of the Act also establish downward adjustments to Medicare payments, beginning with calendar or fiscal year (FY) 2015, for EPs, MA organizations, subsection (d) hospitals, and CAHs that are not meaningful users of CEHRT for certain associated reporting periods. Sections 1903(a)(3)(F) and 1903(t) of the Act provide the statutory basis for the Medicaid incentive payments made to EPs and eligible hospitals for the adoption, implementation, upgrade, and meaningful use of CEHRT. We have implemented these statutory provisions in prior rulemakings to establish the Medicare and Medicaid EHR Incentive Programs.

Under these statutory provisions and the regulations at 42 CFR 495.4, one of the requirements of being a meaningful EHR user is successfully reporting the clinical quality measures selected by CMS to CMS or the states, as applicable, in the form and manner specified by CMS or the states, as applicable. Section 1848(o)(2)(B)(iii) of the Act requires that in selecting clinical quality measures (CQMs) for EPs to report under the EHR Incentive Program, and in establishing the form and manner of reporting, the Secretary shall seek to avoid redundant or duplicative reporting otherwise required, including reporting under section 1848(k)(2)(C) of the Act (the Physician Quality Reporting System). As such, we have taken steps to establish alignments among various quality reporting and payment programs that include the submission of CQMs.

2. Clinical Quality Measure (CQM) Requirements for Meaningful Use in 2016

Under sections 1848(o)(2)(A)(iii) and 1903(t)(6)(C)(i)(II) of the Act and the definition of ''meaningful EHR user'' at § 495.4, EPs must report on CQMs selected by CMS using CEHRT, as part of being a meaningful EHR user under the Medicare and Medicaid EHR Incentive Programs. In the final rule titled ''Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Stage 3 and Modifications to Meaningful Use in 2015 Through 2017,'' we finalized the options for CQM submission for EPs in the Medicare EHR Incentive Program in 2016 as follows (80 FR 62888 through 62889):

- EP Options for Medicare EHR Incentive Program Participation (single program Participation—EHR Incentive Program only):
  - ++ *Option 1:* Attest to CQMs through the EHR Registration & Attestation System.
  - ++ *Option 2:* Electronically report CQMs through Physician Quality Reporting System (PQRS) Portal.
- EP Options for Electronic Reporting for Multiple Programs (for example: EHR Incentive Program plus PQRS participation):
  - ++ *Option 1:* Report individual EP's CQMs through PQRS Portal.
  - ++ *Option 2:* Report group's CQMs through PQRS Portal.

(NOTE: Under option 2, this may include an EP reporting using the group

reporting option, either electronically using QRDA, or via the GPRO Web Interface.)

For the Medicaid EHR Incentive Program, we specified (80 FR 62888) that states would continue to be responsible for determining whether and how electronic reporting of CQMs would occur, or if they wish to allow reporting through attestation. Any changes that states make to their CQM reporting methods must be submitted through the state Medicaid Health IT Plan (SMHP) process for our review and approval prior to being implemented.

We maintained a requirement that EPs report 9 CQMs covering at least 3 NQS domains (80 FR 62888 through 62889). This requirement was established in the final rule titled ''Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Stage 2'' (77 FR 54058).

We also continued (80 FR 62888 through 62889) our existing policy that under Medicare, healthcare providers in any year of participation for the EHR Incentive Program for 2015 through 2017 may electronically report CQM data using the options previously outlined for electronic reporting either for single program participation in the Medicare EHR Incentive Program, or for participation in multiple programs if the requirements of the aligned quality program are also met.

We noted that an EHR certified for CQMs under the 2014 Edition certification criteria does not need to be recertified each time it is updated to a more recent version of the eCQMs (80 FR 62889).

3. CQM Requirements for EPs and Groups Under the Medicare EHR Incentive Program in 2016

As we discussed in section III.F. in this proposed rule, since we finalized these requirements, we have heard from stakeholders through written communications that EPs and groups have found the previously finalized reporting criteria for the CY 2016 reporting period to be complex and had difficulty in understanding the requirements to be a satisfactory reporter, and these same EPs and groups subsequently requested that the CQM reporting requirements for EPs and groups participating in the Medicare EHR Incentive Program in 2016 who chose to report CQMs electronically through the Physician Quality Reporting System (PQRS) Portal be aligned with those of the Quality Payment Program, specifically the Merit-based Incentive Payment System (MIPS).

Therefore, while we are not proposing to collect any additional data for 2016, we are proposing to change the reporting criteria for EPs and groups who chose to electronically report CQMs through the PQRS Portal for purposes of the Medicare EHR Incentive Program. Specifically, we are proposing to change the reporting criteria from 9 CQMs covering at least 3 NQS domains to 6 CQMs with no domain requirement. We are proposing this change so that the reporting criteria for the Medicare EHR Incentive Program would be in alignment with the modified requirement that we are proposing for the final PQRS reporting period (2016) in section III.F. of this proposed rule, as well as the transition year of the Quality Payment Program. We are proposing that an EP or group who satisfies the proposed reporting criteria may qualify for the 2016 incentive payment under section 1848(o) of the Act and may avoid the downward payment adjustment in 2017 and/or 2018 under section 1848(a)(7)(A) of the Act, depending on the EP or group's applicable EHR reporting period for the payment adjustment year. This proposed change would help maintain alignment with PQRS per the requirement under section 1848(o)(2)(B)(iii) of the Act for the Secretary to seek to avoid redundant or duplicative reporting otherwise required, including reporting under section 1848(k)(2)(C) of the Act (the PQRS). We are not proposing to change the previously finalized requirements for CQM reporting in 2016 for eligible hospitals and CAHs; or the previously finalized requirements for EPs who chose to report CQMs through attestation in 2016 for the Medicare EHR Incentive Program (80 FR 62888). Our reasoning for not proposing to change the eligible hospital or CAH requirements for CQM reporting is because the changes proposed for PQRS in section III.F. of this proposed rule and the policies established for the transition year of the Quality Payment Program would only affect clinicians and groups, and therefore, there is no reason to propose changes to the established policy for eligible hospitals or CAHs. We are not proposing to change the requirements for EPs who reported CQMs through attestation because those who attested were successful, therefore we believe there is no need to change the requirement. Additionally, the Registration and Attestation portal is scheduled to sunset as of October 1, 2017 before this final rule is published.

Lastly, we are also not proposing to change the previously finalized requirements for 2016 for EPs participating in the Medicaid EHR Incentive Program. We have already proposed in ''Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2018 Rates; Quality Reporting Requirements for Specific Providers; Medicare and Medicaid Electronic Health Record (EHR) Incentive Program Requirements for Eligible Hospitals, Critical Access Hospitals, and Eligible Professionals; Provider-Based Status of Indian Health Service and Tribal Facilities and Organizations; Costs Reporting and Provider Requirements; Agreement Termination Notices'' that, for 2017, Medicaid EPs would be required to report on any six CQMs that are relevant to the EP's scope of practice (82 FR 20135). In proposing that change, we indicated that it is our intention to align CQM requirements for Medicaid EPs with requirements under the Medicare quality improvement programs, to the extent practicable. However, we believe that due to the timing of when any changes we might propose for 2016 through this rulemaking would take effect (if finalized), the benefits of proposing to extend the policy proposed for Medicare EPs for 2016 to Medicaid EPs for 2016 would not be realized, and the burden on states to implement such a policy would be significant. There is no negative payment adjustment for not participating in the Medicaid EHR Incentive Program, so it is likely that applying the proposed policy for Medicare EPs to Medicaid EPs for 2016 would benefit Medicaid EPs only if they are able to submit new data to states for a Medicaid EHR incentive payment for 2016. Because we anticipate that most states will have completed processing and paying 2016 Medicaid EHR incentive payments by the time such a proposal (if finalized) would take effect, we believe that applying this change to the Medicaid EHR Incentive Program for 2016 would significantly burden states. We seek comment on our assessment of the difficulty states might face implementing this policy for 2016 for Medicaid EPs, and on the number of Medicaid EPs who might benefit if we instead decided to apply this policy in the Medicaid EHR Incentive Program for 2016, to the extent that doing so would be legally permissible.

H. Medicare Shared Savings Program

Under section 1899 of the Act, we established the Medicare Shared Savings Program (Shared Savings Program) to facilitate coordination and

cooperation among health care providers to improve the quality of care for Medicare Fee-For-Service (FFS) beneficiaries and reduce the rate of growth in expenditures under Medicare Parts A and B. Eligible groups of providers and suppliers, including physicians, hospitals, and other health care providers, may participate in the Shared Savings Program by forming or participating in an Accountable Care Organization (ACO). The final rule establishing the Shared Savings Program appeared in the November 2, 2011 **Federal Register** (Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations; Final Rule (76 FR 67802) (hereinafter referred to as the ''November 2011 final rule'')). A subsequent major update to the program rules appeared in the June 9, 2015 **Federal Register** (Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations; Final Rule (80 FR 32692) (hereinafter referred to as the ''June 2015 final rule'')). A final rule addressing changes related to the program's financial benchmark methodology appeared in the June 10, 2016 **Federal Register** (Medicare Program; Medicare Shared Savings Program; Accountable Care Organizations—Revised Benchmark Rebasing Methodology, Facilitating Transition to Performance-Based Risk, and Administrative Finality of Financial Calculations (81 FR 37950) (hereinafter referred to as the ''June 2016 final rule'')). We have also made use of the annual calendar year (CY) Physician Fee Schedule (PFS) rules to address quality reporting and certain other issues. In addition, in the CY 2017 Quality Payment Program final rule (81 FR 77255 through 77256), we finalized policies related to quality performance category scoring for Merit-Based Incentive Payment System (MIPS) eligible clinicians that participate in the Shared Savings Program. In that final rule, we adopted an APM scoring standard that reduces burden for eligible clinicians that participate in Shared Savings Program ACOs by using the same quality data reported by the ACO using the the CMS web interface for purposes of the Shared Savings Program to score the MIPS quality performance category for these eligible clinicians.

In this CY 2018 PFS proposed rule, we propose further refinements to the Shared Savings Program rules. This rule includes two proposed modifications to the Shared Savings Program beneficiary assignment methodology: (1) Revisions to the assignment methodology under 42 CFR part 425, subpart E to reflect the requirement under section 17007 of the 21st Century Cures Act (Pub. L. 114–255, December 13, 2016), that for performance years beginning on or after January 1, 2019, the Secretary determine an appropriate method to assign Medicare FFS beneficiaries to an ACO based on their utilization of services furnished by rural health clinics (RHCs) or federally qualified health centers (FQHCs), and (2) addition of new chronic care management and BHI service codes to our definition of primary care services. In addition, we propose to revise the methodology used in our quality validation audits and the manner in which the results of these audits may be used to adjust an ACO's sharing rate. We also propose to reserve the discretion to redesignate a measure reported through the CMS web interface as pay-for-reporting when substantive changes are made to the measure under the Quality Payment Program.

We also address proposals intended to reduce application burden for stakeholders by reducing certain documentation submission requirements included in the initial Shared Savings Program application and the application for use of the skilled nursing facility (SNF) 3-Day Rule Waiver. We also propose to establish specific procedures to address situations where a Taxpayer Identification Number (TIN) that is an ACO participant in more than one ACO begins to submit claims for services used in the beneficiary assignment process and becomes out of compliance with the ''exclusivity'' requirement in § 425.306(b)(2). Finally, we propose that, for performance year 2018 and subsequent years, we would only include individually beneficiary identifiable payments made under a demonstration, pilot or time limited program that are final and not subject to further reconciliation in financial calculations related to establishing and updating benchmarks and determining performance year expenditures under the Shared Savings Program.

1. Modifications to the Shared Savings Program Beneficiary Assignment Methodology

a. Assignment of Beneficiaries to ACOs That Include RHCs and/or FQHCs

(1) Background

(a) General Shared Savings Program Assignment Methodology

As originally enacted in the Affordable Care Act, section 1899(c) of the Act requires us to assign FFS beneficiaries to an ACO participating in the Shared Savings Program based on the beneficiary's utilization of primary care services rendered by physicians participating in the ACO. Medicare FFS beneficiaries do not enroll in the Shared Savings Program or with a particular ACO, and they retain the right to seek Medicare-covered services from any Medicare-enrolled provider or supplier of their choosing. Furthermore, no exclusions or restrictions based on health conditions or similar factors are applied in the assignment of Medicare FFS beneficiaries. Thus, a beneficiary's choice to receive primary care services during a prior 12 month period (the ''assignment window'') furnished by physicians and certain nonphysician practitioners that are ACO professionals in the ACO determines the beneficiary's assignment to an ACO under the Shared Savings Program.

The regulations governing the assignment methodology under the Shared Savings Program are in part 425, subpart E. Consistent with the statutory requirement to base assignment on the utilization of primary care services furnished by physicians who are ACO professionals, a beneficiary is eligible for assignment to an ACO under § 425.402 if the beneficiary had at least one primary care service during the applicable assignment window furnished by a physician who is an ACO professional in the ACO and who is a primary care physician as defined under § 425.20 or has one of the primary specialty designations specified in § 425.402(c). This initial process for determining whether a beneficiary is eligible for assignment is referred to as the assignment ''pre-step''. Under the first step of the assignment process, a beneficiary who is eligible for assignment to the ACO will be assigned to the ACO if the allowed charges for primary care services furnished to the beneficiary during the assignment window by all primary care physicians who are ACO professionals and non-physician ACO professionals in the ACO are greater than the allowed charges for such services provided during the assignment window by primary care physicians, nurse practitioners, physician assistants, and clinical nurse specialists who are ACO professionals in another ACO or not affiliated with any ACO and are identified by a Medicare-enrolled billing TIN. The second step of the assignment process considers the remainder of beneficiaries who have received at least one primary care service during the assignment window from an ACO physician who is a primary care physician as defined under § 425.20 or who has one of the primary specialty designations specified in § 425.402(c),

but have received no primary care services during the assignment window from a primary care physician, nurse practitioner, physician assistant, or clinical nurse specialist either inside or outside the ACO. These beneficiaries are assigned to the ACO if the allowed charges for primary care services furnished during the assignment window by physicians who are ACO professionals in the ACO with one of the specialty designations specified in § 425.402(c) are greater than the allowed charges for primary care services furnished during the assignment window by physicians with such specialty designations who are ACO professionals in another ACO or who are not affiliated with any ACO and are identified by a Medicare-enrolled billing TIN. Thus, the assignment methodology simultaneously maintains the statutory requirement to focus on physician primary care services in beneficiary assignment, while recognizing the necessary and appropriate role of specialists and non-physician practitioners in providing primary care services, such as in areas with primary care physician shortages.

(b) Retrospective vs Prospective Assignment

As discussed in detail in the November 2011 final rule we finalized a claims-based hybrid approach (called preliminary prospective assignment with retrospective reconciliation) for assigning beneficiaries to an ACO (76 FR 67851 through 67870), which is currently applicable to ACOs participating under Track 1 or Track 2 of the Shared Savings Program. Under this approach, beneficiaries are preliminarily assigned to an ACO at the beginning of a performance year and quarterly thereafter during the performance year, but the final beneficiary assignment is determined after each performance year based on where beneficiaries chose to receive a plurality of their primary care services during the performance year. We adopted this policy because we believe that the methodology balances beneficiary freedom to choose healthcare providers under FFS Medicare during the performance year with the ACO's desire to know in advance about beneficiaries who have chosen to receive such services from practitioners participating in the ACO in the past and who are likely to continue to choose to receive such services during the performance year. Knowing in advance which beneficiaries are likely to receive a plurality of their primary care from ACO practitioners during the performance year gives ACOs greater opportunities to proactively impact the quality and cost of care for beneficiaries who may be assigned to the ACO at the end of the performance year.

In the June 2015 final rule, and in response to stakeholders' suggestions, we implemented an option for ACOs to participate in a new two-sided performance-based risk track, Track 3 (80 FR 32771 through 32781). Under Track 3, beneficiaries are prospectively assigned to the ACO at the beginning of the performance year using the same two-step methodology described previously, based on where the beneficiaries have chosen to receive a plurality of their primary care services during a 12-month assignment window offset from the calendar year that reflects the most recent 12 months for which data are available prior to the start of the performance year. The ACO is held accountable for beneficiaries who are prospectively assigned to it for the performance year. Under limited circumstances, a beneficiary may be excluded from the prospective assignment list during or after the performance year. For example, a beneficiary will be excluded from the prospective assignment list if the beneficiary enrolls in Medicare Advantage during the performance year or no longer lives in the United States or U.S. territories and possessions, based on the most recent available data regarding the beneficiary's residence at the end of the performance year. A beneficiary is not excluded from the ACO's prospective assignment list during the performance year or at the time of reconciliation for most other reasons, such as if the beneficiary chose to receive most or all of his or her primary care during the performance year from providers and suppliers outside the ACO. Additionally, no beneficiaries are added to the ACO's prospective assignment list during the performance year or at the time of reconciliation even if they chose to receive a plurality of their primary care during the performance year from ACO professionals participating in the ACO and were not previously identified on the prospective assignment list. Offering this alternative approach to beneficiary assignment responds to stakeholders who expressed a desire for a prospective assignment approach. These stakeholders believe prospective assignment will provide more certainty about the beneficiaries for whom the ACO will be held accountable during the performance year, thus enabling ACOs to redesign their patient care processes to more efficiently and effectively improve care for specific FFS beneficiaries rather than for all FFS beneficiaries. We note, however, that such certainty is limited because prospectively assigned beneficiaries who meet the exclusion criteria specified in § 425.401(b) during the performance year will not be assigned to the ACO at the end of the year; further, as noted, beneficiaries remain free under FFS Medicare to choose the healthcare providers from whom they receive services.

Finally, in the CY 2017 Physician Fee Schedule final rule (81 FR 80501 through 80510), we further enhanced the claims-based beneficiary assignment methodology by finalizing a policy to incorporate data gathered directly from beneficiaries who designate a ''main doctor'' they believe is responsible for coordinating their overall care. Beginning in performance year 2017, beneficiaries may designate a provider or supplier as responsible for coordinating their overall care using *MyMedicare.gov,* a secure, online, patient portal. Notwithstanding the assignment methodology in § 425.402(b), beneficiaries who designate an ACO professional whose services are used in assignment as responsible for their overall care will be prospectively assigned to the ACO in which that ACO professional participates, provided the beneficiary meets the eligibility criteria established at § 425.401(a) and has had at least one primary care service during the assignment window with an ACO professional in the ACO who is a primary care physician or a physician with one of the primary specialty designations included in § 425.402(c). Such beneficiaries will be added prospectively to the ACO's list of assigned beneficiaries for the subsequent performance year.

(c) Special Assignment Conditions for RHCs and FQHCs

RHCs and FQHCs are facilities that furnish services that are typically furnished in an outpatient clinic setting. Prior to October 1, 2014, FQHCs were paid an all-inclusive rate (AIR) per visit for qualified primary and preventive health services furnished to Medicare beneficiaries. On October 1, 2014, FQHCs began to transition to a new FQHC prospective payment system (PPS). FQHCs were required to use HCPCS coding on all their claims starting on January 1, 2011, to inform the development of the PPS and for limited other purposes, and are now required to use HCPCS coding for payment purposes under the FQHC PPS.

RHCs are paid an AIR per visit for qualified primary and preventive health services furnished to Medicare beneficiaries. Prior to April 1, 2016, RHCs were required to report HCPCS codes for a few services, such as certain preventive services eligible for a waiver of the deductible and/or coinsurance, services subject to frequency limits, and services eligible for payments in addition to the AIR. Effective April 1, 2016, all RHCs are required to report the appropriate HCPCS code for each service furnished during the visit, along with the appropriate revenue code (For additional background, please see the CMS Web site at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/FQHCPPS/Downloads/RHC-Reporting-FAQs.pdf*).

As we noted in the November 2011 final rule, RHC and FQHC claims contain very limited information concerning the individual practitioner, or even the type of health professional (for example, physician, PA, or NP) who provided the service because this information is not necessary to determine payment rates for services in RHCs and FQHCs s (76 FR 67858 through 67861). Therefore, unlike physician fee schedule claims, there is no direct way for us to determine if a claim was for a service furnished by a physician at the RHC or FQHC.

In spite of the difference in claims billing, based on detailed comments from some RHC and FQHC representatives, in the November 2011 final rule, we established a process that allows primary care services furnished in RHCs and FQHCs to be considered in the assignment process for any ACO that includes an RHC or FQHC as an ACO participant. This process is set forth in § 425.404. We assign beneficiaries to ACOs that include RHCs or FQHCs as ACO participants in a manner generally consistent with how we assign beneficiaries to other ACOs based on primary care services performed by certain physicians and non-physician practitioners who are ACO professionals in the ACO, as described previously. However, to address the requirement under section 1899(c) of the Act that beneficiaries be assigned to an ACO based on their use of primary care services furnished by physicians, we require ACOs that include RHCs or FQHCs to identify, through an attestation, the physicians that directly provide patient primary care services in their ACO participant RHCs or FQHCs (see §§ 425.204(c)(5)(iii) and 425.404(a)). We use the combination of the RHC or FQHC ACO participant TIN (and another unique identifier, such as a CCN, where appropriate) and the NPIs of the RHC or FQHC physicians provided to us through the attestation process to identify those beneficiaries who received a primary care service from a physician in the RHC or FQHC and who are therefore eligible to be assigned to the ACO as provided under § 425.402(b)(1), which we refer to as the assignment ''pre-step''. Then, we assign those beneficiaries to the ACO, using the step-wise assignment methodology under § 425.402(b), if they received the plurality of their primary care services, as determined based on allowed charges for the HCPCS codes and revenue center codes included in the definition of primary care services at § 425.20, from ACO professionals in the ACO.

The special procedures that we have established for using RHC and FQHC services in the assignment methodology are discussed in detail in the June 2015 final rule (80 FR 32755 through 32756). RHC and FQHC services are billed on an institutional claim form and require special handling to incorporate them into the beneficiary assignment process. For RHCs and FQHCs that are ACO participants, we treat an RHC or FQHC service reported on an institutional claim as a primary care service performed by a primary care physician if the claim includes a HCPCS or revenue center code that is included in the definition of a primary care service at § 425.20 and the service was furnished by a physician who was identified as directly providing primary care services on the attestation provided under § 425.404(a). All such physicians are considered primary care physicians for purposes of the assignment methodology and no specialty code is required for these claims. If the claim is for a primary care service furnished by someone other than a physician listed on the attestation, we treat the service as a primary care service furnished by a non-physician ACO professional. As a result, all primary care services furnished by an ACO professional in an RHC or FQHC to a beneficiary eligible for assignment to the ACO are considered in step 1 of the assignment methodology. Finally, for RHCs and FQHCs that are not ACO participants, we assume a primary care physician performed all primary care services so that all primary care services furnished by non-ACO RHCs/FQHCs are considered in step 1 of the assignment methodology. We believe this approach helps to ensure that we do not disrupt established relationships between beneficiaries and their caregivers in non-ACO participant RHCs and FQHCs by inappropriately assigning beneficiaries to ACOs that are not primarily responsible for coordinating their overall care.

We developed and implemented these regulatory and operational policies to facilitate full participation of rural providers, including RHCs and FQHCs, in the Shared Savings Program, within the statutory requirements for the program. In general, stakeholders have been appreciative of our policies to include rural providers and suppliers in the Shared Savings Program. However, some stakeholders have expressed concerns that the special conditions required for us to consider RHC and FQHC institutional claims in beneficiary assignment are burdensome and discourage ACOs from including RHCs and FQHCs as ACO participants in the Shared Savings Program. Stakeholders have commented that the requirement for ACOs that include an RHC or FQHC as an ACO participant to provide an attestation identifying ACO professionals who are physicians who directly furnish primary care services at the RHC or FQHC is particularly burdensome. In addition, due to the operational complexities of collecting identifying information about ACO participants, screening them for program integrity and other potential issues, and incorporating claims data for approved ACO participants into beneficiary assignment and financial calculations, we have implemented a policy that limits the addition of entities to the ACO participant list, absent unusual circumstances, to an annual basis. The limitation also applies to changes to the attestation to identify additional physicians who directly furnish primary care services at an ACO participant RHC or FQHC. In contrast, when a new ACO professional begins billing for primary care services under the TIN of an ACO participant that is not an RHC or FQHC, those services will be considered for purposes of assignment in the current performance year. As a result, there are a number of unique burdens and anomalies in the way in which RHC and FQHC institutional claims are used for purposes of assignment under the Shared Savings Program. First, as noted by stakeholders, the required attestation process for submitting physician identifiers requires more effort to ensure the accuracy of the ACO participant list (including the attestation that includes the physician identifiers) than the level of effort required for ACOs that do not include RHCs and FQHCs. Second, we have recognized that the required attestation process for submitting physician identifiers is also prone to error because some RHCs and FQHCs

(particularly rural FQHCs) have multiple locations with potentially hundreds of NPIs to report which, in turn, increases the likelihood that ACOs that include RHCs or FQHCs as ACO participants will make inadvertent clerical errors, such as transposing digits, in submitting the required information. Errors that are not identified and corrected by the specified deadline for additions to the ACO participant list may result in fewer claims being considered for purposes of assignment under the Shared Savings Program than would otherwise occur.

(2) Proposals

Section 17007 of the 21st Century Cures Act, amended section 1899(c) of the Act (42 U.S.C. 1395jjj(c)) to require the Secretary to assign beneficiaries to ACOs participating in the Shared Savings Program based not only on their utilization of primary care services furnished by physicians but also on their utilization of services furnished by RHCs and FQHCs, effective for performance years beginning on or after January 1, 2019. The statute provides the Secretary with broad discretion to determine how to incorporate services provided by RHCs and FQHCs into the Shared Savings Program beneficiary assignment methodology.

We believe that the 21st Century Cures Act provides the Secretary with broad discretion to revise the assignment methodology to address the concerns expressed by certain stakeholders regarding the burdens placed on ACOs that include RHCs and FQHCs as ACO participants, as described above. Section 17007 of the 21st Century Cures Act provides that for performance years beginning on or after January 1, 2019, Medicare services furnished in an FQHC or RHC should be considered in beneficiary assignment for the Shared Savings Program, as may be determined by the Secretary. Accordingly, in implementing section 17007 of the 21st Century Cures Act, we believe it would be appropriate to reduce operational burdens for ACOs that include RHCs or FQHCs as ACO participants and bring greater consistency to the operational method of using claims to assign beneficiaries to ACOs. In order to promote participation of RHCs and FQHCs under the Shared Savings Program, we propose to remove the burdensome attestation requirement and instead treat a service reported on an RHC or FQHC institutional claim as a primary care service furnished by a primary care physician. Consistent with the 21st Century Cures Act, under this proposal: (1) The requirement for an attestation identifying physicians who directly provide primary care services in each RHC or FQHC that is an ACO participant and/or ACO provider/supplier in the ACO would be removed; (2) all RHC and FQHC claims would be used to establish beneficiary eligibility to be assigned to the ACO (pre-step); and (3) all RHC and FQHC claims would be included in step 1. We would note that in considering all services billed under the TIN of the ACO participant RHC or FQHC, we would include services that do not meet the definition of primary care services, and such services would not be limited to those provided by a primary care physician, as defined under program rules. This means that under the proposal, a beneficiary could be furnished services in an RHC and FQHC only by a nurse practitioner, physician assistant, clinical nurse specialist, or any other practitioner in an RHC and FQHC and still be eligible for assignment to the ACO.

More specifically, we are proposing the following changes to our regulations: (1) Remove § 425.204(c)(5)(iii) in its entirety; (2) revise § 425.404; and (3) make conforming changes to the definition of primary care physician found at § 425.20. Under our proposal, for performance year 2019 and subsequent performance years, ACOs with ACO participants that are RHCs and FQHCs would no longer be required to submit NPIs or other identifying information for physicians who directly provide primary care services in the ACO participant RHCs and FQHCs as indicated in § 425.204(c)(5)(iii)(A) and § 425.404(a). Therefore we propose to remove § 425.204(c)(5)(iii) in its entirety. Additionally, we propose revisions to § 425.402 and § 425.404 to reflect that for performance year 2019 and subsequent performance years, we would assign beneficiaries to ACOs based on services furnished in RHCs or FQHCs consistent with the general assignment methodology in § 425.402, by treating a service reported on an RHC or FQHC institutional claim in the same way as a primary care service performed by a primary care physician. We also propose to remove revenue center codes from the definition of primary care services (§ 425.20) for performance year 2019 and subsequent performance years because all RHC and FQHC services will be used for purposes of assignment for benchmark and performance years; therefore, we believe it is appropriate to modify our definition of primary care services for performance year 2019 and subsequent years to no longer include revenue center codes. Additionally, we note that the requirement for an attestation under § 425.404 is also referenced in the definition of primary care physician at § 425.20; accordingly, we propose to make a conforming revision to that definition to remove the reference to the attestation requirement for performance year 2019 and subsequent years.

Consistent with how we have implemented other changes to the assignment methodology (see, for example, 80 FR 32757 through 32758), we propose to adjust all ACO benchmarks at the start of the first performance year in which the new assignment rules are applied so that the ACO benchmarks reflect the use of the same assignment rules as will apply in the performance year. Also consistent with how we have implemented previous changes to the Shared Savings Program assignment methodology, we would use the new methodology each time assignment is determined for purposes of performance year 2019, including using the new methodology in late CY 2018 to determine the eligibility of ACOs wishing to enter into or renew a participation agreement beginning January 1, 2019. Under the Shared Savings Program, ACOs must have and maintain at least 5,000 assigned beneficiaries.

We believe this proposal would reduce administrative burden for ACOs that include RHCs or FQHCs as ACO participants and support our policy goal of assigning beneficiaries to the entity that is primarily responsible for the beneficiary's overall care. That is, including all services furnished by RHCs or FQHCs to establish beneficiary eligibility to be assigned to an ACO (pre-step) and in the stepwise assignment methodology should help to ensure that a beneficiary is assigned to an ACO when the ACO participants in that ACO are providing the plurality of care for that beneficiary and thus the ACO should be accountable for the patient's overall care.

We welcome comments on our proposal to: (1) Remove § 425.204(c)(5)(iii) and modify § 425.402 and § 425.404, for performance year 2019 and subsequent performance years, to eliminate the requirement for ACOs that include an RHC or FQHC as an ACO participant to provide an attestation identifying physicians who directly provide primary care services in each RHC or FQHC that is an ACO participant and/or ACO provider/supplier in the ACO, and make conforming changes to the definition of primary care physician at § 425.20; and (2) for performance year 2019 and subsequent performance years, to: (a)

Use all claims submitted by RHCs and FQHCs in the ''pre-step'' of the assignment methodology under § 425.402 to determine whether a beneficiary is eligible for assignment to an ACO participating in the Shared Savings Program, (b) treat a service reported on an RHC or FQHC claim as if it were a primary care service performed by a primary care physician, and (c) remove revenue center codes from the definition of primary care services.

We recognize the unique needs and challenges of rural and underserved communities and the important role played by providers and suppliers serving these communities in assuring access to primary health care. RHCs, FQHCs, and other providers furnishing care in rural and underserved communities play an important role in the nation's health care delivery system by serving as safety net providers of primary care and other health care services, and we believe these proposed changes will enhance their ability to participate in the Shared Savings Program.

We also invite suggestions on how we might further support participation of RHCs and FQHCs in the Shared Savings Program.

b. Revisions to the Definition of Primary Care Services

(1) Background

Section 1899(c) of the Act requires the Secretary to assign beneficiaries to an ACO ''based on their utilization of primary care services'' provided by a physician. However, the statute does not specify which kinds of services may be considered primary care services for this purpose, nor the amount of those services that would be an appropriate basis for making assignments. In this section of this proposed rule, we summarize how we currently identify the appropriate primary care services on which we base assignment. In addition, we propose a revision to our current policies for defining primary care services for purposes of beneficiary assignment, consistent with our statement in the November 2011 final rule (76 FR 67853), that we intended to monitor this issue and would consider making changes to the definition of primary care services to add or delete HCPCS codes used to identify primary care services, if there were sufficient evidence that revisions were warranted.

We currently define primary care services for purposes of the Shared Savings Program in § 425.20 as the set of services identified by the following HCPCS/CPT codes: 99201 through 99215, 99304 through 99318 (excluding claims including the POS 31 modifier), 99319 through 99340, 99341 through 99350, 99495, 99496, 99490, the Welcome to Medicare visit (G0402), and the annual wellness visits (G0438 and G0439). In addition, we have established a cross-walk for these codes to certain revenue center codes used by FQHCs (for services furnished prior to January 1, 2011) and RHCs so that their services can be included in the beneficiary assignment process. Lastly, we include G0463 for services furnished in electing teaching amendment (ETA) hospitals.

In the November 2011 final rule (76 FR 67853), we established the initial list of codes that we considered to constitute primary care services for several reasons. First, we believed the listed codes represented a reasonable approximation of the kinds of services that are described by the statutory language which refers to assignment of ''Medicare fee-for-service beneficiaries to an ACO based on their utilization of primary care services'' furnished by physicians. In addition, we selected this list to be largely consistent with the definition of primary care services in section 5501 of the Affordable Care Act. That section establishes the Primary Care Incentive Payment Program to expand access to primary care services, and thus its definition of primary care services provides a compelling precedent for adopting a similar list of codes for purposes of the beneficiary assignment process under the Shared Savings Program. We slightly expanded the list of codes found in section 5501 of the Affordable Care Act to include the Welcome to Medicare visit (HCPCS code G0402) and the annual wellness visits (HCPCS codes G0438 and G0439) as primary care services for purposes of the Shared Savings Program. These codes clearly represent primary care services frequently received by Medicare beneficiaries, and in the absence of the special G codes the services provided during these visits would be described by one or more of the regular office visit codes that are included in the list under Section 5501 of the Affordable Care Act.

In the June 2015 final rule (80 FR 32746 through 32748), we expanded the definition of primary care services to include two transitional care management (TCM) codes (CPT codes 99495 and 99496), and one chronic care management (CCM) code, (CPT 99490). As discussed in the final rule, the TCM codes were established to pay a patient's physician or practitioner to coordinate the patient's care in the 30 days following a hospital or skilled nursing facility (SNF) stay. Including these codes in the definition of primary care services reflects our belief that the work of community physicians and practitioners in managing a patient's care following discharge from a hospital or nursing facility to ensure better continuity of care for these patients and help reduce avoidable readmissions is a key aspect of primary care.

In the CY 2017 PFS Final Rule, we finalized a separate payment for three additional CCM service codes, CPT codes 99487 and 99489 (see 81 FR 80251), and an additional add-on code G0506 (see 81 FR 80245), to support care management for the most complex and time-consuming cases of beneficiaries with multiple chronic conditions. These codes are used to report complex CCM services furnished to patients with multiple (two or more) chronic conditions. CCM services generally include regular development and revision of a plan of care, communication with other treating health professionals, and medication management. We explained in the CY 2017 PFS final rule that we believe the addition of the complex CCM codes will retain elements of the CCM service that are characteristic of the changes in medical practice toward advanced primary care, while eliminating redundancy, simplifying provision of the services, and improving access to the services. Additional explanation of required elements for billing CCM services can be found in the CY 2017 PFS Final Rule (81 FR 80243 through 80251).

Finally, in the 2017 PFS final rule (81 FR 80230 through 80243), we finalized a policy to make separate payments to physicians and non-physician practitioners for behavioral health integration (BHI) services they furnish to beneficiaries over a calendar month service period using four new Medicare Part B billing codes. Three of these BHI codes (G0502, G0503, G0504) are used to bill for monthly services furnished using the Psychiatric Collaborative Care Model (CoCM), an approach to BHI shown to improve outcomes in multiple studies. CoCM is a model of BHI that enhances ''usual'' primary care by adding two key services: Care management support for patients receiving behavioral health treatment; and regular psychiatric inter-specialty consultation to the primary care team, particularly regarding patients whose conditions are not improving. The fourth BHI service code (G0507) is used to bill monthly services furnished using BHI models of care other than CoCM that similarly include ''core'' service elements such as systematic assessment and monitoring, care plan revision for

patients whose condition is not improving adequately, and a continuous relationship with a designated care team member. The BHI service codes may be billed by the treating practitioner. Physicians billing for these services would typically be primary care physicians, but may be of another specialty such as cardiology or oncology. Non-physician practitioners (PAs, NPs, CNSs, or CNMs), may also bill for these services.

(2) Proposals

As discussed above, we previously finalized the inclusion of CCM code 99490 in the definition of primary care services for the Shared Savings Program. For the same reason that we included CCM code 99490, we believe that it would be also be appropriate to include the complex CCM service codes 99487, 99489, and G0506 in the definition of primary care services and to utilize these codes in the beneficiary assignment methodology under the Shared Savings Program beginning in 2018 for performance year 2019 and subsequent years. These three additional CCM codes reflect the changes in medical practice toward advanced primary care and differ from each other only in the amount of clinical staff service time provided; the complexity of medical decision-making as defined in the Evaluation and Management guidelines (determined by the problems addressed by the reporting practitioner during the month); and the nature of care planning that was performed (establishment or substantial revision of the care plan for complex CCM versus establishment, implementation, revision, or monitoring of the care plan for non-complex CCM).

In addition, we believe that it would be also be appropriate to include the four BHI codes G0502, G0503, G0504 and G0507 in the definition of primary care services and to utilize these codes in the beneficiary assignment methodology under the Shared Savings Program beginning in 2018 for performance year 2019 and subsequent years. These BHI codes reflect important enhancements in primary care to support improvement and integration of care provided for patients receiving behavioral health treatment. As discussed above, the BHI service codes may be billed by the treating practitioner (a physician and/or non-physician practitioner (PA, NP, CNS, CNM)). Physicians billing for these services would typically be primary care physicians, but may be of another specialty such as cardiology or oncology. (See fact sheet available on our Web site at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Downloads/Behavioral-Health-Integration-Fact-Sheet.pdf.*)

Therefore, we propose to revise the definition of primary care services currently located in § 425.20 to include three additional CCM service codes 99487, 99489, and G0506, and four BHI service codes G0502, G0503, G0504 and G0507, beginning in 2018 for performance year 2019 and subsequent performance years and to include these codes when performing beneficiary assignment under § 425.402. In addition, we propose to move the list of service codes currently listed in the definition in § 425.20 to § 425.400(c). We believe § 425.400, which specifies general requirements related to the assignment methodology and currently contains a cross-reference at § 425.400(c) to the definition of primary care services under § 425.20, is the more appropriate place to specify the particular primary care codes that will be considered in the assignment methodology. We also propose to reorganize the list of service codes, grouping HCPCS codes, G codes, and revenue center codes together, respectively, by relevant performance year(s). We seek comments on this proposal. In addition, we seek comments as to whether there are any additional existing HCPCS/CPT codes, that we should consider adding to the definition of primary care services in future rulemaking for purposes of assignment of beneficiaries to ACOs under the Shared Savings Program.

We also propose to remove paragraph (3) from the definition of primary care services. Paragraph (3) indicates that we will include additional codes designated by us as primary care services, including new HCPCS/CPT and revenue center codes and any subsequently modified or replacement codes for the HCPCS/CPT and revenue center codes identified in the definition. We finalized this policy in the June 2015 final rule (80 FR 32746), explaining that it was intended to promote flexibility for the Shared Savings Program and allow us to respond more quickly to HCPCS/CPT coding changes made in the annual PFS rulemaking process. We now believe this paragraph which directs CMS to respond to HCPCS/CPT coding changes though rulemaking is unnecessary because we always have the flexibility to propose, through the annual PFS rulemaking (or other rulemaking for the Shared Savings Program), to make changes to the definition of primary care services to reflect HCPCS/CPT coding changes made elsewhere in the same PFS rulemaking or in a previous PFS final rule. We therefore believe it would be reasonable to remove this paragraph rather than move it to subpart E under part 425 along with the other paragraphs making up the definition of primary care services.

2. ACO Quality Reporting

a. Changes to the Quality Measure Set Used in Establishing the Quality Performance Standard

(1) Background

Section 1899(b)(3)(A) of the Act requires the Secretary to determine appropriate measures to assess the quality of care furnished by ACOs, such as measures of clinical processes and outcomes; patient and, wherever practicable, caregiver experience of care; and utilization, such as rates of hospital admission for ambulatory sensitive conditions. Section 1899(b)(3)(B) of the Act requires ACOs to submit data in a form and manner specified by the Secretary on measures that the Secretary determines necessary for ACOs to report to evaluate the quality of care furnished by ACOs. Section 1899(b)(3)(C) of the Act states that the Secretary shall establish quality performance standards to assess the quality of care furnished by ACOs and seek to improve the quality of care furnished by ACOs over time by specifying higher standards, new measures, or both. We designate the quality performance standard that will apply for each performance year. The quality performance standard is the overall standard the ACO must meet in order to be eligible for shared savings.

In the November 2011 final rule (76 FR 67973), we initially established a quality performance standard consisting of 33 measures across 4 domains (see § 425.502(d)), including patient experience of care, care coordination/patient safety, preventive health, and at-risk population and a methodology for scoring the measures submitted by ACOs (see § 425.502(e)). Quality measures are submitted by the ACO through the CMS web interface, calculated by us from administrative and claims data, and collected via a patient experience of care survey based on the Clinician and Group Consumer Assessment of Healthcare Providers and Systems (CG–CAHPS) survey. To qualify for shared savings (see §§ 425.604(c), 425.606(c), and 425.610(c)), an ACO must meet or exceed its minimum savings rate, meet the minimum quality performance standards established under § 425.502, and otherwise maintain its eligibility to participate in the Shared Savings Program. For example, under the

regulation at § 425.604(d), an ACO participating in the Shared Savings Program under Track 1 that meets all the requirements for receiving shared savings payments will receive a shared savings payment of 50 percent of all savings under the updated benchmark (up to the performance payment limit).

Since the November 2011 Shared Savings Program final rule, we have continued to review the quality measures used for the Shared Savings Program to ensure that they are up to date with current clinical practice and are aligned with the CMS web interface reporting for PQRS, and most recently, with reporting requirements under the Quality Payment Program. Through the annual rulemaking for the PFS we have reviewed and updated the quality measures reported by ACOs through the CMS web interface, including adding new measures and retiring measures that were redundant or no longer met the goals for group reporting, and ensuring that the ACO CMS web interface reported measures align with the measures reported through the CMS web interface by group practices in other CMS initiatives such as PQRS and the Quality Payment Program. The quality measure set currently includes 31 quality measures (see Tables 42 and 43 at 81 FR 80488 and 80489). To avoid confusion and duplication of rulemaking, and reduce provider burden, we also finalized a policy in the 2017 PFS final rule that future changes to the CMS web interface measure will be made through rulemaking for the Quality Payment Program and will be applicable to ACO quality reporting under the Shared Savings Program (81 FR 80499 and 80500). Under the APM scoring standard finalized in the CY 2017 Quality Payment Program final rule (81 FR 77255 through 77256), measures reported by Shared Savings Program ACOs through the CMS web interface will also be used to determine the Merit-Based Incentive Payment System (MIPS) quality performance category score for eligible clinicians participating in a Shared Savings Program ACO in 2017.

When scoring ACO quality performance in the Shared Savings Program, we designate a performance benchmark and minimum attainment level for each measure. Performance below the minimum attainment level for a measure will receive zero points for that measure and performance equal to or greater than the minimum attainment level for the measure will receive points on a sliding scale based on the level of performance. We update the quality performance benchmarks every 2 years. For the first performance year of an ACO's first agreement period, we define the quality performance standard at the level of complete and accurate reporting for all quality measures. During subsequent performance years of the ACO's first agreement period, the quality performance standard is phased in such that the ACO must continue to report all measures but the ACO will be assessed on performance based on the quality performance benchmark and minimum attainment level for certain measures that are designated a pay for performance. The quality performance standard that applies to an ACO's final year in its first agreement period also applies for each performance year of an ACO's subsequent agreement period. A newly introduced measure is set at the level of complete and accurate reporting for the first 2 reporting periods the measure is required. For subsequent reporting periods, the quality performance standard for the measure will be assessed according to the phase-in schedule for the measure. Pay for reporting measures are worth 2 points each for complete and accurate reporting, whereas pay for performance measures are worth 0–2 points based on ACO performance compared to the established benchmark. The EHR measure (ACO–11), however, is double-weighted and ACOs can earn up to 4 points based on their performance on this measure.

Additionally, as discussed in the CY 2016 PFS final rule with comment period (see 80 FR 71269), occasionally issues arise with measures that cause us to reevaluate whether it is appropriate to hold an ACO accountable for performance on a measure. For instance, in the CY 2015 PFS final rule with comment period we retired measures that were no longer consistent with updated clinical guidelines for cholesterol targets, but we were unable to finalize retirement of the measures for the 2014 reporting year due to the timing of the guideline updates and rulemaking cycle. Because these measures did not align with updated clinicial guidance, in February 2015, we issued an update to the guidance document on the Medicare Shared Savings Program Quality Measure Benchmarks for the 2014 Reporting Year that maintained these measures, including the Diabetes Composite measure, as pay for reporting for the 2014 reporting year. In order to address such issues in the future, we finalized a policy in the CY 2016 PFS final rule with comment period (80 FR 71269) under which we reserve the right to maintain a measure as pay for reporting or revert a pay for performance measure to pay for reporting when the measure owner determines the measure no longer aligns with clinical practice or continued application of the measure may result in patient harm (see § 425.502(a)(5)).

(2) Proposals

As previously noted in the background section, we finalized a policy that future changes to the CMS web interface measures will be adopted through rulemaking for the Quality Payment Program and will be applicable to ACO quality reporting under the Shared Savings Program (81 FR 80501). We also note that, as discussed in the CY 2017 Quality Payment Program final rule with comment period (81 FR 77136), section 1848(q)(2)(D)(i)(II) of the Act requires the Secretary to update the final list of quality measures from the previous year (and publish an updated list in the **Federal Register**) annually. Updates may include the removal of quality measures the addition of new quality measures, and the exclusion of existing quality measures that the Secretary determines have gone through substantive changes. In the CY 2017 Quality Payment Program final rule with comment period, we indicated that in the future we would use rulemaking for the MIPS program to address substantive changes to measures (81 FR 77143). On June 20, 2017, HHS issued a proposed rule that includes a number of proposals to revise certain policies under the Quality Payment Program for CY 2018, including a proposal to make substantive changes to several measures reported through the CMS web interface. For example, substantive changes are proposed for the way ACO–17 Tobacco Use: Screening and Cessation Intervention measure rate is calculated via the CMS web interface (see Table E, 82 FR 30469). This measure was originally developed as a two-part measure: The first part of the measure assessed whether a patient had been screened for tobacco use within the past 24 months; the second part of the measure assessed whether those who had been screened and identified as tobacco users in the first part of the measure also received tobacco cessation intervention (either counseling and/or pharmacotherapy). To date, the two parts of the measure have been combined into a single performance rate. We have identified two notable limitations with this approach, including (1) the performance rate does not show the difference in performance with respect to how well clinicians adhere to performing tobacco use screenings and how well clinicians follow the guidelines to provide tobacco

cessation interventions, and (2) the measure is topped out, meaning it continuously shows a high performance rate. The changes to the measure proposed in the CY 2018 Quality Payment Program proposed rule would not modify the sampling methodology or the data reported into the CMS web interface. The proposed changes would simply revise the measure specifications to measure the percent of tobacco users that received cessation counseling; instead of measuring a combined performance rate for beneficiaries that were screened for tobacco use and for the subset of beneficiaries that are tobacco users that received tobacco cessation counseling.

Substantive changes to other CMS web interface measures are also proposed. A substantive change is proposed to the Influenza Immunization measure (ACO–14), however, the changes apply only to the Registry and EHR data submission methods and not the CMS web interface reporting method (82 FR 30472). Finally, a substantive change is proposed for the Body Mass Index Screening and Follow-Up Plan (ACO–16); specifically, the frequency of documenting BMI will change from 6 to 12 months (82 FR 30471).

Consistent with how we have addressed previous changes to measures, we reviewed the proposed substantive changes to the CMS web interface measures proposed in the CY 2018 Quality Payment Program proposed rule to assess whether the changes, if finalized, would warrant a change in how the measures are used to assess ACO performance under the Shared Savings Program. As part of this review, we considered whether the proposed substantive changes might raise sampling issues or require that we recalculate the measure benchmarks for purposes of the Shared Savings Program. Based on our preliminary review of the Quality Payment Program proposals, we believe the proposed ''substantive'' changes to the CMS web interface measures would not require that we revert these measures to pay for reporting for the 2018 performance year. The Quality Payment Program proposals do not appear to modify the current structure and reporting of the measures for which substantive changes are proposed; rather, in the case of the Tobacco Use: Screening and Cessation Intervention measure, the proposed change would only modify the way the data are manipulated and calculated after the data are submitted. Similarly, we do not believe that the proposed substantive change to the BMI measure to change the frequency of reporting would impact an ACO's ability to perform well compared to the established benchmark for this measure. Finally, the substantive change to the Influenza Immunization measure does not apply to the CMS web interface reporting method. Therefore, we believe that we will have the data necessary from past submission periods to calculate appropriate benchmarks that could be used to assess ACO performance for the CMS web interface measures under consideration for performance year 2018 and subsequent years. Additionally, the recalculation of the benchmark coincides with the biannual timing of the benchmark updates. Therefore, if the proposed changes to the measures are finalized under the Quality Payment Program, we do not believe it would be necessary or appropriate, to revert the measures to pay for reporting under the Shared Savings Program. Instead, we believe it would be appropriate under the Shared Savings Program to: (1) Update the measure specifications through subregulatory guidance in order to continue to align the measures with the measure specifications used under the Quality Payment Program and Million Hearts initiative, and (2) retain the current phase-in schedule for the measures rather than redesignating any of the measures as pay for reporting.

Because the particular substantive changes that are proposed in the CY 2018 Quality Payment Program proposed rule do not appear to change the information that must be collected for these measures (which makes it possible for us to use data submitted previously to determine prior performance under the new measure rate, and therefore calculate an appropriate prospective quality benchmark), we do not believe any changes to the measures' phase-in schedules are necessary. However, the statutory directive under the Quality Payment Program to address substantive changes to measures in rulemaking and the proposals in the CY 2018 Quality Payment Program proposed rule to address substantive changes to certain web interface measures have caused us to evaluate what recourse we might have in the future under the Shared Savings Program rules to modify a measure's phase-in in instances where a substantive change to the measure makes it inappropriate to hold ACOs accountable for performance on a measure that has been substantively modified. We anticipate that there could be future substantive changes to the CMS web interface measures made under the Quality Payment Program that would give us reason to redesignate a measure as pay-for-reporting under the Shared Savings Program. Currently, although the Shared Savings Program rules afford flexibility to redesignate a measure as pay for reporting whem the measure owner determines the measure no longer aligns with clinical practice or causes patient harm, there is no discretion to modify how we assess CMS web interface measures in the event substantive changes are made to those measures under the Quality Payment Program that make it inappropriate to hold ACOs accountable for performance on the measure. Given the timing of the Quality Payment Program proposals in relationship to the timing for when the quality performance benchmarks must be established under the Shared Savings Program, it may in some cases be necessary to have flexibility to designate a pay for performance measure as pay for reporting just before or following the start of a performance year outside of the formal rulemaking process, consistent with the way in which we have redesignated measures in the past when measure owners have made changes after the start of a performance year. Accordingly, we believe it would be appropriate to modify the Shared Savings Program regulations to provide additional flexibility to address substantive changes to CMS web interface measures that are made under the Quality Payment Program and to continue to facilitate alignment of measures with the Quality Payment Program and other CMS initiatives.

We are therefore proposing to modify § 425.502(a)(5) to include the right for CMS to redesignate a measure as pay-for-reporting when a substantive change to a CMS web interface measure is made under the Quality Payment Program. This proposed revision would supplement CMS's existing discretion to redesignate a measure as pay-for-reporting when the measure owner determines the measure no longer aligns with clinical practice or causes patient harm. Specifically, we are proposing to revise the regulation at § 425.502(a)(5) to reserve CMS's right to redesignate CMS web interface measures that have undergone a substantive change as determined under the Quality Payment Program to pay-for-reporting status. Such measures would not necessarily be automatically redesignated as pay for reporting when a substantive change occurs (for example, as indicated previously, we do not believe the currently proposed substantive changes present an impediment to holding ACOs accountable for performance on these measures in performance year 2018 and

subsequent years); however, in the future, substantive changes made to CMS web interface measures under the Quality Payment Program (such as when the substantive change to a measure results in an issue with sampling, calculating performance, or the calculating the quality benchmark) may make it inappropriate to hold an ACO accountable for performance on the measure for the time needed for CMS to obtain the information necessary to calculate a quality benchmark for the substantively changed measure in advance of a performance year and/or until ACOs gain experience reporting the measure, as substantively changed. Although we expect to conduct at least a preliminary assessment of any substantive changes to the CMS web interface measures as part of the annual PFS rulemaking in order to determine whether any change to the phase in schedule for a measure is warranted, because we cannot always anticipate the types of substantive changes that may be finalized under the Quality Payment Program or the effect of those changes on our ability to calculate performance on the measure, this proposal would provide us with additional flexibility to redesignate existing measures undergoing a substantive change as pay-for-reporting on a measure by measure basis. We believe this additional flexibility would enable us to more appropriately assess ACO quality performance, by ensuring that ACOs are not held accountable for performance on a measure when substantive changes to that measure affect our ability to assess performance on that measure appropriately. Otherwise, ACOs could be inappropriately held accountable for performance on such measures until such time as we could undertake rulemaking to modify the phase-in schedule for the measure. As with redesignations that occur when the measure owner determines the measure no longer aligns with clinical practice or causes patient harm, redesignations that occur due to substantive changes to a measure would be communicated to ACOs as soon as possible through operational documents and other typical methods we use to communicate with ACOs. We invite comments on this proposal.

b. Further Refining the Process Used To Validate ACO Quality Data Reporting

(1) Background

In the November 2011 final rule, we finalized a proposal to retain the right to validate the quality measure data ACOs enter into the web interface (76 FR 67893 through 67894). We believe that the data validation process implicitly incentivizes ACOs to keep organized and up-to-date medical records and is necessary to protect against gaming. This validation process, referred to as the Quality Measures Validation audit, was based on the process used in Phase I of the Physician Group Practice (PGP) demonstration. The policy was finalized at § 425.500(e) and involved a process under which we selected a subset of web interface measures and a random sample of 30 confirmed and completely reported beneficiaries for each measure in the subset. The ACO was required to provide medical records to support the data reported in the web interface for those beneficiaries. A measure-specific audit performance rate was then calculated using a multi-phased audit process. If at the conclusion of the third phase there was a discrepancy greater than 10 percent between the quality data reported and the medical records provided during the audit, the ACO was not given credit for meeting the quality target for any measure(s) for which the mismatch rate existed.

In the CY 2017 PFS final rule (81 FR 80489 through 80492), we revisited the quality validation audit process and finalized several significant changes as a result of our experience in conducting audits and in an effort to increase the statistical rigor of the audit methodology while streamlining audit operations. We expressed our intent to align the quality measures validation audit used in the Shared Savings Program more closely with other CMS quality program audits, including those performed in the Physician Quality Reporting Program and the Hospital Inpatient and Outpatient Quality Reporting programs. We therefore finalized four improvements to our audit process that addressed the number of records to be reviewed per measure, the number of audit phases, the calculation of an audit match rate and the consequences if the audit match rate falls below 90 percent. Specifically, we finalized a policy under which we will audit enough medical records to achieve a 90 percent confidence interval; conduct the audit in a single phase; and calculate an overall audit performance rate. If at the conclusion of the audit process the overall match rate between the quality data reported and the medical records provided by the ACO is less than 90 percent, absent unusual circumstances, we will adjust the ACO's overall quality score proportional to the ACO's audit performance. The audit-adjusted quality score is calculated by multiplying the ACO's overall quality score by the ACO's overall audit match rate. For example, if an ACO's quality score is 75 percent and the ACO's audit match rate is 80 percent, the ACO's audit-adjusted quality score would be 60 percent. The audit-adjusted quality score is the quality score that will be used to determine the percentage of any earned savings that the ACO may share or the percentage of any losses for which the ACO is accountable. We note that under the revised audit methodology, our intent was to continue to audit a subset of ACOs, which we would identify by looking for data anomalies such as high skip rates, although we have flexibility to randomly select ACOs or specific measures for audit as we have done in the past.

We also finalized a new requirement at § 425.500(e)(3) that an ACO that has an audit match rate of less than 90 percent may be required to submit a corrective action plan (CAP) under § 425.216 for our approval. In the CAP, the ACO would be required to explain the reasons for the low audit match rate and how it plans to improve the accuracy of its quality reporting in the future. In addition, we noted that we maintain the right, as described in § 425.500(f), to terminate or impose other sanctions on any ACO that does not report quality data accurately, completely, or timely. We indicated that we would begin applying these policies to the quality validation audits beginning in 2017 with the quality validation audits of quality reporting for the 2016 performance year.

(2) Proposals

Since publication of the CY 2017 PFS final rule, we have gained additional experience with the quality validation audits, and have performed additional analyses related to these audits. Our analysis of the 2016 quality measure validation audit results for Shared Savings Program ACOs indicates that the average match rate of ACOs audited in calendar year 2016 was 72 percent and the median performance was 80 percent. Typically, during the audit, we review medical record documentation and work with ACOs to better understand the mismatch between what was reported and what was documented and have determined through our analyses that ACOs continue to experience challenges in understanding certain aspects of the measure specifications, coordinating collection of information across many different providers and practices, and satisfying the requirements for supporting documentation. Many of these errors are not indicative of poor quality of care but rather reflect minor errors in process or

in understanding measure requirements. For instance, we have identified errors by individuals abstracting data from the medical record. In one case, a medical record abstractor incorrectly misinterpreted the less than symbol (<) in the quality measure specifications for the ACO–31 Heart Failure: Beta Blocker Therapy for Left Ventricular Systolic Dysfunction and ACO–33 Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy, and therefore, abstracted the data incorrectly for reporting.

Under our newly finalized single-phase approach to quality validation audits, minor errors are more likely to affect the final audit results and impact the calculation of shared savings or shared losses when the overall match rate is below 90 percent. Additionally, we note that the match rate threshold under the Hospital Inpatient Quality Reporting (HIQR) Program is 75 percent. The HIQR validates data submitted by hospitals, which are entities that generally have more experience with quality reporting, greater health record accessibility and integration, and a longer history of validation of quality data submitted to CMS.

In light of our analyses of the 2016 quality measure validation audit results, we believe it is appropriate to consider making additional modifications to our quality validation audit process. First, we are concerned that the 90 percent match rate adopted in CY 2017 PFS final rule may be too high and could inappropriately penalize ACOs that make quality data reporting errors that are unrelated to care quality. In the early years of phasing in this new audit methodology, we believe that the match rate should instead be based on actual ACO experience in order to focus on holding ACOs accountable for clinically related mismatches in reporting quality measures as they continue to gain experience with how to measure, report and improve quality under the program. We believe that basing the audit match rate threshold on actual validation audit results would strike an appropriate balance between ensuring the accuracy of ACO quality reporting while not unduly penalizing ACOs for minor quality reporting errors that are not necessarily indicative of poor quality care. Accordingly, we believe it would be appropriate to set the audit match rate threshold based on the median match rate (80 percent) for ACOs audited in calendar year 2016 rather than an alternative approach such as the mean match rate because the median match rate would be less affected by data outliers. Therefore, we are proposing to revise § 425.500(e)(2) to indicate that if an ACO has a match rate below 80 percent, absent unusual circumstances, we would adjust the ACO's overall quality score proportional to the ACO's audit performance.

Second, we propose to amend the method by which we adjust an ACO's overall quality score to reflect the ACO's audit performance. Specifically, we propose to revise the methodology described in the 2017 PFS final rule (81 FR 80490) under which the audit-adjusted quality score is calculated by multiplying the ACO's overall quality score by the ACO's audit match rate. Instead, we propose that for each percentage point difference between the ACO's match rate and the match rate considered passing the audit, the ACO's overall quality score would be adjusted downward by 1 percent. That is, if we finalize the proposal to establish an 80 percent match rate as the threshold for passing the quality validation audit, and the ACO's match rate is 75 percent, then under this proposal we would adjust the ACO's overall quality score downward by 5 percent. To illustrate, assuming a match rate threshold of 80 percent, an ACO with an overall quality score of 90 percent would have an audit-adjusted quality score of 85.50 percent, that is, $(90 - [.05 \times 90]) = 85.50$.

Finally, we propose a conforming change to § 425.500(e)(3) to reflect the 80 percent threshold such that if at the conclusion of the audit process CMS determines there is an audit match rate of less than 80 percent, the ACO may be required to submit a CAP.

We believe that over time, as ACOs become more experienced with quality reporting requirements, improve their quality reporting processes and become better clinically integrated, quality validation audit results that show a significant mismatch between the information reported and the underlying medical records will more consistently reflect meaningful, clinically related quality reporting errors for which ACOs should be held accountable. In addition, because the audit process involves the exchange of information regarding medical record review and communication between ACOs and us, the audit process, itself, provides additional education on the quality measures and quality reporting. Accordingly, we will periodically review the audit match threshold and seek to increase the match rate over time. We may also consider requiring a higher match rate for ACOs that have been in the program longer. Therefore, we anticipate that we will continue to closely monitor quality validation audit results and the reasons for mismatches and, over time, seek to increase the audit match rate threshold.

Although at this time we are proposing the change the audit match rate threshold to 80 percent, we also seek comment on an alternative approach we considered to address the quality validation audit match rate and the resulting impact on an ACO's overall quality score.

Consistent with the approach used under the HIQR program, we considered revising § 425.500(e)(2) to provide that we would adjust the ACO's overall quality score if an ACO has a match rate below 75 percent. We did not propose this approach because the results of the Quality Measures Validation Audits conducted on Shared Savings Program ACOs in calendar year 2016 yielded a median match rate of 80 percent, suggesting that a match rate of 75 percent would be too low.

We invite comment on the proposed refinements to the process used to validate ACO quality data reporting and to adjust an ACO's overall quality score to reflect the ACO's audit performance, and on the alternative that was considered, but not proposed.

3. Reducing Shared Savings Program Application Burden

a. SNF 3-Day Rule Waiver Application Requirement That ACOs Report Their Financial Relationships

(1) Background

The Medicare SNF benefit is for beneficiaries who require a short-term intensive stay in a SNF, requiring skilled nursing or skilled rehabilitation care, or both. Under section 1861(i) of the Act, beneficiaries must have a prior inpatient hospital stay of no fewer than 3 consecutive days in order to be eligible for Medicare coverage of inpatient SNF care. In the June 2015 final rule (80 FR 32804 through 32806, 32808), we provided ACOs participating in Track 3 with additional flexibility to attempt to increase quality and decrease costs by allowing these ACOs to apply for a waiver of the SNF 3-day rule to permit their prospectively assigned beneficiaries to receive coverage for inpatient SNF care without a prior 3-day inpatient hospital stay when they are admitted to a ''SNF affiliate,'' that is, a SNF with which the ACO has executed a SNF affiliate agreement, and certain additional eligibility criteria are met (see § 425.612(a)(1)). Waivers are effective upon our notification to the ACO of approval for the waiver or the start date of the ACO's participation agreement, whichever is later (see § 425.612(c)). We stated in the June 2015 final rule that the SNF 3-day rule waiver

would be effective for services furnished on or after January 1, 2017. Program requirements for this waiver are codified at § 425.612. These requirements are primarily based on criteria previously developed under the Pioneer ACO Model. Specifically, under § 425.612(a)(1), we waive the requirement in section 1861(i) of the Act for a 3-day inpatient hospital stay prior to a Medicare covered post-hospital extended care service for eligible beneficiaries prospectively assigned to ACOs participating in Track 3 (and as provided in § 425.612(a)(1)(iv) for certain other beneficiaries), who receive otherwise covered post-hospital extended care services furnished by an eligible SNF that has entered into a written agreement to partner with the ACO for purposes of this waiver. All other provisions of the statute and regulations regarding Medicare Part A post-hospital extended care services continue to apply.

We believe that clarity regarding whether SNF services furnished to a particular beneficiary are eligible for payment under the SNF 3-day rule waiver is important to help ensure compliance with the conditions of the waiver and also improve our ability to monitor waivers for misuse. Therefore, in the June 2015 final rule, we limited the waiver to ACOs in Track 3 because under the prospective assignment methodology used in Track 3, beneficiaries are assigned in advance to the ACO for the entire performance year (unless they meet any of the exclusion criteria under § 425.401(b)), so it will be clearer to a Track 3 ACO and its SNF affiliates whether the waiver applies to SNF services furnished to a particular beneficiary than it would be to an ACO in Track 1 or 2, where beneficiaries are assigned using a preliminary prospective assignment methodology with retrospective reconciliation (80 FR 32804). An ACO's use of the SNF 3-day rule waiver will be associated with a distinct and easily identifiable event, specifically, admission of a prospectively assigned beneficiary to a previously identified SNF affiliate without prior inpatient hospitalization or after an inpatient hospitalization of fewer than 3 days.

Based on our experiences under the Pioneer ACO Model, and in response to comments, we established certain requirements under § 425.612 that ACOs, ACO providers/suppliers, SNF affiliates, and beneficiaries must meet for SNF services to be covered under the SNF 3-day rule waiver under the Shared Savings Program. All ACOs electing to participate in Track 3 are offered the opportunity to apply for a waiver of the SNF 3-day rule for their prospectively assigned beneficiaries at the time of their initial application to participate in Track 3 of the program and annually thereafter while participating in Track 3. The program rules for a waiver of the SNF 3-day rule are under § 425.612 and are discussed in detail in the 2015 final rule (80 FR 32804 through 32806).

To qualify to use the SNF 3-day rule waiver, ACOs must submit a SNF 3-Day Rule Waiver application that includes supplemental information sufficient to demonstrate that the ACO has the capacity to identify and manage beneficiaries who would be either directly admitted to a SNF or admitted to a SNF after an inpatient hospitalization of fewer than 3 days. Required application materials include but are not limited to the following:

- Narratives describing how the ACO plans to implement the waiver. Narratives must include a communication plan between the ACO and its SNF affiliates, a care management plan for beneficiaries admitted to a SNF affiliate, a beneficiary evaluation and admission plan approved by the ACO medical director and the health care professional responsible for the ACO's quality improvement and assurance processes, and a description of any financial relationships between the ACO, SNF, and acute care hospitals.
- A list of SNFs with which the ACO will partner along with executed written SNF affiliate agreements between the ACO and each listed SNF. The agreements must include elements determined by CMS including but not limited to the following:

++ Agreement to comply with the requirements and conditions of the Shared Savings Program.

++ The effective dates of the SNF affiliate agreement.

++ Agreement to implement and comply with the ACO's beneficiary evaluation and admission plan and care management plan.

++ Agreement to validate the eligibility of a beneficiary to receive covered SNF services in accordance with the waiver prior to admission.

++ Remedial processes and penalties that will apply for non-compliance.

- Documentation demonstrating that each SNF included on the submitted list of SNF affiliates has an overall rating of 3 or higher under the CMS 5-star Quality Rating System as reported on CMS's Nursing Home Compare Web site.

In addition, § 425.612(b)(3) provides that we will evaluate the information submitted with the ACO's application for the SNF 3-day rule waiver and any supplemental information submitted in response to a CMS request for information to determine whether the ACO's waiver request satisfies the requirements of § 425.612(a)(1). The effective date and termination date of the waiver are determined in accordance with § 425.612(c). Section 425.612(d) provides for monitoring of the use of the waiver and termination of the waiver, and includes a requirement that ACOs that have been approved for the SNF 3-day rule waiver post their approval to use the waiver as part of public reporting under § 425.308. If our monitoring of an ACO's use of the waiver reveals misuse of the waiver, we may revoke the ACO's approval to use the waiver. Additionally, we may revoke an ACO's approval to use a waiver if the ACO does not successfully meet the quality performance standard or we identify another program integrity issue affecting the ACO's use of the waiver.

To be eligible to receive covered services under the SNF 3-day rule waiver, a beneficiary must be prospectively assigned to the ACO for the performance year in which he or she is admitted to the SNF affiliate, may not reside in a SNF or other long-term care setting, must be medically stable and have an identified skilled nursing or rehabilitation need that cannot be provided as an outpatient, and must meet the other requirements set forth in § 425.612(a)(1)(ii).

We noted in the 2015 final rule that we would continue to evaluate the waiver of the SNF 3-day rule including further lessons learned from Innovation Center models in which a waiver of the SNF 3-day rule is being tested (80 FR 32806). We indicated that in the event we determined that changes were necessary, we would propose these changes through future rulemaking. Subsequently, based on initial experiences with the SNF 3-day rule waiver under the Pioneer ACO Model and Next Generation ACO Model, we proposed and finalized additional SNF 3-day rule waiver beneficiary protections under § 425.612(a)(1)(iv) and (v). (See the CY 2017 PFS final rule (81 FR 80510 through 80515)).

We began accepting SNF 3-Day Rule Waiver applications in the summer of 2016 and approved 26 Track 3 ACOs to begin using the SNF 3-day rule waiver under the Shared Savings Program effective January 1, 2017.

(2) Proposal

As discussed in this proposed rule, the SNF 3-day rule waiver requirements are primarily based on criteria previously developed under the Pioneer

ACO Model. As a result of our recent experience implementing the waiver in the Next Generation ACO Model and the Shared Savings Program, we believe that the rules governing use of the SNF 3-day rule waiver are generally reasonable. However, based on our initial experiences in reviewing SNF 3-Day Rule Waiver applications, we believe there are two requirements, in particular, that impose an unnecessary burden on applicants, without a sufficient benefit to the administration of the Shared Savings Program to justify the burden.

First, the requirement under § 425.612(a)(1)(i)(A)(4) that ACOs submit, as part of their application for the SNF 3-day rule waiver, a narrative describing any financial relationships that exist between the ACO, SNF affiliates, and acute care hospitals is burdensome for ACOs and CMS. As explained in the 2015 final rule (81 FR 32806), the SNF 3-day rule waiver only provides for coverage of SNF services that meet all applicable requirements except the requirement for a prior 3-day inpatient stay. The waiver does not protect financial or other arrangements between or among ACOs, ACO participants, ACOs providers/suppliers, or other individuals or entities providing services to Medicare beneficiaries from liability under the fraud and abuse laws or any other applicable laws (§ 425.612(e)(1)). The Shared Savings Program regulations do not prohibit ACOs or SNFs from having financial arrangements with acute care hospitals, nor do they require such arrangements. Therefore, we have found that the narratives are not useful to us for purposes of determining whether to approve a waiver request. Based on our experience with the implementation of SNF 3-day rule waivers, we are proposing to remove the requirement at § 425.612(a)(1)(i)(A)(*4*) under which ACOs applying for the SNF 3-day rule waiver must submit a narrative describing any financial relationships between the ACO, SNF affiliate, and acute care hospitals. Removing this requirement would not only reduce burden for ACOs applying for the waiver but would also enable us to devote our application review resources to a rigorous review of other, more relevant application elements. Focusing our resources on the review of the information that is most directly relevant to determining an ACO's capacity to manage beneficiaries who are admitted to a SNF without a prior 3-day inpatient hospital stay, along with ongoing oversight and program compliance monitoring of the use of the waiver by approved ACOs (as described in section III.G.3.a.(1) of this proposed rule), would also allow us to more efficiently use our resources to ensure that the SNF 3-day rule waiver is being used appropriately and to address any potential concerns about use of the waiver. Although we do not believe it is necessary for ACOs to submit separate narratives describing their financial relationships for purposes of the SNF 3-day rule waiver, we note that under the Shared Savings Program rules, ACOs, ACO participants, ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO activities, including SNF affiliates, must maintain and give us access to certain documents and information related to items including financial arrangements related to ACO activities (§ 425.314(b)(1)). We continue to retain broad discretion under § 425.316 to audit ACOs, ACO participants, and ACO providers/suppliers for compliance with program rules, and the program rules also make it clear that waivers under § 425.612 do not protect financial or other arrangements between or among ACOs, ACO participants, ACO providers/suppliers, or other individuals or entities providing services to Medicare beneficiaries from liability under the fraud and abuse laws or any other applicable laws (§ 425.612(e)).

Second, we believe that the requirement under § 425.612(a)(1)(i)(C) that ACOs submit documentation demonstrating that each SNF included on their list of SNF affiliates has an overall rating of 3 or higher under the CMS 5-star Quality Rating System is unnecessarily burdensome. In order to meet this requirement, ACOs typically submit a screen shot from the CMS Nursing Home Compare Web site or other Nursing Home Compare information that reflects the star rating for each listed SNF. The submission of this documentation by the ACO does not add value to our review and approval of SNFs included on the ACO's SNF affiliate list. Instead, we obtain the information directly from our Web site during the application review process. In this way, we insure that the most current information is used during the application review process. We also periodically monitor this information after an ACO has been approved to use the waiver because SNF affiliates are required to maintain an overall rating of 3 stars or higher, under § 425.612(a)(1)(iii)(A). Because we are able to obtain the required information directly from the CMS Nursing Home Compare Web site, the additional documentation submitted by the ACO as part of its application does not add value to our ability to review and approve SNF affiliates. Accordingly, we are proposing to eliminate this documentation submission requirement by removing § 425.612(a)(1)(i)(C). We note that we are not proposing to remove or modify the requirement in § 425.612(a)(1)(iii)(A) that SNF affiliates must have and maintain an overall rating of 3 or higher under the CMS 5-star Quality Rating System in order to remain eligible to partner with the ACO for purposes of the SNF 3-day rule waiver. The requirement for SNF affiliates to have and maintain a 3-star or higher rating is retained. Furthermore, as part of the application process, we intend to continue to verify that the ACO has met all requirements related to the SNF 3-day rule waiver, but we believe that the burdensome and duplicative submission of CMS 5-star Quality Rating System documentation is not necessary to ensure compliance with the requirement that the ACO's SNF affiliates have a star rating of 3 or more.

We welcome comments on our proposal to remove § 425.612(a)(1)(i)(A)(*4*) which requires SNF 3-Day Rule Waiver applicants to submit a narrative describing any financial relationships that exist between the ACO, SNF affiliate, and acute care hospitals. We further welcome comments on our proposal to remove § 425.612(a)(1)(i)(C) which requires waiver applicants to submit documentation demonstrating that each SNF affiliate on their SNF affiliate list has an overall rating of 3 or higher under the CMS 5-star Quality Rating System. We also welcome other suggestions on how we might further decrease the burden for ACOs requesting approval to use the SNF 3-day rule waiver, without compromising our ability to ensure that ACOs and their SNF affiliates have the capacity to identify and manage beneficiaries receiving covered SNF services pursuant to the waiver. We may consider any such suggestions in future rulemaking.

b. Modifications to the Shared Savings Program Initial Application

(1) Background

In order to participate in the Shared Savings Program, organizations must meet certain eligibility requirements, including the statutory requirement to define processes to promote evidence-based medicine and patient engagement, report on quality and cost measures, and coordinate care. Additionally, the ACO

must demonstrate it meets patient-centeredness criteria specified by the Secretary, such as the use of patient and caregiver assessments or the use of individualized care plans. We discussed and finalized details for ACO eligibility criteria, including the four required processes and patient-centeredness criteria, in the November 2011 final rule (76 FR 67826 and 67827) and made updates to them in the June 2015 final rule (80 FR 32722 through 32725).

Section 425.204(c)(1) articulates the supporting documents and materials an ACO must submit to demonstrate that the ACO satisfies the eligibility requirements to participate in the Shared Savings Program.

To obtain a determination regarding whether an ACO meets the requirements to participate in the Shared Savings Program, a prospective ACO must submit a complete application in the form and manner required by us by the deadline established by us (§ 425.202(a)(1)). The content of the application is outlined at § 425.204. Section 425.204(c) states that as part of the application, and upon request thereafter, an ACO must submit to us certain supporting documentation to demonstrate that the ACO satisfies the requirements of the Shared Savings Program. Supporting documentation in this section includes:

- Documents (for example, ACO participant agreements, agreements with ACO providers/suppliers, employment contracts, and operating policies) sufficient to describe the ACO participants' and ACO providers'/suppliers' rights and obligations in and representation by the ACO, and how the opportunity to receive shared savings or other financial arrangements will encourage ACO participants and ACO providers/suppliers to adhere to the quality assurance and improvement program and evidence-based clinical guidelines.
- A description, or documents sufficient to describe, how the ACO will implement the required processes and patient-centeredness criteria under § 425.112, including descriptions of the remedial processes and penalties (including the potential for expulsion) that will apply if an ACO participant or an ACO provider/supplier fails to comply with and implement these processes.
- Materials documenting the ACO's organization and management structure, including an organizational chart, a list of committees (including names of committee members) and their structures, and job descriptions for senior administrative and clinical leaders.
- Evidence that the ACO's governing body is an identifiable body, represents a mechanism for shared governance for ACO participants, is composed of representatives of its ACO participants; and is at least 75 percent controlled by its ACO participants.
- Evidence that the governing body includes a Medicare beneficiary representative(s) served by the ACO who does not have a conflict of interest with the ACO, and who has no immediate family member with a conflict of interest with the ACO.
- A copy of the ACO's compliance plan or documentation describing the plan that will be put in place at the time the participation agreement with CMS becomes effective. Additionally, § 425.204(d) states that as part of the application to participate in the Shared Savings Program, an ACO must describe the following:

++ How it plans to use shared savings payments, including the criteria it plans to employ for distributing shared savings among its ACO participants and ACO providers/suppliers.

++ How the proposed plan will achieve the specific goals of the Shared Savings Program.

++ How the proposed plan will achieve the general aims of better care for individuals, better health for populations, and lower growth in expenditures.

Section 425.204(c)(1)(ii) includes a reference to the required processes and patient centeredness criteria under § 425.112. Of note, § 425.112(b)(4)(ii) requires that, as part of its application, an ACO must submit a description of its individualized care program, along with a sample individual care plan, that explains how the ACO's program is used to promote improved outcomes for, at a minimum, its high risk and multiple chronic condition patients (§ 425.112(b)(4)(ii)(A)). The ACO must also, as part of its application, describe additional target populations that would benefit from individualized care plans (§ 425.112(b)(4)(ii)(B)) and describe how it will encourage and promote the use of enabling technologies for improving care coordination for beneficiaries (§ 425.112(b)(4)(ii)(C)). Finally, as part of its application, the ACO must describe how it intends to partner with long-term and post-acute care providers, both inside and outside the ACO, to improve care coordination for its assigned beneficiaries (§ 425.112(b)(4)(ii)(D)).

Once an applicant has submitted the information required under § 425.204, we evaluate it to determine whether the applicant satisfies the Shared Savings Program requirements. We notify ACO applicants during the application review process when information is missing or when supplemental documentation or other information is necessary to make a determination on the ACO's application and provide opportunities for the ACO to submit the requested additional information for review. At the end of the application review process, we approve or deny the application and notify the ACO of our determination.

(2) Proposals

In conducting Shared Savings Program application reviews, we have found that many of the document submission requirements in § 425.204(c)(1) substantially increase application and review burden without lending significant value to our review of an organization's application to confirm that the ACO meets the eligibility requirements for participation in the Shared Savings Program. We believe it would meet program needs and reduce applicant burden if we were to revise § 425.204(c)(1) to remove the requirement to submit supporting documents or narratives and instead provide that we may request these materials if additional information is needed in order to fully assess the ACO's application before making a decision to approve or deny the application.

To illustrate, as discussed in this proposed rule, we require under § 425.204(c)(1)(ii), as part of the application process, that the ACO submit documentation addressing the required processes and patient centeredness criteria under § 425.112. This requirement is addressed in the Medicare Shared Savings Program Initial Application (see application on the CMS Web site at *https://www.cms.gov/medicare/medicare-fee-for-service-payment/sharedsavingsprogram/application.html*) through the requirement that an applicant ACO submit narratives describing how it will define, establish, implement, evaluate, and periodically update each process. In these narratives, the ACO must also describe certain additional details regarding the required processes:

- Process to promote evidence-based medicine. The ACO must describe how it will:

++ Encourage the use of protocols grounded in evidence-based medicine in the case of diagnoses with significant potential for the ACO to achieve quality improvements, while taking into account the circumstances of individual beneficiaries; and

++ Use the internal assessments of this process to continuously improve the ACO's care practices.

• Process to promote beneficiary engagement. The ACO must describe how it will:

++ Evaluate the health needs of its assigned beneficiary population (including consideration of diversity in its patient population) and develop a plan to address the needs of its population;

++ Communicate clinical knowledge/evidence-based medicine to beneficiaries in a way they can understand;

++ Engage beneficiaries in shared decision-making in ways that consider beneficiaries' unique needs, preferences, values and priorities;

++ Establish written standards for beneficiary access and communication as well as a process for beneficiaries to access their medical records; and

++ Use the internal assessments of this process to continuously improve the ACO's care practices.

• Process to internally report quality and cost metrics. The ACO must describe how:

++ The ACO will use these results to improve care and service over time; and

++ The ACO will use the internal assessments of this process to continuously improve the ACO's care practices.

• Process to promote coordination of care. The ACO must describe:

++ The ACO's methods and processes to coordinate care throughout an episode of care and during care transitions, such as discharge from a hospital or transfer of care from a primary care physician to a specialist (both inside and outside the ACO).

++ The ACO's individualized care program, along with a sample individual care plan, and explain how the ACO uses this program to promote improved outcomes for, at a minimum, high-risk and multiple chronic-condition patients.

++ How individual care plans take into account the community resources available to beneficiaries.

++ Additional target populations that would benefit from individualized care plans.

++ How the ACO will use the internal assessments of this process to continuously improve the ACO's care practices.

++ How the ACO will encourage and promote use of enabling technologies for improving care coordination for beneficiaries.

++ How the ACO intends to partner with long-term and post-acute care providers, both inside and outside of the ACO, to improve care coordination for their assigned beneficiaries.

As a result of our experience in reviewing these narratives, we have determined that while they can be helpful to verify that the ACO has established the required processes and defined patient-centeredness criteria prior to its entry into the Shared Savings Program, the specific details of the processes the ACO has established are not particularly important or relevant for purposes of assessing whether the ACO is eligible to participate in the program. In fact, ACOs have indicated that their initial plans for the processes required under § 425.112 as articulated in their program application often change as a result of obtaining additional information about their ACO participants' and ACO providers/suppliers' processes and gaining additional experience during implementation of the processes. We believe such improvements to ACO processes based on program experience are reasonable to expect and should be encouraged. First, under § 425.112(b), ACOs are required to evaluate and periodically update each process and as they do so, initially implemented processes will necessarily change to accommodate lessons learned. Moreover, once the ACO begins to request claims information and other CMS data and to incorporate this information into its operations, the ACO may discover that certain assumptions it made at the time of application should be adjusted to maximally improve the quality of care or cost efficiencies for the ACO's assigned population. In rare instances, particularly in the early days of the program before stakeholders fully understood the implications of program participation, we found review of such narratives useful to understand the level of an ACO's readiness for participation in the Shared Savings Program. However, such narratives have not been particularly useful in determining if the ACO meets the requirements for participation in the Shared Savings Program. In a vast majority of cases, we now believe it is sufficient that the ACO certify at the time of application that it has defined the required processes and patient centeredness criteria consistent with the requirements specified in section § 425.112. Therefore, we believe it would reduce burden for ACOs, without compromising our ability to determine whether an ACO meets the criteria for participation in the Shared Savings Program, to require that the ACO certify that it meets the requirements in § 425.112, and only submit a narrative or other documentation describing how the ACO will implement the required processes and patient-centeredness criteria upon our request. Further, we do not anticipate that this change would have a significant effect on beneficiaries receiving services from ACO providers/suppliers because as noted earlier, we anticipate that ACOs would update each process as they gain experience and, as they do so, initially implemented processes that might have been reflected in the narrative or other supporting documentation submitted with their application would necessarily change to accommodate lessons learned.

Similarly, as part of the application process, the Shared Savings Program regulations require the ACO to submit materials documenting the ACO's organization and management structure, including an organizational chart, a list of committees (including names of committee members) and their structures, and job descriptions for senior administrative and clinical leaders (§ 425.204(c)(1)(iii)). While we have found the organizational chart useful for purposes of our review and approval of an ACO's application, and we anticipate continuing to request this chart from many applicants, we have found that further detail including lists of committees and job descriptions for senior administrative and clinical leaders have not added particular value to our review and approval of applications. Moreover, the receipt of such materials as part of the ACO's application has not significantly impacted our ability to determine whether the ACO meets the requirements regarding leadership and management in § 425.108. We believe, on balance, that our need for such detailed information from all applicants is outweighed by our desire to reduce application burden. In particular circumstances where additional information would aid our review, we believe our need for such detailed information can be reasonably met by requiring applicants to submit such materials upon our request. As a result, we believe it would be less burdensome for us to require ACO applicants to certify that, for example, they meet the leadership and management requirements found at § 425.108 rather than requiring all ACO applicants to submit detailed materials (such as job descriptions) or narratives about the ACO's committees and leadership.

While we do not anticipate having to routinely request such materials to supplement our review and approval of ACO applications to participate in the Shared Savings Program, we believe it is important to retain the discretion to do

so in limited cases where such detail could be useful. Therefore, we propose to make revisions to our application requirements as discussed in this section. We would note that in cases where an ACO is requested to submit additional material for review in conjunction with its application, and we find that the material is inconsistent with program requirements, then we may deny the ACO's application. Similarly, if we discover the inconsistency after the ACO has already been approved to participate in the program, the ACO may be subject to the pre-termination actions set forth in § 425.216, termination under § 425.218, or both.

Additionally, we do not believe it is necessary for ACO applicants to submit narratives describing how they would distribute shared savings payments or how the proposed plan would achieve the specific goals of the Shared Savings Program and the general aims of better care for individuals, better health for populations, and lower growth in expenditures, as required by § 425.204(d). Based on our experience, such narratives have not been useful in determining if the ACO meets requirements for participation in the program or whether an ACO's application should be approved. We believe it would be more useful to us and less burdensome for ACOs if we were instead to require that, an ACO, as part of its application to participate in the Shared Savings Program, certify that it has a method and plan to receive shared savings payments and to distribute those payments to its ACO participants and ACO providers/suppliers, as required by the statute. We note, however, that we continue to believe it is useful to stakeholders to know how various ACOs have chosen to use or distribute the shared savings they earn. Therefore, in the interest of transparency, we will continue to require ACOs to publicly report information on their dedicated Web pages about their shared savings and shared losses, including information about the total proportion of shared savings invested in infrastructure, redesigned care processes, and other resources to support the three-part aim goals of better health for populations, better care for individuals, and lower growth in expenditures, including the proportion distributed among ACO participants, as required under § 425.308(b)(4).

In light of our experience with the review of the documentation submitted as part of the ACO's initial application, we are proposing several modifications to our requirements for document submission. Under this proposal, we would retain all requirements related to ACO eligibility criteria and public reporting, as currently specified under the Shared Savings Program regulations. However, in order to reduce application burden without compromising our ability to evaluate applications effectively for compliance with Shared Savings Program requirements, we propose to modify certain sections of our regulations that require ACOs to submit supporting materials and documentation at the time of application. Instead of requiring submission of certain materials, narratives, or supporting documentation, as discussed in this section, we propose to require ACOs to certify that they meet the applicable eligibility and documentation requirements as specified under our program rules. At the same time, while we are interested in reducing burden, we recognize that there have been instances when the review of supporting documentation and/or narratives has been helpful in making a determination about an ACO's eligibility for participation in the program. Therefore, although we are proposing to eliminate the general requirement that ACOs submit certain documentation as part of their initial application to participate in the Shared Savings Program, we propose to retain the right to request the submission of supporting materials and documentation in cases when such additional information would be useful in making a determination regarding the ACO's application. We believe that this proposed modification to the regulations governing ACO applications would introduce additional flexibility that would reduce the level of burden inherent in the Shared Savings Program application process while also ensuring we are still able to appropriately evaluate an ACO's eligibility for program participation.

Accordingly, in order to reduce application burden while retaining flexibility to obtain additional documentation when necessary to determine ACO eligibility and compliance with program rules, we propose to remove the requirements in §§ 425.204(c)(1) and (d), 425.112(a)(3)(i) and (ii), and 425.112(b)(4)(ii) for the submission of certain specified documents and narratives as part of an ACO's application to participate in the Shared Savings Program. Specifically, we propose to revise paragraph § 425.204(c)(1) to require an ACO, as part of its application, to certify that it satisfies the Shared Savings Program requirements and to submit, upon CMS request, supporting materials (including narratives) and documentation demonstrating that the ACO satisfies program requirements indicated in proposed revised § 425.204(c). Additionally, we propose to revise § 425.204(d) to indicate that the ACO must certify, as part of its application to participate in the Shared Savings Program, that it has a mechanism and plan to receive and use payments for shared savings, including criteria for distributing shared savings among its ACO participants and ACO providers/suppliers. We also propose to make a conforming change to remove paragraphs (d)(1) through (3) of § 425.204, which relate to the submission of narratives related to the ACO's use of shared savings payments. This proposal does not include a requirement that the ACO submit information regarding its mechanism and plan for receiving and using shared savings upon request. We do not intend to request this information as part of the application process because in our experience, how an ACO intends to use or distribute shared savings has not been a relevant consideration during any application cycle to determine whether the ACO has met the eligibility requirements to participate in the Shared Savings Program. However, we note that we continue to believe that information on how an ACO uses and distributes its shared savings is useful for the public, and therefore ACOs will continue to be required to publicly report this information under § 425.308(b)(4)(ii).

We also propose similar changes to the requirements in § 425.112(a)(3)(i), (a)(3)(ii), and (b)(4)(ii) to remove reference to the submission of narratives to explain or describe how the ACO will implement the required elements of the ACO's care processes and patient-centeredness criteria. ACOs must still implement these care processes and adopt a focus on patient-centeredness, however, they will no longer need to submit descriptions of how they will satisfy these requirements as part of their initial application. We note, however, that ACOs may still be required to submit upon request a description or documentation sufficient to describe how the ACO will implement the required processes and patient-centeredness criteria found at § 425.112 because under the proposed revisions to § 425.204(c)(1)(ii), CMS would retain the discretion to request such documentation from the ACO at any time.

In summary, we believe these modifications to the application requirements will significantly reduce

the burden of applying to participate in the Shared Savings Program without reducing our ability to ensure that applicants meet the established eligibility requirements. Rather than requiring every applicant to submit detailed supporting documents or narratives for all of these requirements, we would instead request supporting documents or narratives only if additional information is needed in order to fully assess an ACO's application before making a decision to approve or deny the application. Further, we do not anticipate that the proposed modifications to our application requirements would have any effect on beneficiaries receiving care from providers and suppliers participating in the Shared Saving Program, nor do we believe that the proposed changes would affect our program integrity efforts, because we would retain discretion to request such information (and more targeted and appropriate information) as needed. We seek comment on these proposals and on additional ways to reduce burden in the application process.

4. Addressing Compliance With ACO Participant TIN Exclusivity Requirement

a. Background

Under the Shared Savings Program, ACO participant TINs are not required to be exclusive to one Shared Savings Program ACO unless the TIN submits claims for primary care services used to determine the ACO's assigned population (§ 425.306(b)). The purpose behind this requirement is to ensure that we are able to assign a unique set of beneficiaries to each ACO participating in the Shared Savings Program. Therefore, as part of the Shared Savings Program application process and upon an ACO's request to add an ACO participant TIN, we check the TIN against all other Shared Savings Program ACO participant lists. If the TIN appears on the ACO participant list one or more other ACOs, the TIN is considered to be ''overlapping.'' We then determine whether the overlap is permissible under our program rules. If the overlap is not permissible (because the TIN has a history of billing for primary care services used in our assignment methodology) then we require the ACO that is seeking to add the TIN to its ACO participant list to rectify the overlap by the deadline we have established for making changes to the next performance year's ACO participant list. If the overlap is permissible (because the TIN does not have a history of billing for primary care services used in our assignment methodology) then the ACO participant TIN can be approved to be an ACO participant in more than one ACO for the performance year. Each time we run the assignment algorithm during the course of the performance year, we monitor overlaps to ensure that the overlaps continue to be in compliance with § 425.306(b).

In a few instances, as a result of our monitoring, we have discovered that ACO participant TINs that had been approved to participate in multiple ACOs subsequently began billing for primary care services used in assignment during a benchmark or performance year. For example, for performance year 2016, we identified four TINs that were initially permitted to overlap and participate in more than one ACO because they had not previously billed Medicare for primary care services used in our assignment methodology. At some point during the performance year, however, the TINs began billing Medicare for primary care services that are used to assign beneficiaries to the ACO (including claims for services furnished during the performance year, but submitted during the three-month claims runout for the performance year). This can occur, for example, if a single specialty practice made up of physician specialty types not used in assignment (for example, a practice of ophthalmologists) hires a nurse practitioner who then begins billing Medicare under the billing TIN of the ACO participant for primary care services as defined under the Shared Savings Program rules. Thus, the ACO participant TIN would be used to bill Medicare for primary care services furnished by a practitioner used in our assignment methodology (the nurse practitioner) and would therefore trigger our requirement under § 425.306(b)(2) that the ACO participant TIN be exclusive to a single Shared Savings Program ACO. Although our program rules permit us to take compliance action against ACOs for violations of Shared Savings Program requirements, they do not specifically address what compliance actions we would impose on ACOs in instances where an ACO participant falls out of compliance with § 425.306(b)(2) during a benchmark or performance year or when non-compliance with § 425.306(b)(2) is discovered during the 3-month claims runout for a benchmark or performance year. Moreover, the program rules do not address what modifications to our assignment methodology could be made to account for this overlap. In the case of the four overlapping TINs discovered during the 2016 performance year, we notified the respective ACOs of the overlap and the ACO participant TINs were required to terminate their participation in the ACO of their choice. As a result, each ACO from which the TINs terminated was required to recertify its ACO participant list for the 2016 performance year. Depending on the timing of recertification, such changes to an ACO participant list may also require us to recalculate performance year beneficiary assignment and financial benchmarks. For example, if a TIN, that was previously allowed to appear on more than one ACO participant list, hires a nurse practitioner who begins billing primary care claims in the month of December for the ACO's third benchmark year, we would discover the now impermissible overlap when we begin creating the historical benchmark reports after the 3-month claims runout. We would contact the ACOs involved, each ACO would contact the TIN and ask the TIN to select the ACO it wishes to remain aligned with. The ACO not selected would be asked to remove the TIN from its ACO Participant List and recertify the list. As a result of the recertification of the list, the ACO's assigned population would need to be redetermined and calculation of its benchmark would be delayed. We are therefore concerned about the uncertainty the current process (which includes recertification of ACO participant lists, recalculation of assignment, and resulting delay of calculations for the benchmark or performance year) could introduce for ACOs that may have little influence over or knowledge of ACO participant TIN billing practices.

We believe it is important for ACOs, ACO participants, and ACO providers/suppliers to have updated and accurate information regarding their participation status in the Shared Savings Program. For example, participation in a Shared Savings Program ACO has implications for ACO providers/suppliers under the new Quality Payment Program (see 81 FR 80496 through 80501). The Quality Payment Program replaces a patchwork system of Medicare programs with a flexible system that allows eligible clinicians to choose from two paths that link payments to quality: The Merit-Based Incentive Payment System (MIPS) and participation in Advanced Alternative Payment Models (APMs). The Quality Payment Program, through MIPS and the APM incentive, will impact eligible clinicians' payments

beginning in payment year 2019 based on 2017 reporting.

Under the CY 2017 Quality Payment Program final rule with comment period, eligible clinicians participating in Advanced APMs (including Tracks 2 and 3 under the Shared Savings Program) may become Qualifying APM Participants and receive a 5 percent APM Incentive Payment if they have a sufficient percentage of payments for Part B covered professional services, or a sufficient percentage of Medicare patients that are attributable to services furnished through an Advanced APM for a year. In addition to earning a 5 percent APM Incentive Payment, Qualifying APM Participants are not subject to the MIPS reporting requirements and payment adjustment for the year. As a result, revisions to ACO participant lists that occur mid-year or following the end of a benchmark or performance year could have widespread implications not only for the ACO but also for its ACO providers/suppliers under the Quality Payment Program.

b. Proposals

As participation in the Shared Savings Program grows and more ACOs and ACO participants join the program, we believe the overlap situation described previously is likely to become more common. We also believe that changes to our program rules regarding the claims that will be considered in assigning FFS beneficiaries to an ACO (specifically, the policy finalized in the June 2015 final rule to exclude services furnished by several physician specialty types from the assignment methodology) may result in a greater number of permissible ACO participant TIN overlaps (see 80 FR 32753 and 32754). As a result, we anticipate there could also be an increased number of cases where ACO participant TINs with initially permissible overlaps could become out of compliance with the requirement at § 425.306(b)(2) that an ACO participant TIN be exclusive to a single Shared Savings Program ACO if the TIN bills for primary care services that are used to assign beneficiaries to the ACO. This could occur, for example, if a group practice that initially includes only physician specialty types whose services are excluded from the assignment methodology were to subsequently employ a non-physician practitioner who bills for primary care services. We believe these types of practice arrangements are becoming increasingly common.

We therefore believe it is necessary to streamline our approach to handling such situations in order to reduce the burden and uncertainty for ACOs when changes in ACO participant billing practices result in an ACO participant falling out of compliance with the exclusivity requirement at § 425.306(b)(2). Rather than the current policy under which an ACO may be required to remove an overlapping ACO participant and recertify its ACO participant list for the performance year (thus necessitating redetermination of beneficiary assignment and delays in or revisions to benchmark or performance year calculations), we believe it would be less disruptive for ACOs if we were to permit overlapping TINs that begin billing for services used in assignment during a benchmark or performance year (including claims for services furnished during the benchmark of performance year, but submitted during the 3-month claims runout) to remain on the ACO participant lists for all affected ACOs for the remainder of the performance year in which we determine that an overlap exists. For example, assume that, based on an analysis of claims for services furnished in performance year 2018, we were to identify an impermissibly overlapping TIN in January 2019 after the ACO participant lists for performance year 2019 had already been certified. Under this proposal, the TIN would be able to remain on the ACO participant lists of all affected ACOs for the 2018 performance year as well as the remainder of performance year 2019. In order to ensure that the TIN overlap does not inadvertently result in assignment of the same beneficiaries to multiple ACOs, we would simply exclude any claims for services furnished by the overlapping TIN from the assignment methodology when conducting final beneficiary assignment for any benchmark or performance year in which the TIN bills Medicare for services used in our assignment methodology. The affected ACOs would be required to resolve the overlap prior to recertification of their ACO participant lists for the subsequent performance year. If the overlap remains unresolved when the ACOs certify their ACO participant lists for the next performance year, we would remove the TIN from the ACO participant lists of all ACOs seeking to include the TIN, in accordance with our current policy for resolving overlaps. For example, in the hypothetical case above, if the overlap were to remain unresolved when the ACOs certify their ACO participant lists for performance year 2020, we would remove the TIN from the ACO participant lists for all ACOs seeking to include the TIN as an ACO participant for performance year 2020.

We therefore propose to modify our program rules in § 425.306 and subpart E of part 425 to address this issue. We propose to modify § 425.306(b) to indicate that if, during a benchmark or performance year (including the 3-month claims run out period for such benchmark or performance year), an ACO participant that participates in more than one ACO begins billing for services that would be used in assignment, we would not consider any services billed through that TIN during the relevant performance year when performing beneficiary assignment for the applicable benchmark or performance year. As part of this proposed modification, we would also eliminate the references to ''primary care'' when describing the services used to determine the ACO's assigned beneficiary population in order to conform with our proposal to implement section 17007 of the 21st Century Cures Act under which we would consider all services furnished in FQHCs and RHCs in the assignment methodology as primary care services starting in the 2019 performance year. In addition, the ACOs in which the overlapping TIN is an ACO participant may be subject to compliance action (as provided under § 425.216) or termination under § 425.218. Compliance actions may include requiring each ACO that includes the TIN as an ACO participant to submit a corrective action plan explaining how the ACO plans to work with the overlapping ACO participant to resolve the overlap for the next performance year. If the overlap remains unresolved by the date specified by us in our request for a corrective action plan, we would remove the overlapping ACO participant TIN from the ACO participant list of each ACO for the subsequent performance year.

We also propose to revise our general assignment methodology at § 425.400(a)(1) to add new paragraph (a)(1)(iii) to indicate that when we determine final assignment after the end of each benchmark or performance year, we will exclude claims for services furnished during the benchmark or performance year by an ACO participant that participates in more than one ACO. We believe that this policy will ensure a uniquely assigned beneficiary population for each ACO and prevent the same beneficiaries from being included in determining benchmark or performance year expenditures for more than one ACO.

We believe that implementing this proposed process would improve ACO

and ACO participant understanding of our policies and requirements regarding ACO participant overlaps while also reducing burden for ACOs that currently must recertify ACO participant lists and may be subject to retrospective modifications or delays in assignment and other dependent benchmark or performance year calculations. We also note that this policy allows us to preserve the flexibility that is currently extended to ACO participants that do not bill for services used in assignment, while recognizing the possibility for mid-year changes in care and billing practices by these ACO participants. Additionally, ACO participant TINs and the eligible clinicians that bill through those TINs would be provided greater certainty regarding whether they qualify as participating in an APM or Advanced APM for a performance year. Under this proposed policy, an ACO participant would know for the entire performance year with certainty that it is participating in a particular APM entity.

5. Treatment of Individually Beneficiary Identifiable Payments Made Under a Demonstration, Pilot, or Time Limited Program

a. Background

Under section 1899(d) of Act, ACOs participating in the Shared Savings Program are accountable for the total Parts A and B costs for the Medicare fee-for-service beneficiaries assigned to the ACO. Therefore, we include all payments made from the Medicare Trust Fund for Parts A and B services furnished to assigned Medicare FFS beneficiaries, including individually beneficiary identifiable non-claims based payments made under a demonstration, pilot or time limited program, when computing average per capita Medicare expenditures for an ACO during both the benchmark period and performance years. We believe it is appropriate to take into account non-claims based payments from a demonstration, pilot, or time limited program in Medicare Shared Savings Program financial calculations to ensure that the final shared savings payments that are made to ACOs are accurate and reflect all Parts A and B expenditures for the ACO's assigned beneficiaries. We also review individually beneficiary identifiable payments made under a demonstration, pilot, or time-limited program as part of our efforts to ensure there is no duplication of payments for beneficiaries that may be assigned to both the Shared Savings Program and other Innovation Center models. This general policy of considering individually beneficiary identifiable non-claims based payments made under a demonstration, pilot or time limited program was initially established in the 2011 final rule implementing the Shared Savings Program (76 FR 67915) for:

- Establishing, adjusting, and updating the benchmark for an ACO's first agreement period under § 425.602(a)(1)(ii),
- Calculation of savings under the one-sided model (Track 1) at § 425.604(a)(6)(ii), and
- Calculation of shared savings and losses under Track 2 at § 425.606(a)(6)(ii).

This policy has also been included in subsequent program modifications to the program for:

- Resetting, adjusting, and updating the benchmark for a subsequent agreement period under §§ 425.603(c)(1)(ii) and 425.603(e)(2)(ii), and
- Calculation of shared savings and losses under Track 3 at § 425.610(a)(6)(ii).

More specifically, in addition to Medicare Parts A and B claims, we include non-claims based individually beneficiary identifiable payments when performing financial calculations for the Shared Savings Program, including setting the preliminary and final benchmarks, updating the financial benchmark at the time of reconciliation and calculating performance year expenditures. We internally track non-claims based beneficiary identifiable payments (that is, payments made outside the Medicare fee-for-service claims system) through a separate CMS system that receives and stores these non-claims based payments made from the Medicare Trust Funds under a demonstration, pilot or time limited program. The non-claims based payments are loaded into the separate system at various points in time, depending on the terms of payment under each specific demonstration, pilot or time limited program. The amounts that are reflected in this separate system include interim payment amounts that are subject to final reconciliation and may not reflect the actual final payments to the provider or site. For example, the Bundled Payments for Care Improvement (BPCI) initiative is comprised of four broadly defined models of care, which link payments for the multiple services beneficiaries receive during an episode of care. (See the CMS Web site at *https://innovation.cms.gov/initiatives/bundled-payments/*). Under the retrospective BPCI payment models, Medicare continues to make fee-for-service (FFS) payments for the Part A and Part B services furnished to a beneficiary during an episode; but, the total Part A and Part B expenditures for the episode are later reconciled against a bundled payment amount (the target price) determined by CMS. A payment or recoupment amount is determined by comparing the aggregate expenditures to the target price. Interim payment and recoupment amounts are calculated quarterly but it is only after the BPCI claims run out period that the final reconciliation can be performed and the final expenditure amount is known. In contrast, under certain other demonstrations, pilots, or time limited programs only final non-claims based payment data are loaded into the system. For example, under the Community-based Care Transitions Program (CCTP), the participating community-based organizations were paid an all-inclusive rate per eligible discharge. This final non-claims based payment was then loaded into the system and was not subject to subsequent reconciliations.

To date, when we perform ACO benchmarking and financial calculations under the Shared Savings Program, we have included (in addition to all Medicare Parts A and B claims) all non-claims based beneficiary identifiable payments for the applicable benchmark or performance year that are included in the separate CMS system, including any payments made during the benchmark or performance year's 3-months claims run-out period. This means that to date we have included some interim payments made under a demonstration, pilot or time limited program that will undergo subsequent reconciliation to determine the final payment amount in the calculation of historical benchmarks and performance year expenditures. However, because the various demonstrations, pilots or time limited programs may have different operational schedules to the Shared Savings Program, it is not possible for us to include all interim and final beneficiary identifiable payments made under these initiatives in benchmarking and financial reconciliation calculations for the Shared Savings Program; and, as a result, these calculations have excluded some interim and final non-claims based beneficiary identifiable payments made under certain demonstrations, pilots or time limited programs. For example, because of the timing and availability of BPCI non-claims based payment amounts, to date we have included only up to two quarters of interim payment data for BPCI in ACO benchmarking and financial reconciliation calculations for the

Shared Savings Program and no final payment amounts.

To date, non-claims based individually beneficiary identifiable payments represent a relatively minor proportion of an ACO's total Part A and B beneficiary expenditure amounts as determined under the Shared Savings Program (mean of 0.09 percent overall impact of ACO non-claims based payments on total per capita expenditures and a mean of 137 person-years in an ACO's assigned beneficiary population with a non-claims based payment during the year; minimum -0.72 percent, 0 person-years; maximum 1.24 percent, 1,865 person-years). For the demonstrations, pilots or time limited programs that include interim and final reconciliations, the impact of including the non-claims based payments could be positive or negative for an ACO for a given performance year. Additionally, a preliminary analysis suggests that interim payments made under select demonstrations, pilots or time-limited program fluctuate on a quarterly basis. An examination of trends in total per capita non-claims based payments in 2016 quarterly program reports across 416 Track 1 and 2 ACOs found a mean decline of 14 percent from Quarter 1 to Quarter 2, followed by a mean increase of 144 percent from Quarter 2 to Quarter 3, and a mean increase of 742 percent from Quarter 3 to Quarter 4. Quarterly trends for individual ACOs also tended to fluctuate. Per capita amounts in this analysis were based on those ACOs with at least one non-claims based payment in each quarterly report period. Almost half of the ACOs in the analysis (201 out of 416) had at least one quarter in 2016 with a net negative per capita payment across all beneficiaries with at least one non-claims based payment and at least one quarter with a net positive per capita payment. A review of non-claims based payments incorporated in PY 2017 preliminary historical benchmarks also found similar swings between negative and positive amounts, with roughly one third of ACOs receiving a benchmark (156 of 480) having at least one benchmark year with a net negative per capita payment across all beneficiaries with at least one non-claims based payment and at least one benchmark year with a net positive per capita payment.

These fluctuations in the non-claims based payments for certain initiatives like BPCI have generated stakeholder concern. Further, stakeholders note that the impact of including interim payments in financial calculations may become greater in the future, given the increasingly widespread interest in participation in alternative payment models and the growing number of such models being tested through the CMS Innovation Center. Stakeholders have therefore suggested that we should revise our policies to clarify that only final non-claims based payments made within the 3 months claims run out period under a demonstration, pilot or time limited program will be included in the calculation of an ACO's benchmark and performance year expenditures.

b. Proposals

Our preliminary analysis, as discussed in the background section, suggests that interim non-claims based payments (that is, payments that are subject to reconciliation at a later date) made under a demonstration, pilot, or time limited program can fluctuate significantly from quarter to quarter and may not reflect the actual final reconciled payment amount. Thus, we agree with the stakeholders who have suggested that only final non-claims based payments made under a demonstration, pilot or time limited program should be included in financial calculations related to benchmarks and performance year expenditures under the Shared Savings Program. We believe this would be a reasonable approach to determining Parts A and B expenditures for assigned beneficiaries for both benchmark and performance years given the uncertain impact on ACOs' financial calculations of including interim payments that will be subsequently revised to reflect the final reconciled payment amounts. We also agree that use of interim payments made under a demonstration, pilot or time limited program could have an increasingly large effect on ACO benchmarks and performance year expenditure calculations in the future given widespread stakeholder interest in participating in alternative payment models and CMS interest in testing and expanding additional payment models that may lead to higher quality and more coordinated care at a lower cost to Medicare.

Therefore, we are proposing to revise the applicable regulations to make clear that we would include only final individually beneficiary identifiable payments made under a demonstration, pilot or time limited program in financial calculations related to establishing and updating benchmarks and determining performance year expenditures under the Shared Savings Program. We propose that this policy would be applied to calculations that are necessary to determine ACO performance for the 2018 performance year and subsequent performance years. For ACOs that are in the middle of an agreement period when this revised policy takes effect, we would adjust the benchmarks for these ACOs at the start of the 2018 performance year and each subsequent performance year so that the benchmark for the ACO reflects the use of the same payment information that would apply in expenditure calculations for the performance year. More specifically, we propose to modify our regulations at §§ 425.602(a)(1)(ii), 425.603(c)(1)(ii), and 425.603(e)(2)(ii) to add new provisions to indicate that, (1) when establishing benchmarks for agreement periods before 2018, we will include all individually beneficiary identifiable payments, including interim payments, made under a demonstration, pilot, or time limited program, (2) for agreement periods beginning in 2018 and subsequent years, we would only include individually beneficiary identifiable payments made under a demonstration, pilot or time limited program that are final and not subject to further reconciliation, and (3) For the 2018 performance year and subsequent performance years in agreement periods beginning in 2015, 2016 and 2017, the benchmark would be adjusted to reflect only individually beneficiary identifiable final payments made under a demonstration, pilot or time limited program. Additionally, we propose to add new §§ 425.604(a)(6)(ii)(A), 425.606(a)(6)(ii)(A) and 425.610(a)(6)(ii)(A) indicating that when calculating expenditures for performance years before 2018, we will include all individually beneficiary identifiable payments, including interim payments, made under a demonstration, pilot, or time limited program. We also propose to add new §§ 425.604(a)(6)(ii)(B), 425.606(a)(6)(ii)(B) and 425.610(a)(6)(ii)(B) indicating that when calculating expenditures for performance year 2018 and subsequent performance years, we would only include individually beneficiary identifiable payments made under a demonstration, pilot or time limited program that are final and not subject to further reconciliation. To be consistent with our treatment of claims-based payments, such final payments would have to be available in the separate CMS system by the end of the 3-month claims run out period.

We invite comments on this proposal.

I. Value-Based Payment Modifier and Physician Feedback Program

1. Overview

Section 1848(p) of the Act requires the establishment of a value-based payment modifier (VM) that applies to specific physicians and groups of physicians the Secretary determines appropriate starting January 1, 2015, and to all physicians and groups of physicians by January 1, 2017. On or after January 1, 2017, section 1848(p)(7) of the Act provides the Secretary discretion to apply the VM to eligible professionals (EPs) as defined in section 1848(k)(3)(B) of the Act. Section 1848(p)(4)(C) of the Act requires the VM to be budget neutral. The VM and Physician Feedback programs continue our initiative to recognize and reward clinicians based on the quality and cost of care provided to their patients, increase the transparency of health care quality information and to assist clinicians and beneficiaries in improving medical decision-making and health care delivery. As stated in the CY 2016 PFS final rule with comment period (80 FR 71277), the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10) was enacted on April 16, 2015. Under section 1848(p)(4)(B)(iii) of the Act, as amended by section 101(b)(3) of MACRA, the VM shall not be applied to payments for items and services furnished on or after January 1, 2019. Section 1848(q) of the Act, as added by section 101(c) of MACRA, establishes the Merit-based Incentive Payment System (MIPS) that shall apply to payments for items and services furnished on or after January 1, 2019.

2. Overview of Existing Policies for the VM

In the CY 2013 PFS final rule with comment period, we discussed the goals of the VM and also established that specific principles should govern the implementation of the VM (77 FR 69307). We refer readers to that rule for a detailed discussion. In the CY 2013 PFS final rule with comment period (77 FR 69310), we finalized policies to phase-in the VM by applying it beginning January 1, 2015, to Medicare PFS payments to physicians in groups of 100 or more EPs. A summary of the existing policies that we finalized for the CY 2015 VM can be found in the CY 2014 PFS proposed rule (78 FR 43486 through 43488). Subsequently, in the CY 2014 PFS final rule with comment period (78 FR 74765 through 74787), we finalized policies to continue the phase-in of the VM by applying it starting January 1, 2016, to payments under the Medicare PFS for physicians in groups of 10 or more EPs. Then, in the CY 2015 PFS final rule with comment period (79 FR 67931 through 67966), we finalized policies to complete the phase-in of the VM by applying it starting January 1, 2017, to payments under the Medicare PFS for physicians in groups of 2 or more EPs and to physician solo practitioners. In the CY 2016 PFS final rule with comment period (80 FR 71277 through 71279), we finalized that in the CY 2018 payment adjustment period, the VM will apply to non-physician EPs who are physician assistants (PAs), nurse practitioners (NPs), clinical nurse specialists (CNSs), and certified registered nurse anesthetists (CRNAs) in groups with 2 or more EPs and to PAs, NPs, CNSs, and CRNAs who are solo practitioners.

In the CY 2016 PFS final rule with comment period (80 FR 71288 to 71291), we finalized that we would apply the following adjustments to payments, for items and services furnished under the Medicare PFS in CY 2018, to physicians, PAs, NPs, CNSs, and CRNAs in groups with 10 or more EPs and at least one physician:

- Negative 4 percent (−4.0 percent) for those that fall into Category 2, meaning that they did not meet the criteria to avoid the 2018 PQRS payment adjustment.
- Negative 4 percent (−4.0 percent) under the quality-tiering methodology for those classified as low quality/high cost and negative 2 percent (−2.0 percent) for those classified as either low quality/average cost or average quality/high cost.
- An upward adjustment of four times an adjustment factor (+4.0x) under the quality-tiering methodology for those classified as high quality/low cost and two times an adjustment factor (+2.0x) for those classified as either average quality/low cost or high quality/average cost.

We finalized that we would apply the following adjustments to payments, for items and services furnished under the Medicare PFS in CY 2018, to physician solo practitioners and physicians, PAs, NPs, CNSs, and CRNAs in groups with 2 to 9 EPs and at least one physician:

- Negative 2 percent (−2.0 percent) to those that fall into Category 2, meaning that they did not meet the criteria to avoid the 2018 PQRS payment adjustment.
- Negative 2 percent (−2.0 percent) under the quality tiering methodology for those classified as low quality/high cost and negative 1 percent (-1.0 percent) for those classified as either low quality/average cost or average quality/high cost.
- An upward adjustment of two times an adjustment factor (+2.0x) under the quality-tiering methodology for those classified as high quality/low cost and one times an adjustment factor (+1.0x), for those classified as either average quality/low cost or high quality/average cost.

We finalized that we would apply the following adjustments to payments, for items and services furnished under the Medicare PFS in CY 2018, to non-physician solo practitioners who are PAs, NPs, CNSs, and CRNAs and to PAs, NPs, CNSs, and CRNAs in groups comprised solely of non-physician EPs:

- Negative 2 percent (−2.0 percent) for those who fall in Category 2, meaning that they did not meet the criteria to avoid the 2018 PQRS payment adjustment.
- No downward adjustments under the quality-tiering methodology in CY 2018.
- An upward adjustment of two times an adjustment factor (+2x) under the quality-tiering methodology, for those classified as high quality/low cost and one times an adjustment factor (+1.0x) for those classified as either average quality/low cost or high quality/average cost.

In the CY 2017 PFS final rule with comment period (81 FR 80520–80524), we finalized the following, with regard to Medicare Shared Savings Program ACO participant TINs whose ACO did not successfully report quality data on behalf of its EPs for purposes of PQRS as required by the Shared Savings Program under § 425.504 for the CY 2017 and CY 2018 PQRS payment adjustments:

- For the CY 2017 VM payment adjustment period, we will use the data reported to the PQRS by the EPs under the ACO participant TIN (as a group or as individuals) outside of the ACO during the secondary PQRS reporting period in 2016 to determine whether the TIN would fall in Category 1 or Category 2 under the VM.
- We will apply the two-category approach finalized for the CY 2017 VM based on participation in the PQRS by groups and solo practitioners to determine whether groups and solo practitioners that participate in a Shared Savings Program ACO, but report to the PQRS outside of the ACO, would fall in Category 1 or Category 2 under the VM.
- We will assess the individual EP or group's 2016 data submitted outside the ACO and during the secondary PQRS reporting period against the reporting requirements for the CY 2018 PQRS payment adjustment. Therefore, groups that meet the criteria to avoid the PQRS payment adjustment for CY 2018 as a

group or by having at least 50 percent of the group's EPs meet the criteria to avoid the PQRS payment adjustment for CY 2018 as individuals, based on data submitted outside the ACO and during the secondary PQRS reporting period in 2016, will be included in Category 1 for the CY 2017 VM. In addition, solo practitioners that meet the criteria to avoid the PQRS payment adjustment for CY 2018 as individuals, based on data submitted outside the ACO and during the secondary PQRS reporting period in 2016, will be included in Category 1 for the CY 2017 VM. For these groups and solo practitioners in Category 1, we will classify their quality composite as ''average quality,'' and as established in the CY 2015 PFS final rule with comment period (79 FR 67943), we will classify their cost composite as ''average cost.'' Category 2 will include those groups and solo practitioners subject to the CY 2017 VM that participate in a Shared Savings Program ACO and do not fall within Category 1. We note that we would need to update the group or solo practitioner's status so that they will stop receiving an automatic downward adjustment under the VM for items and services furnished in CY 2017 and reprocess all claims that were previously paid.

For the CY 2018 payment adjustment period, if groups that participate in a Shared Savings Program ACO in 2016 report quality data to the PQRS outside of the ACO and meet the criteria to avoid PQRS payment adjustment for CY 2018 as a group or by having at least 50 percent of the group's EPs meet the criteria to avoid the PQRS payment adjustment for CY 2018 as individuals by reporting quality data to PQRS outside of the ACO, then they will be included in Category 1 for the CY 2018 VM. If solo practitioners that participate in a Shared Savings Program ACO in 2016 report quality data to the PQRS outside of the ACO and meet the criteria to avoid the PQRS payment adjustment for CY 2018 as individuals, then they will also be included in Category 1. We will classify their quality composite for the VM for the CY 2018 payment adjustment period as ''average quality.'' As finalized in the CY 2015 PFS final rule with comment period (79 FR 67943), the cost composite for groups and solo practitioners that participate in a Shared Savings Program ACO is classified as ''average cost.''

3. Provisions of This Proposed Rule

As a general summary, we are proposing the following modifications to the VM policies for the CY 2018 payment adjustment period:

- Reduce the automatic downward adjustment for groups and solo practitioners in Category 2 (those who do not meet the criteria to avoid the 2018 PQRS payment adjustment as individual solo practitioners, as a group practice, or groups that have at least 50 percent of the group's EPs meet the criteria as individuals) to negative 2 percent (−2.0 percent) for groups with 10 or more EPs and at least one physician, and negative 1 percent (−1.0 percent) for groups with between 2 to 9 EPs, physician solo practitioners, and for groups and solo practitioners that consist only of non-physician EPs.
- Hold all groups and solo practitioners who are in Category 1 (those who meet the criteria to avoid the 2018 PQRS payment adjustment as individual solo practitioners, as a group practice, or groups that have at least 50 percent of the group's EPs meet the criteria as individuals) harmless from downward payment adjustments under quality tiering for the last year of the program.
- To provide a smoother transition to the MIPS and to align incentives across all groups and solo practitioners, reduce the maximum upward adjustment under the quality-tiering methodology to two times an adjustment factor (+2.0x) for groups with 10 or more EPs. This is the same maximum upward adjustment under the quality-tiering methodology that we finalized and will maintain for groups with between 2 to 9 EPs, physician solo practitioners, and for groups and solo practitioners that consist only of non-physician EPs.

a. Approach to Setting the VM Adjustment Based on PQRS Participation

Section 1848(p)(4)(B)(iii)(II) of the Act requires the Secretary to apply the VM to items and services furnished under the PFS beginning not later than January 1, 2017, for all physicians and groups of physicians. Therefore, as mentioned in this proposed rule, in the CY 2016 PFS final rule with comment period (80 FR 71277 through 71279), we established that for the CY 2018 payment adjustment period, the VM will apply to non-physician EPs who are PAs, NPs, CNSs, and CRNAs in groups with 2 or more EPs and to PAs, NPs, CNSs, and CRNAs who are solo practitioners.

In the CY 2016 PFS final rule with comment period (80 FR 71280), we adopted a two-category approach for the CY 2018 VM based on participation in the PQRS by groups and solo practitioners. For the purposes of the CY 2018 VM, Category 1 includes the following groups and solo practitioners:

(1) Groups that meet the criteria to avoid the CY 2018 PQRS payment adjustment as a group practice participating in the PQRS GPRO;

(2) Groups that have at least 50 percent of the group's EPs meet the criteria to avoid the PQRS payment adjustment for CY 2018 as individuals;

(3) Solo practitioners that meet the criteria to avoid the CY 2018 PQRS payment adjustment as individuals; and

(4) Groups and solo practitioners that meet the criteria to avoid the CY 2018 PQRS payment adjustment through participation in a Shared Savings Program ACO, if the ACO in which they participate successfully reports quality data as required by the Shared Savings Program.

Category 2 includes those groups and solo practitioners that are subject to the CY 2018 VM payment adjustment and do not fall within Category 1. Groups in Category 1 have been eligible to receive upward, neutral, or downward adjustments under our quality tiering methodology, and groups and solo practitioners in Category 2 receive an automatic downward adjustment under the VM.

As noted in this proposed rule, under section 1848(p)(4)(B)(iii) of the Act, as amended by section 101(b)(3) of MACRA, the VM shall not be applied to payments for items and services furnished on or after January 1, 2019. Section 1848(q) of the Act, as added by section 101(c) of MACRA, establishes the MIPS that shall apply to payments for items and services furnished on or after January 1, 2019. In the interest of program alignment and providing a smooth transition between the VM and MIPS, as well as aligning with the proposed changes to the policies for satisfactory reporting under the final year of PQRS, modifications to the CY 2018 VM payment adjustments are proposed and described in section III.F. of this proposed rule. We are not proposing any change to our existing policy that TINs that avoid the downward payment adjustment under PQRS (either as a group practice participating in the PQRS GPRO or through the individual participation of at least 50 percent of the group's EPs, or as a solo practitioner) will be considered Category 1 under the VM. These TINs therefore will avoid an automatic downward adjustment under the VM.

b. Payment Adjustment Amount

In this section, we are proposing modifications to the VM policies for the CY 2018 payment adjustment period. As discussed in greater detail below, we are proposing these modifications based on our general policy goals of better

alignment and ensuring a smooth transition from the final year of the VM (2018) to the first year of MIPS (2019) as well as continuing to align the VM with the policies established for the PQRS.

To maintain stability in the payment adjustment amounts applicable under the VM as we transition to the MIPS in 2019, we maintained generally the same VM payment adjustment amounts from the CY 2017 payment adjustment period to the CY 2018 payment adjustment period (80 FR 71288 through 71291). Under our existing policy (80 FR 71290), the estimated funds derived from the application of the downward adjustments to groups and solo practitioners in Category 1 and Category 2 are available to all groups and solo practitioners eligible for upward adjustments under the VM. The upward payment adjustment factor (the ''x'' factor) is determined after the performance period has ended based on the aggregate amount of downward payment adjustments. Despite our efforts to ensure a smooth transition from the VM to the MIPS, the 2017 VM adjustment factor has resulted in payment adjustments for some groups and solo practitioners that are significantly higher than the maximum upward adjustment under the MIPS, which will apply to payments starting in 2019, after the sunset of the VM in 2018. The magnitude of the 2017 VM adjustment factor is due in large part to the number of physician practices failing to satisfy the criteria to avoid the PQRS payment adjustment (Category 2). Furthermore, we believe it is likely that many physician practices that fail to meet these criteria and as a result are in Category 2 and are subject to automatic downward adjustments under the 2018 VM will be excluded from MIPS in 2019, due to the low-volume threshold. For example, as noted in the 2015 PQRS Experience Report, CMS foundthat, based on historical data, the participation rate for practices falling below the low volume threshold ''low volume'' (< $30k charges OR <100 beneficiaries) would be approximately 60 percent. Based on historical data, the participation rate among practices falling above the low volume threshold (>= $30k charges AND >=100 beneficiaries) would be approximately 80 percent.

The 2017 VM adjustment factor is 15.48 percent, which is similar to the 2016 VM adjustment factor of 15.92 percent. We would expect, absent any policy change, that the 2018 VM adjustment factor would be similar or higher. The 2018 VM adjustment factor could potentially be higher than the 2017 VM adjustment factor, because non-physician EPs who will be subject to the 2018 VM may be less familiar with quality reporting and may fail to meet the criteria to avoid the CY 2018 PQRS payment adjustment, which would result in a greater number of groups and solo practitioners in Category 2. In addition, groups with 2–9 EPs and solo practitioner physicians will no longer be held harmless from downward adjustments under the quality-tiering methodology in the CY 2018 payment adjustment period.

In section III.F. of this proposed rule, we are proposing to change certain policies for the 2018 PQRS payment adjustment. We discuss the implications of these proposed changes for PQRS with regard to the VM in greater detail below.

- *Quality-Tiering for groups and solo practitioners in Category 1:* As noted in section III.F. of this proposed rule, we are proposing to change the reporting criteria for the 2018 PQRS payment adjustment. We are proposing to lower the number of measures required and to eliminate the requirement for reporting across a number of domains. We recognize that some groups and solo practitioners may have reported differently under PQRS if the PQRS reporting criteria had been established prior to the reporting period. For example, it is possible that groups and solo practitioners may have selected fewer or different PQRS measures to report or may have chosen to report through a different PQRS reporting mechanism, which could have resulted in a higher quality composite score under the VM. Based on these implications for the VM, we are proposing to hold all groups and solo practitioners in Category 1 harmless from downward adjustments under the quality-tiering methodology in the CY 2018 payment adjustment period. This proposal would apply to groups and solo practitioners who would have otherwise received downward adjustments based on their quality composite score and/or cost composite score. A group or solo practitioner that is classified as ''high cost'' based on their cost composite score potentially could have reported differently under the PQRS and received a quality composite score that would be classified as ''high quality,'' if the PQRS reporting criteria proposed in section III.F. of this proposed rule had been established prior to the reporting period. A high quality/high cost classification would have resulted in a neutral adjustment under the VM in 2018.

In contrast to the existing policy for 2018 where only non-physician solo practitioners and groups comprised solely of non-physician EPs would be held harmless from downward adjustments under quality-tiering, this proposed policy would mean that all groups and solo practitioners that meet the criteria to avoid the 2018 PQRS payment adjustment would receive either a neutral or upward adjustment based on performance.

We also propose to reduce the maximum upward adjustment under the quality-tiering methodology in CY 2018 from four times an adjustment factor (+4.0x) to two times an adjustment factor (+2.0x) for those classified as high quality/low cost and from two times an adjustment factor (+2.0x) to one times an adjustment factor (+1.0x), for those classified as either average quality/low cost or high quality/average cost. This proposal would align the upward adjustments for groups with ten or more eligible professionals with the existing policy for smaller groups and solo practitioners, as well as groups comprised solely of non-physician EPs (80 FR 71290). We are proposing this change based on our concern that the 2018 VM adjustment factor (the ''x'' factor used to determine upward adjustments) could potentially be higher than the 2017 VM adjustment factor, as discussed above. Lowering the maximum upward adjustment in 2018 would mitigate the effect of a high adjustment factor and ensure a smoother transition from the VM adjustment in 2018 to the MIPS adjustment in 2019. We welcome public comment on this proposal.

We are not proposing any change to the existing policy (80 FR 71291) that groups and solo practitioners that are eligible for upward adjustments under the quality-tiering methodology and have average beneficiary risk score that is in the top 25 percent of all beneficiary risk scores will earn an additional upward adjustment of one times an adjustment factor (+1x). We are also not proposing any change to the existing policy (81 FR 80520 through 80524) (a) for the CY 2017 payment adjustment period for groups and solo practitioners that would be in Category 1 as a result of meeting the proposed reduced PQRS reporting criteria (see section III.F. of this proposed rule) outside of their Shared Savings Program ACO during the secondary PQRS reporting period in 2016 or (b) for the CY 2018 payment adjustment period for groups and solo practitioners that would be Category 1 as a result of reporting outside of their Shared Savings Program ACO because their ACO failed to successfully report on their behalf to avoid the PQRS payment adjustment. As stated

previously, under the existing policy, these groups and solo practitioners in Category 1 would be classified as ''average quality'' and ''average cost'' for purposes of the CY 2017 VM.

Tables 22 through 24 illustrate how the proposed policies differ from the existing policies for each group size and composition.

TABLE 22—CURRENT AND PROPOSED CY 2018 VM AMOUNTS UNDER THE QUALITY-TIERING APPROACH FOR PHYSICIANS, NPS, PAS, CNSS, & CRNAS IN GROUPS OF PHYSICIANS WITH 10+ EPS

Cost/quality	Low quality		Average quality		High quality	
VM Payment adjustment	Current (%)	Proposed (%)	Current	Proposed	Current	Proposed
Low Cost	+0.0	+0.0	+2.0x*	+1.0x*	+4.0x*	+2.0x*
Average Cost	−2.0	+0.0	+0.0%	+0.0%	+2.0x*	+1.0x*
High Cost	−4.0	+0.0	−2.0%	+0.0%	+0.0%	+0.0%

* Under existing policy, these groups are eligible for an additional +1.0x if their average beneficiary risk score is in the top 25 percent of all beneficiary risk scores, where 'x' represents the upward payment adjustment factor.

TABLE 23—CURRENT AND PROPOSED CY 2018 VM AMOUNTS UNDER THE QUALITY-TIERING APPROACH FOR PHYSICIANS, PAS, NPS, CNSS, & CRNAS IN GROUPS OF PHYSICIANS WITH 2–9 EPS AND PHYSICIAN SOLO PRACTITIONERS

Cost/quality	Low quality		Average quality		High quality	
VM Payment adjustment	Current (%)	Proposed (%)	Current	Proposed	Current	Proposed
Low Cost	+0.0	+0.0	+1.0x*	+1.0x*	+2.0x*	+2.0x*
Average Cost	−1.0	+0.0	+0.0%	+0.0%	+1.0x*	+1.0x*
High Cost	−2.0	+0.0	−1.0%	+0.0%	+0.0%	+0.0%

* Under existing policy, these groups and solo practitioners are eligible for an additional +1.0x if their average beneficiary risk score is in the top 25 percent of all beneficiary risk scores, where 'x' represents the upward payment adjustment factor.

TABLE 24—CURRENT AND PROPOSED CY 2018 VM AMOUNTS UNDER THE QUALITY-TIERING APPROACH FOR PAS, NPS, CNSS, & CRNAS WHO ARE SOLO PRACTITIONERS OR IN GROUPS CONSISTING OF NON-PHYSICIAN EPS ONLY

Cost/quality	Low quality		Average quality		High quality	
VM Payment adjustment	Current (%)	Proposed (%)	Current	Proposed	Current	Proposed
Low Cost	+0.0	+0.0	+1.0x*	+1.0x*	+2.0x*	+2.0x*
Average Cost	+0.0	+0.0	+0.0%	+0.0%	+1.0x*	+1.0x*
High Cost	+0.0	+0.0	+0.0%	+0.0%	+0.0%	+0.0%

* Under existing policy, these groups and solo practitioners are eligible for an additional +1.0x if their average beneficiary risk score is in the top 25 percent of all beneficiary risk scores, where 'x' represents the upward payment adjustment factor.

Table 25 displays the proposed 2018 VM adjustments under the quality-tiering methodology, for groups and solo practitioners in Category 1. Under the proposed policies, groups of any size and composition would be subject to the same upward adjustments under quality tiering and would be held harmless from any downward adjustments based on performance.

TABLE 25—PROPOSED CY 2018 VM AMOUNTS UNDER THE QUALITY-TIERING APPROACH FOR PHYSICIANS, PAS, NPS, CNSS, AND CRNAS WHO ARE SOLO PRACTITIONERS AND THOSE IN GROUPS OF ANY SIZE

Cost/quality	Low quality (%)	Average quality	High quality
Low cost	+0.0	+1.0x*	+2.0x*
Average cost	+0.0	+0.0%	+1.0x*
High cost	+0.0	+0.0%	+0.0%

* Under existing policy, these groups and solo practitioners are eligible for an additional +1.0x if their average beneficiary risk score is in the top 25 percent of all beneficiary risk scores, where 'x' represents the upward payment adjustment factor.

• *Automatic Downward Adjustments for groups and solo practitioners in Category 2.* Under existing policy, the total maximum downward adjustment in 2018 under the PQRS and VM programs combined is negative 6 percent (−6.0 percent), while the maximum downward adjustment under MIPS in 2019 is negative 4 percent (−4.0 percent). In order to ensure a smoother transition to the downward payment adjustments under MIPS, we are proposing to reduce the amount of the automatic downward adjustments applied to payments for TINs

categorized as Category 2 (those that do not avoid the PQRS payment adjustment as individual solo practitioners, as a group practice, or as a group that has at least 50 percent of the group's EPs meet the criteria to avoid the payment adjustment as individuals).

For physicians, PAs, NPs, CNSs, and CRNAs in groups with 10 or more EPs and at least one physician, we propose to reduce the automatic downward VM adjustment from negative 4 percent (−4.0 percent) to negative 2 percent (−2.0 percent) for those that fall in Category 2, meaning they did not meet the criteria to avoid the 2018 PQRS payment adjustment. We welcome public comment on this proposal.

For physician, PA, NP, CNS, and CRNA solo practitioners; physicians, PAs, NPs, CNSs, and CRNAs in groups with 2 to 9 EPs; and for PAs, NPs, CNSs, and CRNAs who are in groups comprised solely of non-physician EPs, we propose to reduce the automatic downward VM adjustment from negative 2 percent (−2.0 percent) to negative 1 percent (−1.0 percent) for those that fall in Category 2. We welcome public comment on this proposal.

Section 1848(p) of the Act does not specify the amount of payment that should be subject to the adjustment for the VM; however, section 1848(p)(4)(C) of the Act requires the VM be implemented in a budget neutral manner. In the past, under the VM, we have achieved budget neutrality by increasing payments for some groups and solo practitioners based on high performance and decreasing them for others based on low performance or failing to meet the criteria to avoid the PQRS payment adjustment as a group or as individuals. Under the proposals discussed above for the CY 2018 payment adjustment period, we would not decrease payments to groups and solo practitioners based on performance under the quality-tiering methodology, provided that they are classified as Category 1 under the VM (meaning that they meet the criteria to avoid the CY 2018 PQRS payment adjustment as individual solo practitioners, as a group practice, or as a group that has at least 50 percent of the group's EPs meet the criteria). We would continue to decrease payments to groups and solo practitioners in Category 2 (meaning that they did not meet the criteria to avoid the CY 2018 PQRS payment adjustment as individual solo practitioners, as a group practice, or as a group that has at least 50 percent of the group's EPs meet the criteria). Regardless of the proposals discussed above for the CY 2018 payment adjustment period, the aggregate expected amount of Medicare spending in any given year for physician and non-physician EP services paid under the Medicare PFS will not change as a result of the application of the VM. As discussed above, because the VM must be implemented in a budget neutral manner, the amount available for upward adjustments for high performers would decrease under our proposals. In other words, groups and solo practitioners that performed well on cost and quality would receive a smaller increase in payment. For this reason, we seek comment on whether we have appropriately balanced the interests of high and low-performing groups and solo practitioners through this proposed change to the policy.

We propose to make conforming revisions to §§ 414.1270, and 414.1275(c)(4) and (d)(3) to reflect the proposals described in this section. We seek public comment on these proposed changes to the regulation text.

J. MACRA Patient Relationship Categories and Codes

1. Development of Patient Relationship Categories and Codes To Improve Identification of Physician-Patient Relationship

a. Overview

The Quality Payment Program (QPP) aims to improve health outcomes, promote smarter spending, minimize burden of participation, and provide fairness and transparency in operations. These aims are centered on improving beneficiary outcomes and engaging patients through patient-centered policies, and enhancing clinician experience through flexible and transparent program design and interactions with easy-to-use program tools.

The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10) was enacted on April 16, 2015. Section 101(f) of MACRA amended section 1848 of the Act to create a new subsection (r) entitled Collaborating with the Physician, Practitioner, and Other Stakeholder Communities to Improve Resource Use Measurement. Section 1848(r)(2) of the Act requires the development of care episode and patient condition groups, and classification codes for such groups. To facilitate the attribution of patients and episodes to one or more clinicians, section 1848(r)(3) of the Act requires the development of patient relationship categories and codes that define and distinguish the relationship and responsibility of a physician or applicable practitioner with a patient at the time of furnishing an item or service. The categories shall include different relationships of the clinician to the patient and reflect various types of responsibility for and frequency of furnishing care. Pursuant to section 1848(r)(3)(C) of the Act, we posted a draft list of patient relationship categories in April 2016 and solicited public comment on the categories and the policy principles that were used in developing them.[4] In December 2016, we solicited additional comment on potential modifications to these categories based on comments received previously, as well as a method to operationalize the coding of these categories on the Medicare claim.[5]

2. Operational List of Patient Relationship Categories

Based on the public comments received and consultation with stakeholders and experts regarding the draft list of patient relationship categories posted in April 2016 and the list of modified patient relationship categories posted in December 2016, we posted the operational list of patient relationship categories on May 17, 2017, pursuant to section 1848(r)(3)(E) of the Act, which is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/CMS-Patient-Relationship-Categories-and-Codes.pdf*. The patient relationship categories on the operational list are the following:

- Continuous/Broad Services.
- Continuous/Focused Services.
- Episodic/Broad services.
- Episodic/Focused Services.
- Only as Ordered by Another Clinician.

3. Subsequent Revisions

Section 1848(r)(3)(F) of the Act requires that after the posting of the operational list of patient relationship categories and codes, not later than November 1st of each year (beginning with 2018), the Secretary shall, through rulemaking, make revisions to the operational list of patient relationship categories and codes as the Secretary determines appropriate. The revisions may be based on experience, new information and input from stakeholders. In preparation for

[4] *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/Patient-Relationship-Categories-and-Codes.pdf* (assessed 04/26/2017).

[5] *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/Patient-Relationship-Categories-and-Codes-Posting-FINAL.pdf.*

potential subsequent revisions by November 1, 2018, we seek comment on the operational list of patient relationship categories available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/CMS-Patient-Relationship-Categories-and-Codes.pdf.*

4. Reporting of Patient Relationship Codes Using Modifiers

Section 1848(r)(4) of the Act requires that claims submitted for items and services furnished by a physician or applicable practitioner on or after January 1, 2018, shall, as determined appropriate by the Secretary, include the applicable codes established for care episode groups, patient condition groups, and patient relationship categories under sections 1848(r)(2) and (3) of the Act, as well as the NPI of the ordering physician or applicable practitioner (if different from the billing physician or applicable practitioner). Applicable practitioners are defined in section 1848(r)(9)(B) of the Act as a physician assistant, nurse practitioner, and clinical nurse specialist (as such terms are defined in section 1861(aa)(5)), and a certified registered nurse anesthetist (as defined in section 1861(bb)(2)), and beginning January 1, 2019, such other eligible professionals (as defined in subsection (k)(3)(B)) as specified by the Secretary.

We have been planning for the use of procedure code modifiers for the reporting of patient relationships codes on Medicare claims. In December 2016, as described above, when we solicited comments on the potential modifications to the patient relationship categories, we also sought comment on the use of Level II Healthcare Common Procedure Coding System (HCPCS) Modifiers for the patient relationship codes. Public comments indicated that Current Procedural Terminology (CPT) Modifiers would be the best way to operationalize the reporting of patient relationship codes.[6]

We worked with the American Medical Association's (AMA) CPT Editorial Panel, which is responsible for maintaining the CPT code set. We submitted an application for the CPT modifiers for reporting of the patient relationship codes. The CPT Editorial Panel, at their June 2017 meeting determined that AMA would not include the modifiers in the CPT code set, pending future finalization of the modifiers by CMS, whereby CMS publishes the modifiers as Level II HCPCS Modifiers. Therefore, we are proposing the Level II HCPCS Modifiers in Table 26 as the patient relationship codes, which we would add to the operational list if we adopt them in the final rule.

TABLE 26—PROPOSED PATIENT RELATIONSHIP HCPCS MODIFIERS AND CATEGORIES

No.	Proposed HCPCS modifier	Patient relationship categories
1x	X1	Continuous/broad services
2x	X2	Continuous/focused services
3x	X3	Episodic/broad services
4x	X4	Episodic/focused services
5x	X5	Only as ordered by another clinician

We are proposing that Medicare claims submitted for items and services furnished by a physician or applicable practitioner on or after January 1, 2018, should include the applicable HCPCS modifiers in Table 26, as well as the NPI of the ordering physician or applicable practitioner (if different from the billing physician or applicable practitioner). We anticipate there will be a learning curve with the use of the modifiers to report patient relationships, and believe that time would be needed to work with clinicians to ensure they gain experience in using these modifiers. Therefore, for at least an initial period while clinicians gain familiarity, we are proposing that the HCPCS modifiers may be voluntarily reported on Medicare claims, and the use and selection of the modifiers would not be a condition of payment. Claims would be paid regardless of whether and how the modifiers are included. We would work with clinicians to educate them about the proper use of the modifiers.

The use of modifiers to report patient relationships would not change the meaning of the procedure codes used to report items and services and guidelines associated with use of such procedure codes. The modifiers would also not be tied or related to intensity of services (evaluation and management services). Finally, we note that, while we may work with clinicians to explore incorporating these codes into the QPP in future years, the measures we have proposed and finalized to date, those we have proposed for 2018, and those we are currently developing for future rulemaking for the MIPS performance categories do not require patient relationship codes to properly measure clinicians' quality and resource use in the Medicare program.

We solicit comment on our proposal for voluntary reporting of the proposed HCPCS modifiers on claims submitted for items and services furnished by a physician or applicable practitioner on or after January 1, 2018 and on the proposed list of HCPCS modifiers in Table 26. We seek comments on our intention to resubmit these patient relationship modifiers to AMA for future consideration into the CPT modifier code set.

K. Proposed Changes to the Medicare Diabetes Prevention Program (MDPP) Expanded Model

1. Background

a. Authority for and Establishment of the MDPP Expanded Model

In the November 15, 2016 **Federal Register**, we issued a final rule to implement aspects of the Medicare Diabetes Prevention Program (MDPP) expanded model (81 FR 80459 through 80475 and 80552 through 80558) as part of the CY 2017 PFS final rule.

Section 1115A(c) of the Act provides the Secretary with the authority to expand, through rulemaking (including implementation on a nationwide basis), the duration and scope of a model that is being tested under section 1115A(b) of the Act if certain determinations specified in the Act are made, taking into account the evaluation of the model under section 1115A(b)(4) of the Act. The MDPP expanded model is an

[6] The CMS Level II HCPCS Coding Workgroup meets regularly (generally monthly) to consider requests for new HCPCS codes and modifiers. Information on the code request and approval process is available at *https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/index.html* (assessed 04/26/2017).

expansion of CMS' Center for Medicare and Medicaid Innovation's (Innovation Center) Diabetes Prevention Program (DPP) model test under the authority of section 1115A of the Act. The Secretary expanded the DPP model test in duration and scope under the authority of section 1115A(c) of the Act. For further information on the DPP model test, and the associated National DPP administered by the Centers for Disease Control and Prevention (CDC), we refer readers to the CY 2017 PFS final rule and the following Web sites: *https://Innovation.cms.gov/initiatives/Health-Care-Innovation-Awards/* and *https://www.cdc.gov/diabetes/prevention/index.html* .

The aim of the MDPP expanded model is to continue to test a method of prevention of the onset of type 2 diabetes among Medicare beneficiaries with an indication of prediabetes as defined by the MDPP beneficiary eligibility criteria (finalized at § 410.79(c)(1)). Services available through the MDPP expanded model are MDPP services furnished in community and health care settings by coaches, such as trained community health workers or health professionals. We have designated services under the MDPP expanded model to be covered as additional preventive services under Medicare, as defined in section 1861(ddd) of the Act.

For a detailed discussion of the DPP model test and the development of aspects of the MDPP expanded model, we refer readers to the July 15, 2016 MDPP proposed rule (''Proposed Expansion of the Diabetes Prevention Program (DPP) Model'') (81 FR 46413 through 46418), and the CY 2017 PFS final rule (81 FR 80459 through 80475).

In the CY 2017 PFS final rule, we responded to and incorporated certain suggestions from the public comments we received that were within the scope of the MDPP proposals presented in the July 15, 2016 MDPP proposed rule. We indicated in that final rule (81 FR 80459) that the MDPP expanded model would be implemented through at least two rounds of rulemaking. In the CY 2017 PFS final rule, we finalized MDPP policies that will enable CDC-recognized organizations to prepare for enrollment, including finalizing the framework for the MDPP expanded model, details of the MDPP expanded model (codified at § 410.79(a) and (b)), beneficiary eligibility criteria (codified at § 410.79(c) and (d)), supplier eligibility criteria and supplier enrollment requirements (codified at § 424.59, proposed in this rule to be redesignated as § 424.205). We also identified several issues, including some issues raised by commenters that we deferred to future rulemaking. The proposals in this proposed rule address a number of issues raised by the public in response to the July 15, 2016 MDPP proposed rule. We also are making additional proposals to implement the MDPP expanded model.

b. Summary of Provisions Finalized 2017 PFS Final Rule

In the CY 2017 PFS final rule (81 FR 80465 through 80468), we finalized the structure of MDPP services. We provided that the MDPP core benefit consists of at least 16 weekly core sessions over months 1 through 6 and at least 6 monthly core maintenance sessions over months 7 through 12, furnished regardless of weight loss (§ 410.79(b) and (c)(2)). We also finalized that Medicare will cover ongoing maintenance sessions after the 12-month core set of MDPP services if beneficiaries achieve and maintain the required minimum weight loss of 5 percent. In section III.K.2.b. of this proposed rule, we are proposing to further revise the structure of MDPP services as a 3-year service period, generally contingent upon a beneficiary's attainment of two performance goals: achievement and maintenance of weight loss and attendance at a certain number of MDPP sessions.

As used in this proposed rule, the term ''MDPP services period'' refers to the time period in which MDPP services are furnished under the MDPP expanded model over a minimum of 12 consecutive months and a maximum of 36 consecutive months from the date of the first core session the beneficiary attends. We use the term ''set of MDPP services'' to include the entirety of MDPP services available under the MDPP expanded model, including core sessions, core maintenance sessions, and, subject to paragraph § 410.79(c)(3), ongoing maintenance sessions offered over the course of the MDPP services period. For purposes of this proposed rule and the expanded model, MDPP services would be covered under the ''additional preventive services'' benefit category under section 1861(ddd)(1) of the Act and paid through the Medicare Part B Trust Fund. As indicated in the CY 2017 PFS, we intended to begin supplier enrollment before MDPP services became available, and we finalized an expanded model start date of January 1, 2018.

In this proposed rule, we propose a new start date for the furnishing of MDPP services within the expanded model of April 1, 2018. That is, MDPP suppliers will not be able to furnish MDPP services, or to receive payment for these services, prior to April 1, 2018. We note that if finalized as part of the CY 2018 PFS, the supplier enrollment and compliance policies will become effective on January 1, 2018. This change to delay the furnishing of MDPP services would allow time for organizations to enroll in Medicare before they begin furnishing and billing for MDPP services.

In the CY 2017 PFS final rule (81 FR 80459), we described a possible payment structure for MDPP services, but deferred full development of the payment structure to future rulemaking. In section III.K.2.d. of this proposed rule, we discuss our proposed payment structure for MDPP services. This proposal takes into consideration the significant number of public comments we received in response to the possible payment structure we described in the July 15, 2016 MDPP proposed rule. We also are proposing payment policies for instances in which an MDPP beneficiary switches MDPP suppliers.

In the CY 2017 PFS final rule (81 FR 80471 through 80474), we required CDC-recognized organizations that will bill Medicare for MDPP services to enroll in Medicare as MDPP suppliers. We also finalized the requirements for coaches furnishing MDPP services. We finalized policies regarding CDC Diabetes Prevention Recognition Program (DPRP) full recognition for MDPP suppliers and we indicated an intention to propose policies in future rulemaking regarding whether a DPP organization without full CDC recognition could enroll as an MDPP supplier. We are proposing an interim MDPP preliminary recognition standard in section III.K.2.e. of this proposed rule. Also, in this section of this proposed rule, we are proposing revisions to the supplier eligibility and enrollment requirements, including establishment of standards and implementation of appropriate program integrity safeguards. In section III.K.2.f. of this proposed rule, we are proposing policies related to MDPP beneficiary engagement incentives furnished by MDPP suppliers.

In the CY 2017 PFS final rule (81 FR 80459), we deferred establishing policies related to organizations delivering ''virtual'' DPP services, where services are not furnished in person. In section III.K.3. of this proposed rule, we explain that the MDPP expanded model covers in-person MDPP services (other than ad hoc virtual make-up sessions discussed in section III.K.2.c.iv.(3) of this proposed rule), and thus, explain why we are not currently making any proposals related to MDPP services

furnished 100 percent virtual and state that we are considering a separate model under CMS's Innovation Center authority to test and evaluate virtual DPP services.

2. Proposed Policy Changes

a. Proposed Changes to Effective Date of MDPP Services

In the CY 2017 PFS final rule, we established at § 410.79(a) that MDPP services would be available on January 1, 2018. We are proposing to change § 410.79(a) to state that MDPP services would be available on April 1, 2018. We are proposing this change because we want to ensure that MDPP suppliers have sufficient time to enroll in Medicare after the effective date of the CY 2018 PFS final rule.

Therefore, beneficiaries will not be able to receive MDPP services immediately on January 1, 2018 due to the time needed for supplier enrollment. For this reason, we are proposing April 1, 2018 as the expanded model start date, which we believe allows a sufficient amount of time (90 days) for eligible suppliers to enroll in Medicare before furnishing and billing for MDPP services. Subject to this proposed change, the following regulatory provisions, if finalized, would be effective April 1, 2018: § 414.84 related to payment for MDPP services; and § 424.210 related to beneficiary engagement incentives. All other sections, if finalized, will be effective on January 1, 2018, including the policies proposed in section III.K.2.e. related to supplier enrollment and compliance. We seek comment on this new expanded model start date and whether 90 days is a sufficient amount of time for organizations to enroll in Medicare and prepare to furnish and bill for MDPP services.

b. Proposed Changes to the Set of MDPP Services

In the CY 2017 PFS final rule, we established the parameters of MDPP services. The policies and terms proposed in this proposed rule seek to clarify, build on, and at times change these previously finalized policies. In particular, we propose to refine and add terms related to the different aspects of ''MDPP services.'' In this proposed rule, we propose to slightly refine the term ''MDPP services'' to refer to structured health behavior change sessions that are furnished under the MDPP expanded model with the goal of preventing diabetes among Medicare beneficiaries with prediabetes, and that follow a CDC-approved curriculum (proposed § 410.79(b)). The sessions provide practical training in long-term dietary change, increased physical activity, and problem-solving strategies for overcoming challenges to maintaining weight loss and a healthy lifestyle.

In the preamble to the CY 2017 PFS final rule, we referenced the set of MDPP services covered under the expanded model as the ''MDPP benefit.'' In this proposed rule, we propose to update this terminology. In cases where we would have previously referred to the term ''benefit'' to describe the entire set of MDPP sessions covered under the MDPP model, we propose to use the phrase ''set of MDPP services.'' ''Set of MDPP services'' means the series of MDPP sessions, composed of core sessions, core maintenance sessions, and ongoing maintenance sessions, offered over the course of the MDPP services period (proposed § 410.79(b)).

In cases where we would have previously used the term ''benefit'' to describe a period of time, we propose to refer to the ''MDPP services period.'' The MDPP services period means the time period, beginning on the date an MDPP beneficiary attends his or her first core session, over which the set of MDPP services is furnished to the MDPP beneficiary, to include the core services period described in paragraph § 410.79(c)(2)(i) and, subject to paragraph § 410.79(c)(3), one or more ongoing maintenance session intervals during the ongoing services period described in paragraph § 410.79(c)(2)(ii) (proposed § 410.79(b)). The duration of the MDPP services period is discussed further in section III.K.2.c.iv. of this proposed rule. As noted throughout this section, the term ''benefit'' would no longer be used. We propose to remove the term ''MDPP core benefit'' from the list of definitions.

In the CY 2017 PFS final rule, we included a definition for ''core sessions'' that referred to the set of core sessions covered under the MDPP expanded model. We propose to revise the definition for ''core sessions,'' and instead define the singular ''core session'' as an MDPP service that is furnished by an MDPP supplier to an MDPP beneficiary during months 1 through 6 of the MDPP services period, is approximately 1 hour in length, and adheres to a CDC-approved DPP curriculum for core sessions (proposed § 410.79(b)). We believe that having a definition for the individual core session would be more uniform with other MDPP definitions, which are defined in the singular form. We propose to revise the definition of ''core maintenance session'' as an MDPP service that is furnished by an MDPP supplier to an MDPP beneficiary during a core maintenance session interval, is approximately 1 hour in length, and adheres to a CDC-approved DPP curriculum for maintenance sessions (under proposed revised § 410.79(b)).

We propose to revise the definition of an ''ongoing maintenance session'' as an MDPP service that is furnished by an MDPP supplier to an MDPP beneficiary during an ongoing maintenance session interval; is approximately 1 hour in length and adheres to a CDC-approved DPP curriculum for maintenance sessions (proposed revised § 410.79(b)). The proposed time period over which MDPP suppliers offer ongoing maintenance sessions, which differs from our previously finalized policy, is discussed in section III.K.2.b.i. of this proposed rule.

We propose to add a definition for ''MDPP session,'' which means a core session, a core maintenance session, or an ongoing maintenance session (proposed § 410.79(b)).

We invite public comments on these proposals.

i. Ongoing Maintenance Session Time Limit

In the CY 2017 PFS final rule, we finalized that ''MDPP eligible beneficiaries,'' a term we now propose to remove and replace with ''MDPP beneficiary,'' as described further in section III.K.2.c. of this proposed rule, would have Medicare coverage for ongoing maintenance sessions for an unspecified length of time, provided that they maintained the required minimum weight loss, which is 5 percent weight loss from baseline. Based on public comments indicating the limited administrative and operational capability of many MDPP suppliers to provide ongoing maintenance sessions for an individual indefinitely (81 FR 80468), we stated our intent to propose a limit on the number or duration of ongoing maintenance sessions to be covered in the set of MDPP services, although we did not finalize a policy that would do so.

In this rule, we propose a 2-year limit on Medicare coverage for ongoing maintenance sessions (proposed § 410.79(c)(2)(ii)). The CMS Chief Actuary noted in the certification of the expansion of the DPP model test that continued participation in a type 2 diabetes DPP after 3 years has generally been untested. In addition, a DPP clinical trial conducted by the National Institutes of Health from 1996 to 2001 followed participants in a DPP for 3 years and found that, at the end of the study, diabetes incidence was reduced by 58 percent in the group that received a DPP lifestyle intervention when

compared to the placebo group.[7] Based on the lack of evidence about DPP services beyond 3 years and evidence of positive effects from DPP participation for 3 years, in this proposed rule, we propose a total MDPP services period of up to 3 years (consisting of 1 year of core sessions and core maintenance sessions, followed by up to 2 years of ongoing maintenance sessions, (proposed § 410.79(b)).

We considered alternatives to this proposal, such as limiting Medicare coverage for ongoing maintenance sessions to 1 year, which would limit the total MDPP services period to 2 years. Because the CDC DPRP does not require organizations to offer ongoing maintenance sessions, we also considered not covering ongoing maintenance sessions altogether, which would limit the total MDPP services period to 1 year. However, we believe that beneficiaries can benefit from maintenance sessions beyond the 6 months of core maintenance sessions because weight loss is difficult to achieve and can be even more difficult to sustain. We believe that the behavior changes necessary to sustain weight loss will be more deeply ingrained through beneficiary participation in ongoing maintenance sessions. Existing evidence also supports the effectiveness of participation in a DPP through 3 years.

We did not consider alternatives that would extend Medicare coverage for ongoing maintenance sessions beyond 2 years, and therefore, create an MDPP services period that would last longer than 3 years. Therefore, we propose to continue to include ongoing maintenance sessions, but with a limit of up to 2 years. As stated earlier, we believe there is not enough evidence available to support the effectiveness of participation in a DPP beyond 3 years. We also believe, based on public comments received in response to the July 15, 2016 MDPP proposed rule, that many suppliers have limited administrative and operational capacity to offer MDPP ongoing maintenance sessions indefinitely to all MDPP beneficiaries who maintain eligibility. As noted in section III.K.2.e.iv.4 of this proposed rule, an example of a capacity limit could include a situation where an MDPP supplier has met its class size maximum and therefore could not accept additional beneficiaries. We are inviting public comments on our proposal and the alternatives we considered.

[7] Available at *http://www.nejm.org/doi/full/10.1056/NEJMoa012512.*

ii. MDPP Services Period Clarifications

At § 410.79(b), we propose to remove the existing definition of ''maintenance session bundle,'' and to establish new definitions for ''core maintenance session interval,'' and ''ongoing maintenance session interval,'' which we believe will more directly reflect the structure of the set of MDPP services, as well as support the proposed policies in this proposed rule. Through these proposed definition changes, we are seeking to clarify the differences between the two types of intervals. We propose to define ''core maintenance session interval'' as one of the two consecutive 3-month time periods during months 7 through 12 of the MDPP services period, during which an MDPP supplier offers an MDPP beneficiary at least one core maintenance session per month. We propose to define ''ongoing maintenance session interval'' as one of the up to eight consecutive 3-month time periods during the ongoing services period described in paragraph § 410.79(c)(2)(ii), during which an MDPP supplier offers at least one ongoing maintenance session to an MDPP beneficiary per month.

We are making the proposal to use the term ''interval'' instead of ''bundle'' because the proposed performance payments are tied to attendance and weight loss performance goals and, in aggregate, constitute the payment to MDPP suppliers for furnishing MDPP services during the MDPP services period, but they do not provide specific payments for a particular subset of sessions. Therefore, we believe that the term ''bundle'' is not appropriate for describing performance payments for these time intervals. The proposed new terms allow us to more appropriately describe the relationship of the performance payments to the specific time periods where performance is measured. Furthermore, we propose to define ''make-up session'' as a core session, a core maintenance session, or an ongoing maintenance session furnished to an MDPP beneficiary when the MDPP beneficiary misses a regularly scheduled core session, core maintenance session, or ongoing maintenance session (proposed at § 410.79(b)). We propose to define ''virtual make-up session'' as a make-up session that is not furnished in person and that is furnished in a manner consistent with the DPRP standards for virtual sessions (proposed § 410.79(b)). Policies describing the parameters of make-up sessions and virtual make-up sessions are described further in section III.K.2.c.iv.(3).

We propose an additional term that helps describe key aspects of the MDPP expanded model: ''Performance goal.'' This term refers to an attendance or weight loss goal that an MDPP beneficiary must achieve during the MDPP services period for an MDPP supplier to be paid a performance payment (proposed § 414.84(a)). Because we propose this term that more broadly speaks to the performance goals of this expanded model, we propose to remove the definition of ''maintenance of weight loss.'' We also propose to move the definition of ''coach'' from § 410.79(b) to § 424.205(a) (we propose in section III.K.2.e to redesignate § 424.59, Requirements for Medicare Diabetes Prevention Program suppliers to § 424.205). We propose to revise the definition of ''MDPP supplier'' to mean an entity that is enrolled in Medicare to furnish MDPP services as provided in § 424.59 (proposed to be redesignated as § 424.205).

We invite public comments on these proposals.

c. Proposed Changes Related to Beneficiary Eligibility

In the CY 2017 PFS final rule, we established the eligibility criteria for Medicare beneficiaries to have coverage of the set of MDPP services, codified at §§ 410.79(c)(1) and 410.79(d), respectively. We previously finalized that an individual who met these criteria would be referred as an ''MDPP eligible beneficiary.'' However, in this proposed rule, we propose to remove this term, and instead, add the definition of ''MDPP beneficiary'' to mean a Medicare beneficiary who meets the criteria specified in paragraph § 410.79(c)(1)(i), who has initiated the MDPP services period by attending the first core session, and for whom the MDPP services period has not ended as specified in paragraph § 410.79(c)(3) (proposed § 410.79(b)). We believe that this revised definition will provide more clarity about when a beneficiary qualifies to receive MDPP services. We propose to remove the definition of ''MDPP eligible beneficiary'' to avoid confusion between the two definitions, and we propose conforming changes to § 410.79 to remove the term ''MDPP eligible beneficiary'' and use the term ''MDPP beneficiary'' in its place, where appropriate.

In the CY 2017 PFS final rule (81 FR 80470), we specified at § 410.79(c)(1) that Medicare beneficiaries are eligible for MDPP services if they meet all of the following criteria:

- Are enrolled in Medicare Part B.
- Have, as of the date of attendance at the first core session, a body mass

index (BMI) of at least 25 if not self-identified as Asian or a BMI of at least 23 if self-identified as Asian (please see our discussion of BMI parameters in the CY 2017 PFS final rule at 81 FR 80468).

- Have, within the 12 months prior to attending the first core session, a hemoglobin A1c test with a value between 5.7 and 6.4 percent, a fasting plasma glucose of 110–125 mg/dL, or a 2-hour plasma glucose of 140–199 mg/dL (oral glucose tolerance test).
- Have no previous diagnosis of type 1 or type 2 diabetes (other than gestational diabetes).
- Do not have end-stage renal disease (ESRD).

In this proposed rule, we propose changes to these eligibility criteria at § 410.79(c)(1) to clarify the eligibility limitations related to previous type 1 or type 2 diabetes diagnosis (described further in section III.K.2.c.ii. of this proposed rule), move and edit the regulation text that specifies that each beneficiary can only receive the set of MDPP services once in their lifetime (described further in section III.K.2.c.iii. of this proposed rule), and make editorial changes so that the provisions are specific to an individual beneficiary. We also are taking this opportunity to clarify some of these eligibility criteria.

i. Clarifying MDPP Eligibility Criteria Related to Gestational Diabetes and End-Stage Renal Disease (ESRD)

We note that we are not excluding beneficiaries with a prior history of gestational diabetes from eligibility for MDPP services, while beneficiaries with a prior history of a diagnosis of type 1 or type 2 diabetes are ineligible. The eligibility criteria are intended to identify a beneficiary at high risk for the development of type 2 diabetes in an individual that has not been diagnosed with type 1 or type 2 diabetes. Gestational diabetes is a condition that develops during pregnancy and typically resolves after delivery, although an individual with a history of gestational diabetes is at increased risk of subsequent type 2 diabetes development and may benefit from the set of MDPP services. Because of the clinical differences between gestational diabetes and type 1 or type 2 diabetes, we determined that it was appropriate not to exclude a beneficiary with a prior history of gestational diabetes from eligibility for MDPP services.

We also are clarifying that a beneficiary who is diagnosed with ESRD after having begun receiving MDPP services would lose eligibility. We do not believe MDPP services are appropriate for beneficiaries with ESRD because beneficiaries with ESRD require dialysis, and the nutrition requirements for individuals on dialysis are very specific and therefore MDPP curriculum will not apply.[8] We believe that a beneficiary receiving MDPP services who develops ESRD will be best suited by ceasing to receive MDPP services and receiving attention by other health care professionals specifically suited to address his or her condition. Additionally, individuals with ESRD were not included in the DPP model test. Suppliers can use the online HIPAA Eligibility Transaction System (HETS) to verify if a beneficiary has ESRD by checking his or her eligibility status as a Part B or ESRD Medicare beneficiary. Suppliers can find more information on this system at *https://www.cms.gov/hetshelp/*. We recognize that some Medicare beneficiaries may have other serious conditions, such as heart disease or cancer, and therefore may also have specific dietary requirements. We recommend that beneficiaries with complex dietary needs consult their health care provider as to whether they should participate in MDPP.

In summary, a beneficiary must maintain Medicare Part B coverage and not have ESRD throughout the duration of the MDPP services period to remain eligible to receive coverage for MDPP services. In conjunction with our proposal in this proposed rule related to diabetes diagnosis (explained further in section III.K.2.c.ii. of this proposed rule), a beneficiary must meet the eligibility requirements related to prediabetes and diabetes (including BMI, blood test results, and no diagnosis of diabetes other than gestational diabetes) as of the date of attendance at the first core session.

We invite public comments on these proposals.

ii. Diabetes Diagnosis During the MDPP Services Period

In the CY 2017 PFS final rule, we finalized that to be eligible for coverage for the set of MDPP services, a Medicare beneficiary must have prediabetes, as shown through a qualifying BMI and blood test results, and must have no previous diagnosis of type 1 or type 2 diabetes (other than gestational diabetes). We received public comments in response to the July 15, 2016 MDPP proposed rule that asked whether a beneficiary would remain eligible for the set of MDPP services if the beneficiary developed diabetes during the MDPP services period. In the CY 2017 PFS final rule, we deferred action in response to these public comments and are now addressing them in this proposed rule.

We propose that the diabetes diagnosis exclusion applies only at the time of the first core session (that is, if a beneficiary develops diabetes during the MDPP services period, it would not affect the beneficiary's eligibility to continue receiving MDPP services). Specifically, we propose to revise the eligibility requirements for MDPP services to state that a beneficiary has, as of the date of attendance at the first core session, no previous diagnosis of diabetes, other than gestational diabetes (proposed § 410.79(c)(1)(i)(E)). This proposed policy is based in part on the fact that the DPP model test, which demonstrated cost savings, did not exclude from the model individuals who developed diabetes. Additionally, whereas suppliers can check HETS to verify a beneficiary's ESRD status fairly easily, we believe requiring a supplier to reassess other beneficiary eligibility criteria such as diabetes status and blood test results, and subsequently removing those who no longer meet the eligibility criteria is impractical and unduly burdensome.

Alternatively, we considered deeming any beneficiary who develops diabetes during the MDPP services period to be ineligible to continue to receive coverage for MDPP services because these services are intended to be preventive. If a beneficiary progresses to type 2 diabetes, other treatment options, such as Diabetes Self-Management Training (DSMT), may be more appropriate than services that seek to prevent a condition the beneficiary already has. However, it is important to note that the receipt of MDPP services does not preclude a beneficiary from accessing other treatments for diabetes during the time period that the beneficiary is covered for MDPP services. An MDPP beneficiary who ultimately also receives DSMT at some time during the MDPP services period because he or she develops diabetes after beginning the set of MDPP services will receive different types of information and training. For example, a beneficiary receiving DSMT furnished by certified diabetes educators acquires knowledge for self-care and life style

[8] WE Mitch, ''Beneficial responses to modified diets in treating patients with chronic kidney disease,'' *Kidney International Supplements* April, 94 (2005): S133–5, *https://www.ncbi.nlm.nih.gov/pubmed/15752230*. J *Rysz et al.,* ''The Effect of Diet on the Survival of Patients with Chronic Kidney Disease,'' Nutrients 9, no. 5 (2017): E495, *https://www.ncbi.nlm.nih.gov/pubmed/28505087*. ME Chen et al., ''Correlations of dietary energy and protein intakes with renal function impairment in chronic kidney disease patients with or without diabetes,'' *The Kaohsiung Journal of Medical Sciences* 33, no. 5 (2017):252–259, *https://www.ncbi.nlm.nih.gov/pubmed/28433072*.

changes including blood sugar monitoring, insulin usage, medication management, and crisis management. In contrast, MDPP services are furnished by trained coaches who teach patients with prediabetes how to lower their risk of progressing to type 2 diabetes with methods that do not include medication or other interventions for patients diagnosed with diabetes. Despite some common elements, the interventions for the MDPP expanded model and the DSMT benefit target different populations and furnish different services.

We are seeking public comments on our proposal and whether individuals who develop diabetes during the MDPP services period should continue to be eligible for coverage of MDPP services for the full duration of the MDPP services period.

iii. Once-Per-Lifetime Set of Services

In the CY 2017 PFS final rule, we specified that coverage for the set of core MDPP services is available only once per lifetime for each MDPP beneficiary (codified at § 410.79(d)(1)). In this rule, we propose to delete § 410.79(d)(1) and move this provision to proposed § 410.79(c)(1)(i)(B) to place it with other MDPP beneficiary eligibility criteria. We also propose to edit this provision to specify that coverage for the full set of MDPP services, inclusive of ongoing maintenance sessions as opposed to only core MDPP services, is available only once per lifetime per MDPP beneficiary. Now that we propose to limit the ongoing services period to 2 years, we believe that this proposed revision is necessary to clarify that coverage for the entire set of MDPP services is subject to this limitation—otherwise, the once-per-lifetime limitation has no practical effect because an MDPP beneficiary could continue to attend ongoing maintenance sessions long after the MDPP beneficiary has completed the core services period. In addition, for the reasons stated previously, we do not have evidence to support coverage of MDPP services for more than 3 years. We also are clarifying that the once-per-lifetime coverage limit applies to a beneficiary who receives a set of MDPP services under the MDPP model expansion. This limitation would not apply to beneficiaries who participated in a DPP as part of the DPP model test unless they receive the set of MDPP services under the MDPP expanded model. We invite public comments on our proposal.

In the CY 2017 PFS final rule, we stated that beneficiaries could self-report to MDPP suppliers that they had not previously received MDPP services. We recognize that self-reported information may not be the most reliable source for MDPP suppliers to use before submitting claims for MDPP beneficiaries, and there is a risk that information that is inaccurately self-reported could result in the denial of payments for MDPP services. We are considering ways MDPP suppliers would be able to reliably verify if a beneficiary has received coverage of MDPP services from another supplier, such as through a standardized tracker described in section III.K.2.d.v of this proposed rule, and we are seeking public comments on any additional ways MDPP suppliers could access this information. We intend to provide administrative guidance on any resources to assist MDPP suppliers in identifying beneficiaries' previous receipt of covered MDPP sessions, as appropriate.

iv. Eligibility Throughout the MDPP Services Period

In the CY 2017 PFS final rule, we specified the minimum number and frequency of sessions that MDPP suppliers must offer to MDPP beneficiaries (codified at §§ 410.79(c)(2)(i) and 410.79(c)(2)(ii)). We finalized that MDPP suppliers must furnish ongoing maintenance session intervals to MDPP eligible beneficiaries who have maintained 5 percent weight loss from their baseline weight as measured during the previous maintenance session interval. As defined at § 410.79(b), ''baseline weight'' is the MDPP beneficiary's body weight recorded during that beneficiary's first core session.

However, because in this proposed rule we propose to tie payment for MDPP services to the beneficiary's achievement of performance goals, we propose additional changes to tie the beneficiary's eligibility for continued coverage of ongoing maintenance session intervals to his or her achievement of performance goals, namely requiring a minimum level of attendance. Because our proposed policies for payment and coverage differ somewhat, we are addressing them separately below.

(1) MDPP Services Period

As discussed in section III.K.2.b. of this proposed rule, we propose to revise § 410.79(c)(2), which describes MDPP services periods, to specify that the MDPP services period means the time period, beginning on the date an MDPP beneficiary attends his or her first core session, over which the set of MDPP services is furnished to the MDPP beneficiary, to include the core services period described in paragraph § 410.79(c)(2)(i) and, subject to paragraph § 410.79(c)(3), one or more ongoing maintenance session intervals during the ongoing services period described in paragraph § 410.79(c)(2)(ii).

We propose to revise § 410.79(c)(2) to specify that there are two service periods in which Medicare will cover MDPP services for a beneficiary: The core services period; and the ongoing services period. Together these would make up the MDPP services period. The core services period is the first 12 months of the MDPP services period, and consists of core sessions and core maintenance sessions. There are 16 core sessions that are offered at least a week apart in months 1 through 6, beginning on the date of attendance at the first core session. Core maintenance sessions are offered at least once per month in months 7 through 12 of the core services period. We propose to move the requirements for MDPP suppliers to offer these services to § 424.205(d)(9) because they are more appropriately included among other requirements for MDPP suppliers. Consistent with our policies finalized in the CY 2017 PFS final rule, we do not condition coverage for the core services period upon weight loss or attendance. Medicare will pay for the set of core MDPP services, regardless of how many sessions the beneficiary attends and regardless of his or her weight loss. However, we note that an MDPP beneficiary must attend at least one core session to initiate the MDPP services period.

These proposals would align with CDC's 1-year curriculum, divided into two 6-month periods. We recognize that framing the MDPP services period in terms of months may cause some confusion because the CDC terminology uses weeks. However, we believe that framing the MDPP services period in months would better align with our proposed payment structure. We did not make eligibility for the core maintenance sessions contingent upon an attendance-based performance goal; because the CDC DPP curriculum covers 12 months of sessions, we believe that coverage for the 12 months of the core services period should be available to all MDPP beneficiaries, regardless of attendance. The 12-month CDC DPP curriculum is based on evidence from the original DPP randomized clinical trial, and the curriculum used in that trial, which achieved a 58 percent reduction in type 2 diabetes risk (with

71 percent reduction in those over age 60).[9]

As discussed in section III.K.2.e.iv.4 of this proposed rule, MDPP suppliers must offer a minimum of 16 core sessions, no more frequently than once each week, in months 1 through 6, and at least 1 core maintenance session each month in months 7 through 12 of the core services period. However, some MDPP suppliers may choose to furnish more than the minimum number of sessions, and these proposed coverage parameters would allow beneficiaries to receive more than the minimum number of sessions if the MDPP supplier elects to furnish them.

We invite public comments on our proposals.

(2) Ongoing Services Period

As discussed in section III.K.2.b.i. of this proposed rule, we propose to revise § 410.79(c)(2)(ii) to clarify that the ongoing services period consists of up to eight 3-month ongoing maintenance session intervals offered during months 13 through 36 of the MDPP services period. Medicare's coverage of the ongoing services period is subject to limitations proposed subsequently in this section.

(a) Eligibility for the Ongoing Services Period

Our existing regulations at § 410.79(b) affirm that Medicare will cover MDPP services in the first 12 months of the MDPP services period, without regards to a beneficiary's achievement of performance goals, whereas § 410.79(d)(2) specifies that, for coverage of ongoing maintenance sessions, the beneficiary must have achieved weight loss of 5 percent from his or her baseline weight. In this proposed rule, we propose to delete § 410.79(d)(2) and move this provision to § 410.79(c)(1) with other MDPP beneficiary eligibility criteria. We also propose to add paragraph (c)(1)(ii) to § 410.79 to specify that beneficiaries must also attend at least one in-person core maintenance session in months 10 through 12 of the MDPP services period and achieve or maintain required minimum weight loss at a minimum of one in-person session during the final core maintenance session interval to be eligible for coverage of the first ongoing maintenance session interval. We propose to establish that a beneficiary must attend at least one in-person core maintenance session in months 10 through 12 of the MDPP services period because, as stated in the CY 2017 PFS final rule, an MDPP beneficiary must achieve at least 5 percent weight loss from baseline at least once during the previous maintenance session interval to have coverage of an ongoing maintenance session.

Because we propose that weight measurements used for determining beneficiary eligibility for coverage or supplier payment must be taken in person by an MDPP supplier at an MDPP core maintenance or ongoing maintenance session (proposed § 410.79(c)(1)(iv)), a beneficiary must attend at least one in-person core maintenance session during months 10 through 12 to have his or her weight measured to determine whether he or she qualifies for coverage of the first ongoing maintenance session interval. We believe that in-person measurements are the most feasible method for weight ascertainment at this time for services where the beneficiary would have regular in-person sessions with the MDPP supplier. We believe that self-reported weight loss is not reliable for the purposes of determining continued coverage of MDPP services for a beneficiary. We invite public comments on these proposals.

(b) Eligibility for Ongoing Maintenance Session Intervals 2 Through 8

In addition to achieving weight loss performance goals, as previously finalized in the CY 2017 PFS final rule, we propose that beneficiaries must also meet an attendance-related performance goal in order for Medicare to cover ongoing maintenance session intervals. We propose to add paragraph (c)(1)(iii) to § 410.79 to specify that for coverage of ongoing maintenance session intervals 2 through 8, an MDPP beneficiary must attend at least 3 ongoing maintenance sessions during the previous ongoing maintenance session interval, in addition to maintaining 5 percent weight loss from baseline at least once during the previous ongoing maintenance session interval.

We believe that adding an attendance-related performance goal during the ongoing services period is important because it will provide an incentive to keep MDPP beneficiaries engaged after the core services period. MDPP beneficiaries who meet the specified attendance and weight loss goals will have Medicare coverage of ongoing maintenance sessions, which are a part of the set of MDPP services, but not a part of the CDC DPP curriculum. We believe that the subsequent attendance goal requirements during ongoing maintenance session intervals will motivate beneficiaries to take on more individual responsibility for their behavior changes over time because coverage of these services is dependent upon their attendance and achievement and maintenance of weight loss.

In addition, this proposed policy closely aligns with our proposed policy for supplier payment for ongoing maintenance session intervals. As described further in section III.K.2.d.iii.5. of this proposed rule, we propose that a supplier would be paid for furnishing an ongoing maintenance session interval only if the MDPP beneficiary both attended three sessions, as well as maintained a 5 percent weight loss from baseline measured at least once in that interval. However, in light of our proposal to pay MDPP suppliers upon the beneficiary's attendance of three ongoing maintenance sessions (in addition to maintaining at least a 5 percent weight loss), we believe that we similarly need to have attendance goals for beneficiaries to continue to have coverage of ongoing maintenance sessions. Without requiring attendance, an MDPP beneficiary who maintained 5 percent weight loss but only attended two ongoing maintenance sessions in an ongoing maintenance session interval would be eligible for coverage of ongoing maintenance sessions, but the supplier would not receive payment for furnishing that ongoing maintenance session interval. In effect, the MDPP supplier could be required to furnish up to 24 months of MDPP services without payment. For this reason, we propose to require beneficiaries to attend all three sessions within an ongoing maintenance session interval to have coverage of the subsequent interval.

We considered an alternative where a beneficiary would have continued coverage of ongoing maintenance session intervals if he or she attends at least one in-person ongoing maintenance session during an ongoing maintenance session interval, as long as that beneficiary maintained at least 5 percent weight loss from baseline at least once during that interval. However, we do not believe that this alternative would align with our proposed supplier payment requirements for ongoing maintenance sessions discussed in section III.K.2.d.iii.5 of this proposed rule, which would require suppliers to furnish, and the beneficiary to attend, all three sessions of the ongoing maintenance session interval for the supplier to receive payment for that

[9] WC Knowler et al., ''Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin,'' New England Journal of Medicine 346, 6 (2002): 393–403, *https://www.ncbi.nlm.nih.gov/pubmed/11832527*. The Diabetes Prevention Program (DPP) Research Group, ''The Diabetes Prevention Program,'' Diabetes Care 25, 12 (2002): 2165–2171, *http://care.diabetesjournals.org/content/25/12/2165.long*.

interval. We are inviting public comments on our proposal and the alternative we considered.

(c) Limitations on the Set of MDPP Services

In this proposed rule, we propose to add § 410.79(c)(3) to specify that coverage of the MDPP services period would end upon completion of the core services period for a beneficiary that is not eligible for the first ongoing maintenance session interval as proposed under § 410.79(c)(1)(ii); that is, if the beneficiary does not attend at least one in-person core maintenance session during the second core maintenance session interval and/or does not achieve the required minimum weight loss during this interval. For any beneficiary who is eligible for at least one ongoing maintenance sessions interval, but who does not meet the requirements for coverage of a subsequent interval based on failure to meet attendance or weight loss goals proposed at § 410.79(c)(1)(iii), the beneficiary's coverage of the set of MDPP services would end upon completion of his or her current ongoing maintenance session interval. It is important to note that proposed performance payments, discussed in section III.K.2.d.iii.5. of this proposed rule, would be tied to the achievement of the same performance goals a beneficiary must meet to have coverage for the ongoing maintenance session intervals. Therefore, if an MDPP beneficiary does not meet weight loss or attendance goals to access the subsequent ongoing maintenance session interval, the supplier will not receive payment for that ongoing maintenance session interval or any subsequent performance payments related to that beneficiary.

We are inviting public comments on these proposed policies.

(d) Beneficiaries Who Change MDPP Suppliers During the MDPP Services Period

In the CY 2017 PFS final rule, we indicated that a beneficiary may change MDPP suppliers at any time. However, we deferred to future rulemaking specific policies to address coverage of and payment for MDPP services when beneficiaries change MDPP suppliers. In this proposed rule, we are clarifying that a beneficiary may change MDPP suppliers at any time during his or her MDPP services period, subject to beneficiary eligibility requirements. Based on evidence from the CDC DPRP, we believe that the instances of beneficiaries changing MDPP suppliers will be relatively infrequent. However, we intend to monitor how often beneficiaries change MDPP suppliers, as well as MDPP suppliers' billing patterns to detect any aberrant billing patterns suggestive of fraudulent or discriminatory practices. Payment policies related to when a beneficiary changes MDPP suppliers are discussed in section III.K.2.d.v.

(3) Make-Up Sessions

(a) General Requirements

In this proposed rule, we propose at § 410.79(d)(1) that suppliers may offer make-up sessions to an MDPP beneficiary who missed a regularly scheduled session. As defined at proposed § 410.79(b), ''make-up session'' means a core session, core maintenance session, or ongoing maintenance session furnished to an MDPP beneficiary when the MDPP beneficiary misses a regularly scheduled core session, core maintenance session, or ongoing maintenance session. Make-up sessions may be delivered in person or virtually, although virtual make-up sessions are subject to additional requirements proposed in this rule (and the term ''virtual make-up session'' is separately defined). We propose the availability of make-up sessions to be consistent with CDC's DPRP standards and to ensure that MDPP beneficiaries have the opportunity to receive the full DPRP curriculum, even if they are unable to attend a particular regularly scheduled MDPP session.

We propose that the curriculum delivered during a make-up session must address the same CDC-approved DPP curriculum topic as the session that the beneficiary missed (proposed § 410.79(d)(1)(i)). To be consistent with CDC's proposed 2018 DPRP standards, we propose that the MDPP supplier may furnish to the beneficiary a maximum of one make-up session on the same day as a regularly scheduled session (proposed § 410.79(d)(1)(ii)) and the MDPP supplier may furnish to the beneficiary a maximum of one make-up session per week (proposed § 410.79(d)(1)(iii)).

(b) Virtual Make-Up Sessions

There is a growing area of research examining the effectiveness of DPP delivered virtually. CDC began recognizing Virtual DPP organizations in 2015 and emerging evidence suggests that virtual delivery of DPP services can show similarly successful participant weight loss and health benefits to DPP delivered in other settings, including among Medicare-age participants.[10] Since CDC's DPRP standards permit virtual make-up sessions, and we recognize that MDPP beneficiaries may encounter situations where they are unable to attend in-person make-up sessions, we propose to allow MDPP suppliers to offer a limited number of virtual make-up sessions (proposed § 410.79(d)(2)). As proposed in § 410.79(b), ''virtual make-up session'' means a make-up session that is not furnished in person and that is furnished in a manner consistent with the DPRP standards for virtual sessions. All requirements proposed in § 410.79(d)(1) apply to virtual make-up sessions. In addition, we propose that virtual make-up sessions are subject to additional requirements.

First, as indicated by the applicable definition, virtual make-up sessions must be furnished in a manner consistent with CDC's DPRP standards for virtual sessions (proposed § 410.79(d)(2)(i)). To align with CDC's DPRP standards, virtual make-up sessions refer to any modality, or method of furnishing MDPP services, that is not in person. This includes, but is not limited to:

(1) Furnishing services online where the behavior change program is furnished 100 percent online, with participants accessing course resources and a coach via a computer, laptop, tablet, smart phone, or other device with Internet access. This modality requires that the MDPP beneficiary have an Internet connection to participate in all aspects of the virtual make-up session;

(2) Furnishing services online with other means of support by a coach (for example, telecommunications, video conferencing). This modality requires that the MDPP beneficiary have an Internet connection for some aspects of the virtual make-up session, but not all; and

(3) Distance learning, where a coach is present in one location and participants are calling, video-conferencing, or otherwise using telecommunications technology to access the coach from another location.

[10] See, for example: F Chen et al., ''Clinical and Economic Impact of a Digital, Remotely-Delivered Intensive Behavioral Counseling Program on Medicare Beneficiaries at Risk for Diabetes and Cardiovascular Disease.'' PLoS ONE 11, 10 (2016), *https://doi.org/10.1371/journal.pone.0163627.* W Su et al., ''Return on Investment for Digital Behavioral Counseling in Patients With Prediabetes and Cardiovascular Disease.'' Preventing Chronic Disease 13 (2016), *http://dx.doi.org/10.5888/pcd13.150357.* J Ma et al., ''Translating the Diabetes Prevention Program lifestyle intervention for weight loss into primary care: A randomized trial.'' JAMA Intern Med. 173, 2 (2013): 113–21, *https://www.ncbi.nlm.nih.gov/pubmed/23229846.* CS Sepah et al., ''Translating the diabetes prevention program into an online social network: Validation against CDC standards.'' The Diabetes Educator 40, 4 (2014): 435–443, *https://www.ncbi.nlm.nih.gov/pubmed/24723130.*

This modality does not require that the MDPP beneficiary have an Internet connection for any of the aspects of the virtual make-up session.

By defining MDPP virtual make-up sessions as being consistent with CDC's DPRP standards for virtual sessions, we allow our definition to change over time as such standards are updated.

Second, a supplier may only offer virtual make-up sessions based on an individual MDPP beneficiary's request (proposed § 410.79(d)(2)(ii)). A supplier may not cancel a regularly scheduled MDPP session and offer the session to all MDPP beneficiaries virtually. However, the supplier may cancel a regularly scheduled MDPP session and offer the session to all MDPP beneficiaries in person. We believe that this is necessary to ensure that the MDPP expanded model remains a model predominantly delivered in person. Individual beneficiary needs may be accommodated, but suppliers should not use virtual make-up sessions as a means to move toward virtually-delivered MDPP sessions more generally.

Third, to further ensure that MDPP services are largely provided in-person, we propose at § 410.79(d)(2)(iii) that a supplier may offer: (a) No more than 4 virtual make-up sessions within the core services period to an MDPP beneficiary, of which no more than 2 virtual make-up sessions may be core maintenance sessions; and (b) no more than 3 virtual make-up sessions that are ongoing maintenance sessions to an MDPP beneficiary during any rolling 12-month time period. At § 410.79(d)(3), we propose that these same limitations on the number of virtual make-up sessions also apply for the purposes of determining whether a beneficiary has attended a sufficient number of MDPP sessions in order to be eligible for ongoing maintenance sessions (proposed § 410.79(c)(1)) and for assessing whether a beneficiary has met the attendance-related performance goals used to determine whether an MDPP supplier is eligible to receive a performance payment (proposed § 414.84(b)). The limitation on the number of make-up sessions is not applicable to in-person make-up sessions.

We assume not all suppliers will have the ability to offer virtual make-up sessions, and we are not requiring suppliers to offer virtual make-up sessions. Conversely, an MDPP supplier could offer only virtual make-up sessions and no in-person make up sessions if the supplier chooses as long as the proposed limits for these sessions are not exceeded. We believe that allowing fewer than these proposed number of virtual make-up sessions will make it difficult for suppliers to meet DPRP standards, and therefore remain enrolled as an eligible MDPP supplier. However, the DPP model test only offered in-person sessions (no virtual sessions) and therefore the MDPP expanded model is intended to predominantly offer services in person. Allowing more than the proposed number of virtual make-up sessions would not support an evaluation of an in-person MDPP curriculum. We seek comment on our proposals and specifically on the proposed limitations on virtual make-up sessions.

We considered the following alternatives to this proposal. We considered not allowing any make-up sessions to be furnished virtually. However, we believe that this would place undue restrictions on MDPP suppliers who are willing and would like to offer virtual make-up sessions to MDPP beneficiaries, particularly if these are offered to other DPP participants who are not Medicare beneficiaries.

We also considered allowing an MDPP supplier to furnish between one and three sessions within the core services period and either one or two ongoing maintenance sessions each year as virtual make-up sessions per MDPP beneficiary. However, we believe that allowing fewer sessions to be furnished as virtual make-up sessions than proposed would not provide sufficient flexibility for MDPP suppliers to meet CDC's DPRP standards, which require organizations to meet attendance requirements for their panel of participants. Organizations may struggle to meet DPRP attendance requirements without the flexibility to provide virtual make-up sessions.

We also considered permitting suppliers to offer any number of virtual make-up sessions, and for attendance at any number of virtual make-up sessions to count toward attendance goals. However, as stated previously, since the DPP model test only offered DPP services in person, the MDPP expanded model is intended to predominantly offer MDPP sessions in person as well. Therefore we believe that it is important to limit the number of virtual make-up sessions so that MDPP beneficiaries are predominantly receiving MDPP sessions in person.

We propose that the payment policies detailed in section III.K.2.d. of this proposed rule apply to virtual make-up sessions. Specifically, as indicated in sections III.K.2.c.1.iv. and III.K.2.d.iii.10.b. of this proposed rule, weight measurements used for the purposes of determining the achievement or maintenance of weight loss for weight loss performance payments, or for determining eligibility for coverage of ongoing maintenance sessions, would be required to be taken at an in-person session, not during a virtual make-up session. We are seeking public comments on these proposals and the alternatives considered.

d. Payment for MDPP Services

i. MDPP Payment Discussion in Prior Rulemaking

In the July 15, 2016 MDPP proposed rule (81 FR 46415 through 46416), we discussed a potential MDPP payment structure and the associated payment amounts and sought information from the public to inform future MDPP proposals. We received a number of public comments on these topics and have considered this information in the development of our proposals for the MDPP payment structure, payment amounts, and related issues discussed in this section.

ii. Conceptual Framework for Payment for MDPP Services

In this proposed rule, we are proposing to pay for the set of MDPP services through a performance-based payment methodology that makes periodic performance payments to MDPP suppliers during the MDPP services period. The aggregate of all performance payments constitutes the total performance-based payment amount for the set of MDPP services. As discussed in detail throughout this section, we are proposing a maximum total performance payment amount per beneficiary for the set of MDPP services of $810. Performance payments would be made to MDPP suppliers periodically during the course of a beneficiary's MDPP services period based upon a number of factors, including the beneficiary's completion of a specified number of MDPP sessions and the achievement of the required minimum weight loss that is associated with a reduced incidence of type 2 diabetes, rather than individual payments being made upon the furnishing of any service as is typical of payment in the traditional Medicare program.

The aggregate amount of the performance payments proposed in this section would equal the total performance-based payment amount for the set of MDPP services during the MDPP services period, including core sessions, core maintenance sessions, and ongoing maintenance sessions. Even though these performance payments would be made periodically and in amounts that would not be

evenly distributed across the course of sessions furnished during the MDPP services period, payment for each session would be included in the total performance-based payment amount. For example, the proposed performance payment of $25 that would be paid to MDPP suppliers upon furnishing the first MDPP core session is relatively large on a per-session basis compared to other attendance-based performance payments (as calculated on a per-session basis) ranging from approximately $3 to $20 made during the MDPP services period. However, the performance payment for the first core session would make payment for some of the MDPP supplier resources used in furnishing the first session, as well as make a partial prospective payment attributable to the MDPP supplier furnishing subsequent sessions.

Once the required minimum weight loss is achieved and the 12-month core services period, described at proposed § 410.79(c)(2)(i), concludes, we would make additional 3-month interval performance payments for ongoing maintenance sessions when the required minimum weight loss is maintained, whereas no additional interval performance payments would be made for ongoing maintenance sessions if the required minimum weight loss is not maintained. Finally, when a beneficiary achieves a significant percentage of weight loss, specifically a level of 5 percent (the required minimum weight loss) or 9 percent, we are proposing to make additional performance payments to the MDPP supplier. This proposal would provide performance payments in addition to the performance payments we may have already made for the previous MDPP sessions furnished to the beneficiary because those sessions resulted in the beneficiary achieving the weight loss performance goal.

In total, based on our consultation with DPP providers holding commercial contracts, review of information related to DPP providers that currently hold or are in the process of obtaining CDC recognition, and comments received on the discussion of the payment structure and payment amounts for the set of MDPP services included in the July 15, 2016 MDPP proposed rule (81 FR 46415 through 46416), we believe the proposed performance-based payment methodology would pay MDPP suppliers appropriately for the resources used in furnishing MDPP services throughout the MDPP services period. We note that we sought public comment on the payment structure and payment amounts for the set of MDPP services in the July 15, 2016 MDPP proposed rule, and we have used the information provided by commenters in developing the proposed performance-based payments included in this proposed rule.

In this performance-based payment structure, it is important to note that a beneficiary's performance goals are not considered in the same way for beneficiary coverage and supplier payment during each specific period within the MDPP services period. During the core services period, a beneficiary would not be required to achieve attendance and/or weight loss performance goals for coverage of MDPP services, although a beneficiary would be required to achieve specified performance goals for an MDPP supplier to receive performance payments during this period. In contrast, achieving performance goals would be required for both coverage of MDPP services and performance payments during the ongoing services period.

For example, a supplier is required to offer a minimum of 16 core sessions during the core services period according to § 410.79(c)(2)(i) but a beneficiary would not need to achieve an attendance or weight loss performance goal to be eligible for coverage of core maintenance sessions. However, MDPP supplier performance payments during the core services period would be based on the beneficiary's achievement of attendance and/or weight loss performance goals. During the ongoing services period, achievement of performance goals would affect both coverage and supplier payment. We note that a beneficiary would need to attend at least 1 core session to initiate the core services period, and attend at least 1 core maintenance session during the final core maintenance session interval to determine whether he or she has achieved the required minimum weight loss to have coverage of ongoing maintenance sessions. Because we are proposing in section III.K.2.d.iii.4 of this proposed rule to make a performance payment for core maintenance sessions only when the beneficiary attends at least 3 sessions within a 3-month interval, it is possible that an MDPP supplier would not be paid a separate performance payment for the second core maintenance session interval, but the beneficiary would still have coverage of the first ongoing maintenance session interval. This would occur if the beneficiary attended only 1 or 2 core maintenance sessions during the second core maintenance session interval and achieved or maintained the required minimum weight loss as measured at 1 of those 2 sessions.

iii. Performance Payments for MDPP Services

(1) Overview of Public Comments on Discussion of Payment for MDPP Services in Prior Rulemaking

In addition to requests for clarification on certain details of the payment structure, such as the timing of beneficiary achievement of weight loss, which are addressed subsequently in this section, commenters on the discussion of payment for MDPP services in the July 15, 2016 MDPP proposed rule (81 FR 46415 through 46416) expressed a variety of perspectives on the performance-based payment methodology presented in that proposed rule. In general, commenters urged us to set payment amounts that are sufficient to ensure MDPP supplier participation.

Several commenters recommended that a sustainable payment rate structure should mirror performance-based payment models in the existing employer marketplace. A number of commenters requested that we not tie Medicare payment to weight loss or that we make separate weight loss and attendance payments; that we tie payment to aggregate, rather than individual, beneficiary weight loss; or that we tie payment to other factors besides or in addition to weight loss. Other commenters urged us to provide payment based on sessions furnished by MDPP suppliers rather than basing payment on an individual beneficiary's success, arguing that the payment structure presented would not be a sustainable model for MDPP suppliers that would expend resources furnishing sessions but would have little influence over beneficiaries' achievement of attendance and/or weight loss performance goals.

Several commenters requested that we provide information on how the payment rates included in the discussion were determined. Some commenters expressed concern that the magnitude of MDPP payments was not consistent with payments for other similar services.

A number of commenters urged that higher payments be made at the beginning of the MDPP services period to cover program start-up costs, that we decrease supplier financial risk by providing sufficient payment for beneficiaries who do not achieve weight loss performance goals, and that we implement risk-stratification of payments to reduce the risk of MDPP suppliers preferentially seeking to

furnish MDPP services to low-risk beneficiaries most likely to achieve weight loss and avoiding high-risk beneficiaries. In addition, several commenters requested that we update the payment rates annually for inflation and the increasing costs experienced by MDPP suppliers.

As discussed in this section, the proposed MDPP payment structure is generally similar to that which was discussed in the July 15, 2016 MDPP proposed rule (81 FR 46415 through 46416). However, the proposed performance payment amounts for core sessions, core maintenance session 3-month intervals, and ongoing maintenance session 3-month intervals differ somewhat based on our consideration of the comments received in response to the July 15, 2016 MDPP proposed rule in the context of our policy goal to prioritize the achievement and maintenance of the required minimum weight loss that is associated with a reduction in the incidence of type 2 diabetes. In this proposed rule, we are proposing a payment structure for MDPP services that is performance-based in relation to two meaningful performance goals.

First, the proposed payment structure values beneficiary weight loss most significantly. Weight loss is a key indicator of success among individuals enrolled in a DPP due to the strong association between weight loss and reduction in the risk of type 2 diabetes.[11] Second, the proposed payment structure values beneficiary attendance because, in the DPP model test, session attendance was associated with greater weight loss. According to the second year independent evaluation of the DPP model test, those beneficiaries who attended at least 1 core session lost an average of 7.6 pounds, while beneficiaries who attended at least 4 core sessions lost an average of 9 pounds. Body mass index was reduced from 32.9 to 31.5 among Medicare beneficiaries who attended at least 4 core sessions.[12]

In addition to weight loss, we considered linking other criteria such as hemoglobin A1c level to MDPP performance payments, or using aggregate instead of individual weight loss for MDPP payments. However, the MDPP expanded model was determined to meet the statutory requirements for expansion based on the DPP model test, which demonstrated that weight loss was associated with reductions in Medicare expenditures. Although elevated hemoglobin A1c levels were included as part of the beneficiary eligibility criteria in the DPP model test, hemoglobin A1c levels were not evaluated post-intervention in that model. Therefore, we are not proposing to use hemoglobin A1c blood values in the performance-based payment methodology for MDPP services. The use of hemoglobin A1c blood values in the MDPP payment methodology would have incorporated changes in values for which there was no evidence that could be used to support the determination that the MDPP expanded model meets the statutory requirements for expansion. We further note that the CDC does not require post-MDPP services hemoglobin A1c blood values to be determined as part of its 2015 DPRP standards, and we aim to align with the CDC DPRP standards as much as possible. While 5 percent weight loss is considered a performance measure for DPRP recognition, the CDC does not examine pre-post DPP differences in hemoglobin A1c as part of its DPRP standards.

The proposed MDPP payment structure incentivizes MDPP suppliers to prioritize the achievement and maintenance of beneficiary weight loss by furnishing MDPP services, and provides a balance between performance-based payments related to weight loss and session attendance. We do not believe that it would be appropriate for payment to be tied to attendance alone because weight loss is more directly associated with a reduction in the incidence of type 2 diabetes than attendance at MDPP sessions. We further believe that the proposed performance-based payment structure based on individual beneficiary success, rather than average weight loss across all MDPP beneficiaries who receive MDPP services from an MDPP supplier, maximizes the focus of MDPP suppliers on the achievement of the performance goals for all beneficiaries, including those beneficiaries who experience challenges with achieving attendance and/or weight loss performance goals. Therefore, we do not believe it would be appropriate to use aggregate beneficiary information (that is, average weight loss) in the proposed performance-based payment methodology.

(2) Overall Approach To Setting Performance Payment Amounts

We are proposing to establish the rules governing payment for MDPP services at new § 414.84. We note that as discussed in section III.K.2.a. of this proposed rule, we are proposing that MDPP services may be furnished and payment made under the MDPP expanded model starting April 1, 2018. Therefore, we are proposing that the effective date of § 414.84 would be April 1, 2018. Only MDPP services furnished on or after April 1, 2018, would be eligible for payment when all requirements for billing for performance payments for those services are met.

At proposed § 414.84(a)(1), we are proposing to define ''performance goal'' as an attendance or weight loss goal that an MDPP beneficiary must achieve for an MDPP supplier to be paid a performance payment. We are proposing to define ''performance payment'' as a payment to an MDPP supplier for furnishing certain MDPP services when an MDPP beneficiary achieves the applicable performance goal. These definitions are used in our proposals for payment of MDPP services.

To align with the once-per-lifetime policy, we are proposing at § 414.84(b) that each performance payment made based on attendance of a specified number of core sessions, for a specific 3-month core maintenance or ongoing maintenance interval during the MDPP services period, or for achieving a weight loss performance goal, is made only once per MDPP beneficiary.

(a) Total Amount and Distribution of Performance Payments Across the Set of MDPP Services

As displayed in Table 27, we are proposing a maximum total performance payment amount per beneficiary for the set of MDPP services of $810. This amount is the aggregate of the maximum performance payments for core sessions, core maintenance sessions, and ongoing maintenance sessions furnished to MDPP beneficiaries who achieve weight loss of at least 9 percent over the 36 months of the MDPP services period. This performance payment amount would be made for a minimum of 46 MDPP sessions required to be offered to the beneficiary in the set of MDPP services. Although CMS would make performance payments to MDPP suppliers at intervals throughout the MDPP services period in varying amounts, payment for each session furnished would be included in the total

[11] RF Hamman et al., ''Effects of Weight Loss with Lifestyle Intervention on Risk of Diabetes,'' *Diabetes Care* 29, no. 9 (2006): 2102–2107.

[12] Hinnant L, Razi S, Lewis R, Sun A, Alva M, Hoerger T, Jacobs S, Halpern M. Evaluation of the Health Care Innovation Awards: Community Resource Planning, Prevention, and Monitoring, Annual Report 2015. Awardee-Level Findings: YMCA of the USA; 2016. Table 17. Average/Frequencies Health Outcomes of all Participants through Q11, p. 36. RTI Project Number 0212790.010.001.004, Contract HHSM–500–2010–00021I. Sponsored by the Centers for Medicare & Medicaid Services.

performance payment amount a supplier was paid for the set of MDPP services.

While we are not proposing that payment for MDPP services utilize a fee-for-service payment methodology, we note that, estimated on a per-session basis, the maximum MDPP payment amount for achievement of all the performance goals would equate to approximately $18 per session. For comparison, Medicare pays under the PFS approximately $10 (excluding physician work and malpractice) for CPT code 98962 (Education and training for patient self-management by a qualified, nonphysician health care professional using a standardized curriculum, face-to-face with the patient (could include caregiver/family) each 30 minutes; 5–8 patients), a service that may bear some resemblance to an MDPP session furnished by an MDPP supplier, although an MDPP session would be furnished by a coach (not necessarily a health care professional), has a duration of 1 hour, and has no explicit limitation on group size.

However, this estimated per-session MDPP payment amount would result only from the furnishing of MDPP services to those beneficiaries who achieve the highest attendance and weight loss performance goals under the proposed performance-based payment methodology for MDPP services. For beneficiaries who do not achieve the highest performance goals, the estimated per-session MDPP payment amount would generally be significantly lower, with the amount based upon the actual attendance and weight loss performance of the beneficiary. The differences between the estimated MDPP per-session payment amounts and between the MDPP and PFS payment amounts result from the proposed performance-based methodology for MDPP services. We note that under the PFS payments are based on suppliers' relative resources used to furnish services. On the other hand, we believe that that the estimated per-session MDPP payment amounts under our proposal for beneficiaries who achieve specified attendance and weight loss performance goals are appropriate in the context of a performance-based payment methodology for the set of MDPP services that differs from the methodology used under the PFS.

Finally, we note that there are also some administrative costs that MDPP suppliers would bear to enroll in Medicare and ensure compliance with the requirements for furnishing MDPP services. The total MDPP performance payment across all Medicare beneficiaries would provide some payment for the resources that would be used by MDPP suppliers to meet the administrative requirements for furnishing MDPP services.

In terms of the proposed distribution of the maximum total performance payment amount for MDPP services across the types of performance payments, as discussed in detail in sections III.K.2.d.iii.(3) and (4) of this proposed rule and displayed in Table 27, we are proposing that, for those beneficiaries achieving the highest core services period performance goals, approximately 13 percent of the maximum of $810 would be paid for attendance at core sessions during the initial 6 months of the core services period, while approximately 15 percent would be paid for core maintenance sessions during months 7 to 12 of the core services period. We believe that payment of a similar percentage of the maximum total performance payment amount during the initial 6 months of the core services period for beneficiaries who meet attendance performance goals and during months 7 to 12 for beneficiaries who meet both weight loss and attendance performance goals is appropriate to balance performance payment for attendance and weight loss throughout the core services period.

In addition, as discussed in detail in section III.K.2.d.iii.(5) of this proposed rule, we are proposing that approximately 49 percent of the maximum of $810 would be paid for ongoing maintenance sessions over a 24-month period, or 24.5 percent per each 12-month period, for those beneficiaries who maintain the required minimum weight loss. The focus of ongoing maintenance sessions is on maintenance of weight loss that has already been achieved, and there would typically be an established relationship between the MDPP supplier and the MDPP beneficiary during the ongoing services period. Therefore, the totality of MDPP sessions furnished during this 24-month period would result in a slightly lower performance payment per 12-month period than the totality of those sessions furnished when the required minimum weight loss is achieved during the 12 months of the core services period, when 28 percent of the maximum total performance payment amount would be paid.

Finally, due to the importance of weight loss as a meaningful outcome of MDPP services because of its association with a reduction in the incidence of type 2 diabetes, as discussed in detail in section III.K.2.d.iii.(6) of this proposed rule, we are proposing that 23 percent of the maximum total performance payment amount would be paid for weight loss performance payments to provide additional payments for MDPP sessions that are effective (that is, lead to specified percentages of weight loss). We note that, in the DPP model test, 44.7 percent of participants achieved 5 percent weight loss, which under our proposal would result in a weight loss performance payment of approximately 20 percent of the maximum total performance payment amount.[13] Moreover, according to estimates from CDC's DPRP, approximately 12 percent of program participants attending at least 2 sessions achieved 9 percent or greater weight loss.[14]

Table 27 summarizes the proposed maximum total amount and distribution of performance payments for the set of MDPP services.

TABLE 27—PROPOSED MAXIMUM TOTAL AMOUNT AND DISTRIBUTION OF PERFORMANCE PAYMENTS FOR THE SET OF MDPP SERVICES

Type of performance payment	Maximum performance payment for achieving attendance and/or weight-loss performance goals ($)	Percentage of maximum total performance payment
Core sessions	105	13
Core maintenance session intervals	120	15
Ongoing maintenance session intervals	400	49

[13] National Council of Young Men's Christian Associations, Measurement and Monitoring Report. CMS Health Care Innovation Awards, Round One, Sixteenth Quarterly Reporting Period (16QR), April, May, and June 2016.

[14] CDC's Diabetes Prevention Recognition Program dataset as of March 1, 2017.

TABLE 27—PROPOSED MAXIMUM TOTAL AMOUNT AND DISTRIBUTION OF PERFORMANCE PAYMENTS FOR THE SET OF MDPP SERVICES—Continued

Type of performance payment	Maximum performance payment for achieving attendance and/or weight-loss performance goals ($)	Percentage of maximum total performance payment
Weight loss	185	23
Total performance payment	810	100

We are inviting public comments on our proposals for the maximum total performance payment amount and the distribution of performance payments for MDPP services across the set of MDPP services.

(b) Payment Considerations Related to Coverage of MDPP Services for Beneficiaries With Social Risk Factors

We understand that social risk factors such as income, education, race and ethnicity, employment, disability, community resources, and social support play a major role in health. The Office of the Assistant Secretary for Planning and Evaluation (ASPE) and the National Academies of Sciences, Engineering, and Medicine recently released reports on the issue of accounting for social risk factors in CMS programs.[15] [16] We have previously sought public comment on accounting for social risk factors in CMS programs, primarily on the topics of quality measurement and reporting, such as in the Request for Information Regarding Implementation of the Merit-Based Incentive Payment System, Promotion of Alternative Payment Models, and Incentive Payments for Participation in Eligible Alternative Payment Models published in the October 1, 2015 **Federal Register** (80 FR 59105, 59109, 59110, and 59113).

In the CY 2017 PFS final rule (81 FR 80466), we acknowledged commenters' concerns regarding the potential unintended consequences if the MDPP expanded model were to result in low-income or other disadvantaged populations having less access to ongoing maintenance sessions due to their failure to achieve or maintain the weight loss performance goal required for coverage of these sessions. In addition, through listening sessions, stakeholders have provided us with anecdotal information suggesting that racial and ethnic minorities and low socioeconomic status populations lose about 1 percent less weight, on average, than higher socioeconomic groups and non-Hispanic whites.

We are proposing an MDPP payment structure for the set of MDPP services that is similar to the structure presented in the July 15, 2016 MDPP proposed rule (81 FR 46416), where performance payments are tied to attendance at MDPP sessions and/or weight loss. Based on information provided to us by stakeholders, we acknowledge that tying performance payment to a specific threshold of weight loss and/or attendance may make achieving the performance goals required for the highest performance payments and beneficiary eligibility for coverage of ongoing maintenance sessions more challenging for MDPP suppliers furnishing services to individuals with social risk factors. We note that our proposal for beneficiary engagement incentives as discussed in section III.K.2.f. of this proposed rule would provide MDPP suppliers with the flexibility under certain conditions to furnish in-kind patient engagement incentives, such as transportation, to support beneficiaries in achieving the MDPP expanded model performance goals, including session attendance and weight loss. We expect these beneficiary engagement incentives may be helpful to MDPP suppliers furnishing services to beneficiaries, including those with social risk factors that could increase their risk of not achieving the MDPP performance goals.

We are not proposing to risk-adjust MDPP payments for social risk factors or to adopt additional special payment policies to specifically encourage MDPP suppliers to furnish sessions to beneficiaries with social risk factors because, for the MDPP expanded model, we do not believe that such approaches are necessary to ensure access to MDPP services for all beneficiaries. This is because we believe that the proposed performance goals upon which the performance payments for the set of MDPP services would be based, as well as the payment policies that recognize that weight loss is a gradual process that may occur slowly over the 12 months of the core services period, should allow MDPP suppliers sufficient time to work with all eligible beneficiaries, including beneficiaries with social risk factors, toward achieving the attendance and weight loss performance goals of the MDPP expanded model. However, we may consider proposing additional payment policies for the MDPP expanded model in the future.

We are requesting comments about social risk factors in the context of the set of MDPP services that could inform any future considerations of additional payment policies for the MDPP expanded model. We also are inviting public comments on other types of strategies that we could utilize throughout the testing of the MDPP expanded model to assist MDPP suppliers in providing robust access to MDPP services for beneficiaries with social risk factors, such as learning activities to share best practices among MDPP suppliers in providing the set of MDPP services.

(3) Performance Payments for Core Sessions

The payment structure presented in the July 15, 2016 MDPP proposed rule (81 FR 46415 through 46416) would have made attendance-based payments of $25 for the first core session, $50 for 4 total core sessions, and $100 for 9 total core sessions. Based on our consideration of information provided in the public comments on that proposed rule and our increased emphasis in the performance payments on the achievement and maintenance of the required minimum weight loss as the outcome of MDPP services, our proposal for the attendance-based performance payments for 4 and 9 core sessions differs from these payment amounts.

We are proposing that an MDPP supplier would be paid a $25 performance payment the first time it furnishes an MDPP session to an MDPP beneficiary as displayed in Table 28. This performance payment would be

[15] Available at *https://aspe.hhs.gov/sites/default/files/pdf/253971/ASPESESRTCfull.pdf.*

[16] Available at *http://nationalacademies.org/hmd/Reports.aspx?filters=inmeta:activity=Committee+on+Accounting+for+SES+in+Medicare+Payment+Programs.*

available once per beneficiary for the beneficiary's first core session.

We are proposing that an MDPP supplier would be paid the performance payment upon furnishing the first core session to a beneficiary who initiates the MDPP services period, regardless of whether the MDPP supplier qualifies for any of the additional performance payments for that beneficiary. As we are proposing in the sections that follow, additional performance payments would depend upon the beneficiary's achievement of the performance goals for attendance and/or weight loss. We believe that making the first performance payment based on beneficiary attendance at the first core session is appropriate because the MDPP supplier would use significant resources to furnish the first session, including collecting administrative information on the beneficiary who is not already known to the supplier, regardless of whether the beneficiary goes on to receive further MDPP services from that supplier.

On a per-session basis, the performance payment for the first MDPP core session would be the highest performance payment amount for any core session during the core services period. Of note, the first core session performance payment also provides some payment for MDPP supplier activities to encourage the beneficiary's attendance at additional core sessions following the first session. Such supplier activities could include sending electronic messages or making reminder phone calls about upcoming sessions or providing transportation to the next session under the beneficiary engagement incentives policy proposed in section III.K.2.f. of this proposed rule. It is only through attendance at the first core session with an MDPP supplier that a beneficiary initiates the MDPP services period and has the potential to achieve weight loss through receiving MDPP services.

Further, we are proposing that suppliers would be paid a performance payment for the interval (which we are referring to in this proposed rule as an ''interval performance payment'' to distinguish it from other performance payments, such as the performance payment upon an MDPP beneficiary's achievement of the required minimum weight loss, that do not require attendance at multiple sessions) upon a beneficiary's attendance at 4 total core sessions, and again upon a beneficiary's attendance at 9 total core sessions—that is, attendance of 5 more core sessions after having attended his or her first 4. We are proposing an interval performance payment of $30 upon a beneficiary attending 4 core sessions and an interval performance payment of $50 upon a beneficiary attending 9 core sessions as displayed in Table 28. Although an MDPP supplier must offer at least 16 core sessions to a beneficiary during the initial 6 month of the MDPP core services period, we are not proposing any other interval performance payment for the core sessions after the performance payment for attendance at 9 core sessions. We note that while these proposed payment amounts are somewhat lower than the payment amounts for these milestones presented in the July 15, 2016 MDPP proposed rule (81 FR 46415 through 46416), they follow a similar pattern of a higher payment amount associated with attendance at a larger cumulative number of core sessions to provide a significant financial incentive for MDPP suppliers to encourage MDPP beneficiary attendance at core sessions in the first 6 months of the core services period.

On a per-session basis, the payments for attendance at 4 total core sessions and 9 total core sessions would be approximately $10 and $4 to $10, respectively, depending upon the number of sessions attended by the beneficiary beyond the 9 required for the second interval performance payment up to the maximum of 16 core sessions that must be offered to the beneficiary by the MDPP supplier during the initial 6 months of the MDPP core services period. Because the performance payments for core sessions would be based solely on the achievement of attendance performance goals, we believe these per-session performance payment amounts that are lower than the proposed performance payment amount for the first core session are still appropriate because we expect that fewer MDPP supplier resources would be used to furnish sessions to beneficiaries with whom the MDPP supplier has an established relationship. The per-session payment amounts for core sessions are set based on attendance at these sessions, which is associated with ultimate achievement of the required minimum weight loss.

We are proposing to make the first interval performance payment for core sessions when the beneficiary has attended 4 core sessions for the following reasons. First, beneficiary attendance at 4 core sessions was a significant attendance milestone in the evaluation of the DPP model test, which provided evidence that meeting this milestone is tied to weight loss outcomes.[17] According to the second year independent evaluation of the DPP model test, those beneficiaries who attended at least 1 core session lost an average of 7.6 pounds while beneficiaries who attended at least 4 core sessions lost an average of 9 pounds. BMI was reduced from 32.9 to 31.5 among Medicare beneficiaries who attended at least 4 core sessions. Second, in examining CDC's DPRP participant trend data, we found that a higher percentage of participants drop out after 3 core sessions as compared to those who drop out after 4 core sessions, meaning that if a beneficiary completes the 4th core session, he or she is more likely to remain in the DPP for the 12-month program.[18] Therefore, we believe making the first interval performance payment after beneficiary attendance at 4 core sessions would be appropriate.

We are proposing to make the second interval performance payment when the beneficiary has attended 9 core sessions because attending a higher amount of sessions in the initial 6 months of the MDPP core services period, beginning at session 9, has been shown to greatly improve weight loss outcomes. Specifically, according to CDC data, there is a 125 percent increase in weight loss comparing beneficiaries who attend 4 to 8 sessions (1.6 percent weight loss on average) and beneficiaries who attend 9 to 16 sessions (3.6 percent weight loss on average).[19] Therefore, we believe that attendance at 9 sessions reflects clinically meaningful attendance at core sessions and would provide an incentive to MDPP suppliers to encourage beneficiaries to continue into the second 6 months of the MDPP core services period, which is when the 5 percent weight loss from baseline is usually achieved or exceeded. Additionally, 9 is the number of core sessions, on average, that a participant must attend in CDC's National DPP in the first 6 months for a CDC-recognized organization to achieve full CDC recognition.

MDPP suppliers would be paid these performance payments when beneficiaries achieve these core session

[17] Hinnant L, Razi S, Lewis R, Sun A, Alva M, Hoerger T, Jacobs S, Halpern M. Evaluation of the Health Care Innovation Awards: Community Resource Planning, Prevention, and Monitoring, Annual Report 2015. Awardee-Level Findings: YMCA of the USA; 2016. Table 17. Average/Frequencies Health Outcomes of all Participants through Q11, p. 36. RTI Project Number 0212790.010.001.004, Contract HHSM–500–2010–00021I. Sponsored by the Centers for Medicare & Medicaid Services.

[18] CDC's Diabetes Prevention Recognition Program dataset as of March 1, 2017.

[19] CDC's Diabetes Prevention Recognition Program dataset as of February 28, 2017.

attendance performance goals, regardless of weight loss. Although we are proposing to base performance payments during the MDPP services period substantially on weight loss, which is directly associated with a significant decrease in the incidence of type 2 diabetes, we recognize that weight loss is a gradual process and that MDPP suppliers utilize resources to furnish MDPP services during the period of time when the beneficiary is losing weight. Therefore, we are proposing that performance payments for beneficiary attendance at core sessions during the first 6 months of the core services period be based on attendance only. The maximum total performance payment to MDPP suppliers for furnishing MDPP core sessions would be $105 per beneficiary, as displayed in Table 28.

TABLE 28—PROPOSED ATTENDANCE-BASED PERFORMANCE PAYMENTS FOR MDPP CORE SESSIONS

Performance goal	Attendance-based performance payment per beneficiary ($)
1st core session attended (performance payment)	25
4 total core sessions attended (interval performance payment)	30
9 total core sessions attended (interval performance payment)	50
Maximum total performance payment for core sessions	105

We considered alternatives to this proposed payment structure for core sessions, such as making higher payments for attendance at the earlier sessions to provide MDPP suppliers with additional funds for the resources necessary for start-up of the MDPP expanded model. Although we understand that there are some up-front supplier costs associated with implementing the MDPP expanded model, we believe these costs would disproportionately be related to start-up and not generally be ongoing costs borne by the MDPP supplier. In addition, because we expect that many MDPP suppliers are currently offering DPPs through contracts with commercial payers, MDPP suppliers may be able to minimize start-up costs by relying on their relevant experience with offering other DPPs. Finally, we believe that our proposal for payment of MDPP core sessions already includes substantial payment for session attendance early in a beneficiary's participation with the MDPP supplier, considering that MDPP suppliers would be paid an initial $25 performance payment for the first core session attended by the beneficiary and would then be paid performance payments for beneficiary attendance of up to 9 core sessions, regardless of weight loss. We believe that increasing the initial payments for attendance at MDPP sessions would shift the nature of the payment for the set of MDPP services from a performance-based structure based on a balance of attendance and weight loss considerations toward a payment structure that is based on attendance at each session furnished.

The proposed attendance-based performance payments for MDPP core sessions are included at proposed § 414.84(b)(1), (2), and (3). We are inviting public comments on these proposals. We also are inviting public comments on the alternative considered.

(4) Performance Payments for Core Maintenance Session Intervals

We are proposing that performance payments for core maintenance sessions would be tied to the beneficiary's achievement of attendance and weight loss performance goals during a core maintenance session interval. A core maintenance session interval, as we are proposing to define it at § 410.79(b), means one of the two consecutive 3-month time periods during months 7 through 12 of the MDPP services period, during which an MDPP supplier offers at least one core maintenance session per month to an MDPP beneficiary.

The payment structure presented in the July 15, 2016 MDPP proposed rule (81 FR 46415 through 46416) would have required the MDPP beneficiary to attend 3 core maintenance sessions and achieve or maintain a minimum 5 percent weight loss for a $45 payment to be made to an MDPP supplier for the core maintenance session interval. If 5 percent weight loss was not achieved or maintained during the core maintenance session interval, no separate performance payment would be made. MDPP suppliers would still have been required to offer (and furnish if the beneficiary attended) MDPP services during core maintenance intervals to beneficiaries regardless of weight loss. Based on our consideration of information provided in the public comments on that proposed rule and our increased emphasis in the performance payments on the achievement and maintenance of the required minimum weight loss as the outcome of MDPP services, our proposal for the performance payments for core maintenance sessions differs from the payment amounts included in the July 15, 2016 MDPP proposed rule (81 FR 46415 through 46416).

For the MDPP expanded model, we are proposing performance payments amounts for core maintenance session intervals that value achievement of both session attendance and the required minimum weight loss, with an emphasis on achieving the weight loss performance goal. We are proposing that an MDPP supplier would be paid a performance payment for a core maintenance session interval if a beneficiary achieves the performance goal of attending at least 3 core maintenance sessions during the interval. The specific performance payment amount would be determined by whether the beneficiary has also achieved or maintained the required minimum weight loss within the interval. The achievement or maintenance of the required minimum weight loss within the 3-month core maintenance session interval would be determined based on a measurement taken in-person during any 1 session within that 3-month interval. We are proposing that MDPP suppliers would be paid a performance payment for no more than two core maintenance session intervals for each MDPP beneficiary.

As discussed previously, we recognize that weight loss is a process that may still be ongoing for some beneficiaries during the final months of the core services period. According to an analysis of participant data from CDC's DPRP, the longer a participant remains in the lifestyle change program, the greater his or her average weight loss achieved.[20] Findings indicate that it takes an average of 17 DPP sessions attended to exceed the required minimum weight loss, and the 9 percent or greater weight loss goal is more likely to be achieved upon attending 19 sessions on average. This average number of sessions exceeds the 16 core sessions that must be offered to the MDPP beneficiary during the first 6 months of the MDPP services period and emphasizes the importance of core maintenance sessions to achievement of meaningful weight loss goals.

Of further note, the National DPP's core maintenance sessions were developed based on results from the original 2002 DPP Randomized Control Trial and CDC's DPRP standards were developed with this science in mind.[21]

[20] CDC's Diabetes Prevention Recognition Program dataset as of March 1, 2017.

[21] Available at *https://www.niddk.nih.gov/about-niddk/research-areas/diabetes/diabetes-prevention-program-dpp/Documents/DPP_508.pdf.*

Core maintenance sessions are integral for the expected reduction in the incidence of type 2 diabetes to be experienced by MDPP beneficiaries. These findings were recently confirmed in a literature review on combined diet and physical activity programs to prevent type 2 diabetes conducted by the Community Preventive Services Task Force that reiterated the year-long intensity and duration of the National DPP.[22]

Therefore, we believe that providing no performance payment to MDPP suppliers for furnishing core maintenance sessions to beneficiaries who have not achieved the required minimum weight loss prior to or during months 7 to 12 of the core services period could reduce the opportunity for MDPP beneficiaries to achieve the weight loss performance goal. Such a payment methodology could reduce the likelihood that MDPP suppliers would continue to work to engage beneficiaries in the weight loss process if those beneficiaries had not achieved the required minimum weight loss after completion of the initial 6 months of the MDPP core services period. We note that, as finalized in the CY 2017 PFS final rule (81 FR 80459), suppliers must offer a minimum of 1 core maintenance session per month in months 7 to 12 of the core services period to eligible beneficiaries, regardless of the beneficiary's weight loss. We believe that it is possible for some beneficiaries to have achieved the required minimum weight loss performance goal by the time the core sessions have been completed, and we want to incentivize MDPP suppliers to work toward the weight loss performance goal in that timeframe. However, we believe that it is also appropriate to place some value on achieving attendance performance goals alone through performance payments for core maintenance session intervals so that MDPP suppliers continue to work to engage all beneficiaries in striving to achieve the required minimum weight loss performance goal.

As discussed in section III.K.2.d.iii.(2)(a) of this proposed rule, we are proposing that the maximum total performance payment for MDPP core maintenance sessions would be $120 for beneficiaries who achieve both the attendance and weight loss performance goals during months 7 to 12 of the core services period. Specifically, we are proposing to pay MDPP suppliers $60 for a core maintenance session interval if a beneficiary attends 3 sessions and achieves or maintains the required minimum weight loss during that interval, and to pay MDPP suppliers $10 for a core maintenance session interval if the beneficiary attends 3 sessions but does not achieve or maintain the required minimum weight loss during that core maintenance session interval.

As compared to the payment amounts with and without achievement or maintenance of the required minimum weight loss that were presented for core maintenance session intervals in the July 15, 2016 MDPP proposed rule (81 FR 46415 through 46416), these payment amounts are both higher. As discussed previously in this section, we believe it is appropriate in months 7 to 12 of the core services period to provide some performance payment for achievement of attendance performance goals even if the required minimum weight loss is not achieved, in order to provide the greatest opportunity for beneficiaries to achieve the required minimum weight loss over the full core services period. In addition, we are proposing a higher payment amount for core maintenance session intervals with achievement or maintenance of the required minimum weight loss to recognize that achievement and maintenance of the required minimum weight loss are necessary for the reduced incidence of type 2 diabetes and to encourage MDPP suppliers to work to engage beneficiaries in achieving weight loss and sustaining their weight loss over time.

Proposed performance payments for the core maintenance session intervals are displayed in Table 29. On a per-session basis, these payments would be approximately $20 and $3, respectively. While both of these payment amounts provide payment to MDPP suppliers for the resources involved with furnishing core maintenance sessions, we believe the relatively high per-session performance payment of $20 in comparison to the per-session performance payment amounts for core sessions is appropriate due to the achievement or maintenance of both the required minimum weight loss and beneficiary attendance at core maintenance sessions, as compared to core sessions where the performance payment is based solely on attendance. On the other hand, we believe that the relatively low per-session payment amount in our core maintenance session interval performance payment proposal for core maintenance sessions for those beneficiaries who do not achieve the weight loss performance goal, while providing some performance payment for attendance at core maintenance sessions by beneficiaries still working to achieve the required minimum weight loss, is appropriate because these sessions have not yet resulted in those beneficiaries achieving the weight loss performance goal.

TABLE 29—PROPOSED PERFORMANCE PAYMENTS FOR CORE MAINTENANCE SESSION INTERVALS

Performance goal	Performance payment per beneficiary (*with* achievement or maintenance of required minimum weight loss)	Performance Payment per beneficiary (*without* achievement or maintenance of required minimum weight loss)
3 sessions attended in first core maintenance session interval (months 7–9 of the MDPP core services period)	$60	$10
3 sessions attended in second core maintenance session interval (months 10–12 of the MDPP core services period)	60	10
Maximum total performance payment for core maintenance session intervals (two consecutive 3-month intervals over months 7–12 of the MDPP core services period)	120	20

[22] Available at *http://www.thecommunityguide.org/diabetes/combineddietandpa.html.*

The proposed core maintenance session interval performance payments for core maintenance sessions are included at proposed § 414.84(b)(4). We are inviting public comments on these proposals.

(5) Performance Payments for Ongoing Maintenance Session Intervals

Similar to our proposal for the payment of core maintenance session intervals described previously, we are proposing to make performance payments to MDPP suppliers for 3-month ongoing maintenance session intervals. This payment would be made when suppliers furnish ongoing maintenance sessions during the 24 months of the ongoing services period after the 12-month MDPP core services period ends. We are proposing that an MDPP supplier would be paid a performance payment for an ongoing maintenance session interval if an MDPP beneficiary achieves the performance goals of attending at least 3 ongoing maintenance sessions and maintaining the required minimum weight loss from baseline measured in person during a session at least once within that interval. Under this proposal, an MDPP supplier would not be paid a performance payment unless the beneficiary has achieved these both of these performance goals within that 3-month interval. An ongoing maintenance session interval, as we are proposing to define it at § 410.79(b), means one of the up to eight consecutive 3-month time periods during the ongoing services period, during which an MDPP supplier offers at least one ongoing maintenance session to an MDPP beneficiary per month.

The payment structure presented in the July 15, 2016 MDPP proposed rule (81 FR 46415 through 46416) would have required the MDPP beneficiary to attend 3 ongoing maintenance sessions and maintain the required minimum weight loss for a $45 payment to be made to an MDPP supplier for the ongoing maintenance session interval. Based on our consideration of information provided in the public comments on that proposed rule and our increased emphasis in the performance payments on the achievement and maintenance of weight loss as the outcome of MDPP services, our proposal for the performance payment for ongoing maintenance session intervals differs from that payment amount.

We are proposing that MDPP suppliers could be paid up to 8 performance payments of $50 each for ongoing maintenance session intervals. Just like the other proposals for performance payments, we are proposing this payment in CY 2018 dollars to ensure consistency in calendar year dollars among performance payments for a given calendar year. However, we note that no ongoing maintenance session interval payments, available only for intervals in the ongoing services period during months 13 through 36 of an MDPP beneficiary's MDPP services period, would be made in CY 2018 based on our proposal in section III.K.2.a. of this proposed rule that MDPP services be available on April 1, 2018. Under this proposal, MDPP services would only be available for 9 months of CY 2018 so no MDPP beneficiaries would attend ongoing maintenance sessions in CY 2018. The first ongoing maintenance session interval performance payments would be made in CY 2019 and would equal $50 adjusted by the percent change in the Consumer Price Index for All Urban Consumers (CPI–U) (U.S. city average) for the 12-month period ending June 30th, 2018, as discussed in section III.K.2.d.iii.(9) of this proposed rule.

This proposed payment amount is somewhat higher than the potential payment discussed in the July 15, 2016 MDPP proposed rule (81 FR 46415 through 46416) to recognize that maintenance of the required minimum weight loss is necessary for the reduced incidence of type 2 diabetes and to encourage MDPP suppliers to work to engage beneficiaries in sustaining their weight loss over time. The maximum total performance payment for MDPP ongoing maintenance sessions would be $400, as displayed in Table 30. On a per-session basis, this payment would be approximately $17, which we believe is appropriate for MDPP suppliers that furnish ongoing maintenance sessions to beneficiaries who maintain the required minimum weight loss during ongoing maintenance session interval. We note that this per-session payment amount would be somewhat lower than the $20 per-session payment amount included in the core maintenance session interval performance payment for beneficiaries who achieve attendance and weight loss performance goals during the 3-month intervals in months 7 to 12 of the MDPP core services period. Like the proposed performance payment for core maintenance session intervals, the proposed performance payment for ongoing maintenance session intervals values both attendance and weight loss. However, during core maintenance session intervals it is likely that the required minimum weight loss would first be achieved, and we believe that a somewhat higher per-session payment amount is appropriate under these circumstances. In contrast, we believe that a somewhat lower per-session payment amount for ongoing maintenance sessions during intervals where the required minimum weight loss is maintained, rather achieved, is appropriate.

We considered an alternative policy in which an MDPP supplier would receive a payment for an ongoing maintenance session interval so long as the beneficiary attended at least *1* ongoing maintenance session during the interval and maintained the required minimum loss. In this scenario, we considered that the MDPP supplier would still be required to offer at least 2 additional ongoing maintenance sessions (at least one per month) to the beneficiary over the 3-month interval. However, we believe that the goal of ongoing maintenance sessions is to promote both sustained beneficiary engagement and weight loss and, therefore, we believe that ongoing maintenance session interval performance payments should be tied to achieving both attendance and weight loss performance goals.

The proposed payment policy also would align with the service limitations for ongoing maintenance sessions at § 410.79(c)(1)(iii) in that beneficiaries also would be required to attend all 3 sessions within a given ongoing maintenance session 3-month interval to be covered for the subsequent 3-month interval. We note that the proposed coverage and payment policies are aligned for ongoing maintenance session intervals, where attendance at 3 sessions within an interval is required for a performance payment as well as for coverage of ongoing maintenance sessions in the next interval. In contrast, MDPP suppliers are required to offer core maintenance sessions in both core maintenance session intervals for all beneficiaries, regardless of a beneficiary's attendance at core maintenance sessions, although attendance is required for a performance payment to be made for the core maintenance session interval.

TABLE 30—PROPOSED PERFORMANCE PAYMENTS FOR ONGOING MAINTENANCE SESSION INTERVALS

Performance goal	Performance payment per beneficiary (*with* maintenance of the required minimum weight loss)	Performance payment per beneficiary (*without* maintenance of the required minimum weight loss)
3 sessions attended in 1 ongoing maintenance session interval	$50	$0
Maximum total performance payment for ongoing maintenance session intervals (8 consecutive 3-month intervals over months 13–36 of the MDPP ongoing services period)	400	* 0–350

* = The specific payment amount depends on whether the beneficiary has coverage of 1 to 7 ongoing maintenance session intervals, as well as whether the beneficiary meets the performance goals for the performance payment for that ongoing maintenance session interval.

The proposed ongoing maintenance session interval performance payments for ongoing maintenance sessions are included at proposed § 414.84(b)(5). We are inviting public comments on these proposals. We also are inviting public comments on the alternative considered.

(6) Weight Loss Performance Payments

We are proposing that if a beneficiary achieves the required minimum weight loss measured at any session attended during the core services period, an MDPP supplier would be paid the weight loss performance payment of $160 displayed in Table 31. As discussed in section III.K.2.d.iii.(2)(a) of this proposed rule, we are proposing that 23 percent of the maximum total performance payment amount for the set of MDPP services would be paid for the achievement of weight loss, regardless of session attendance, because weight loss is the most important outcome for the MDPP expanded model. The proposed performance payment of $160 for the required minimum weight loss, which constitutes approximately 90 percent of the maximum total weight loss performance payment, was set to be the large majority of the available weight loss performance payment based on the strong evidence for the association of the required minimum weight loss with a reduction in the incidence of type 2 diabetes.

We note that this association is evidenced by the CDC's National DPP, which is based on the 2002 DPP Randomized Control Trial and follow-up efficacy trials.[23] All of the trials found that the greater the intensity and duration of the diabetes prevention program—with 1 year being the most effective program ''dose''—the greater the reduction in the incidence of type 2 diabetes. Specially, persons at high-risk for type 2 diabetes who participated in a year-long lifestyle change program, focused on modest weight loss (5–7 percent), experienced a 58 percent lower incidence of type 2 diabetes than those who did not receive the lifestyle intervention. The DPP Randomized Control Trial, as well as the DPP model test, involved the provision of 16 weekly core sessions and 6 monthly core maintenance sessions (all approximately 1 hour in length), similar to the set of core services in the MDPP expanded model. We recognize that not all beneficiaries would be able to achieve the required minimum weight loss within the first 6 months, which is the period when core sessions are furnished. Therefore, we believe that our proposed policy for payment of the performance payment upon achievement of the required minimum weight loss any time during the 12 months of the MDPP core services period would allow MDPP suppliers the greatest flexibility to work throughout the full MDPP core services period with beneficiaries who face difficulty in achieving this weight loss performance goal.

We also are proposing that, in addition to the weight loss performance payment for the required minimum weight loss, an MDPP supplier would be paid an additional weight loss performance payment of $25 if the beneficiary achieves at least 9 percent weight loss from his or her baseline weight at any time during the MDPP services period as displayed in Table 31. We are proposing this additional weight loss performance payment based on information from stakeholders that commercial payers paying for DPPs frequently include an incentive payment for 9 percent weight loss as an incentive to try to encourage greater and/or continued weight loss and behavior change. We believe that making an additional weight loss performance payment for 9 percent weight loss at any time during the MDPP services period would provide an additional incentive for MDPP suppliers to continue weight loss efforts with beneficiaries, especially during the ongoing services period, which may extend for a period of up to 24 months.

We are proposing that MDPP suppliers may submit claims for these weigh loss performance payments on the date when the beneficiary first reaches the required minimum or 9 percent weight loss, as measured in person during a session, respectively, and each weight loss performance payment would be paid to only one supplier and only once per beneficiary. In the unusual circumstance where the beneficiary achieved 9 percent weight loss as the first weight loss change measured from baseline, the MDPP supplier could bill and be paid both the 5 percent and 9 percent weight loss performance payments.

TABLE 31—PROPOSED WEIGHT LOSS PERFORMANCE PAYMENTS

Performance goal	Performance payment per beneficiary
5 percent weight loss (required minimum weight loss)	$160
9 percent weight loss	25
Maximum total performance payment for weight loss	185

The proposed weight loss performance payments are included at proposed § 414.84(b)(6) and (7). We are inviting public comments on these proposals.

(7) Summary Table of Performance Payments for the Set of MDPP Services

In summary, for furnishing MDPP services during the MDPP services period, we are proposing that MDPP suppliers could be paid a minimum of $25 per beneficiary (if the beneficiary attends the first core session) and a maximum total of $810 per beneficiary (if the beneficiary achieves all performance goals, maintains eligibility for 36 months, and does not change

[23] Available at *https://www.niddk.nih.gov/about-niddk/research-areas/diabetes/diabetes-prevention-program-dpp/Documents/DPP_508.pdf.*

MDPP suppliers). Table 32 summarizes all of the proposed performance payments for the set of MDPP services that are discussed in sections III.K.2.d.iii.(3) through (6) of this proposed rule.

TABLE 32—PROPOSED PERFORMANCE PAYMENTS FOR THE SET OF MDPP SERVICES

Performance goal	Performance payment per beneficiary (*with* the required minimum weight loss)	Performance payment per beneficiary (*without* the required minimum weight loss)
1st core session attended	$25	
4 total core sessions attended	30	
9 total core sessions attended	50	
3 sessions attended in first core maintenance session interval (months 7–9 of the MDPP core services period)	*60	10
3 sessions attended in second core maintenance session interval (months 10–12 of the MDPP core services period)	*60	10
5 percent weight loss achieved	160	0
9 percent weight loss achieved	25	0
3 sessions attended in ongoing maintenance session interval (eight consecutive 3-month intervals over months 13–36 of the MDPP ongoing services period)	*50	**0
Total performance payment	810	125

*The required minimum weight loss from baseline must be achieved or maintained during the core maintenance session 3-month interval or maintained during the ongoing maintenance session 3-month interval.

**A beneficiary attends at least 1 core session during the core services period to initiate the MDPP services period; must attend at least 1 session during the final core maintenance session 3-month interval; and must achieve or maintain the required minimum weight loss at least once during the final core maintenance session 3-month interval to have coverage of the first ongoing maintenance session interval. Then, a beneficiary must attend at least 3 sessions and maintain the required minimum weight loss at least once during an ongoing maintenance session 3-month interval to have coverage of the next ongoing maintenance session interval.

(8) Considerations Related to Potential Future Geographic Adjustment of MDPP Payments

Although Medicare is a national program, it frequently adjusts fee-for-service payments to hospitals, physicians, and other providers and suppliers according to the geographic locations in which they furnish services. These adjustments generally account for differences in the relative costs of doing business in different geographic areas compared to the national average. For example, section 1886(d)(3)(E) of the Act requires that, as part of the methodology for determining prospective payments to hospitals, the Secretary must adjust the standardized amounts for area differences in hospital wage levels by a factor (established by the Secretary) reflecting the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level. This adjustment factor for hospitals is the wage index, and we currently define hospital geographic areas (labor market areas) based on the definitions of Core-Based Statistical Areas (CBSAs) established by the Office of Management and Budget. Similarly, a geographic adjustment is also made for services paid under the PFS, and a geographic practice cost index (GPCI) has been established for every Medicare PFS payment locality, many of which are statewide, for each of the three components of a service's relative value units (that is, the relative value units for work, practice expense, and malpractice).

We are proposing to make performance-based payments to MDPP suppliers in intervals based on achievement of performance goals, rather than fee-for-service payments for individual services furnished. While we intend for those performance payments to make payment to MDPP suppliers for MDPP services that involve the use of supplier resources, we are unsure if there is notable variation in the relative costs of furnishing MDPP services among geographic areas. Because the DPP model test was carried out in only eight States, we do not have the data to determine whether there are geographic differences nationwide. In addition, because a substantial portion of the proposed MDPP performance payments are based on the beneficiary's achievement of weight loss performance goals, we are uncertain about the appropriateness of geographically adjusting such performance-based payments.

Therefore, we are not proposing geographic adjustment of performance payments for MDPP services. However, we are inviting public comments on issues related to geographic adjustment of payment for MDPP services in the context of the MDPP performance-based payment methodology, including appropriate sources of information for determining any geographic cost differences. We may consider proposing additional payment policies for the MDPP expanded model in the future. We request that commenters submitting information on these issues provide justification, including any relevant analysis, to support any suggestions regarding potential future geographic adjustment of performance-based payments for MDPP services.

(9) Updating MDPP Payment Amounts

To account for inflation, we are proposing to update MDPP payment amounts annually based on the CPI–U. The CPI–U is a measure of the average change over time in prices paid for a market basket of consumer goods and services, and is a measure of economy-wide inflation. There are no statutory requirements for the update factor for payments for MDPP services so there is no requirement that a productivity adjustment be applied to the MDPP services update factor as there are for certain other Medicare-covered items and services where prices are updated by the CPI–U, such as the Clinical Laboratory Fee Schedule; Durable Medical Equipment, Prosthetics/Orthotics, and Supplies Fee Schedule; Ambulance Fee Schedule; and Ambulatory Surgical Center payment system.

We considered using other indices such as the Medicare Economic Index (MEI) to update the MDPP payment amounts. The MEI measures price changes in the inputs required to operate a self-employed physician practice. We do not believe that the MEI would be appropriate to update MDPP payment amounts because MDPP suppliers are not similar to self-employed physician practices. We note that the CPI–U by definition is an economy-wide measure of inflation and, therefore, in the absence of an appropriate specific index for MDPP services, we believe the CPI–U to be the most technically appropriate index available to update payments for MDPP services. We further note that the CPI–U is used to update Medicare payments for other Medicare-covered items and services, such as ambulance, clinical laboratory, and ambulatory surgical center services.

We are proposing to update MDPP performance payments and the bridge payment (a proposed one-time payment to an MDPP supplier for furnishing its first session to an MDPP beneficiary who has previously received MDPP services from a different MDPP supplier as discussed in detail in section III.K.2.d.v. of this proposed rule) that may be paid to MDPP suppliers in the following manner:

- Beginning in CY 2019 and each year forward, the performance payment and bridge payment amounts will be adjusted by the 12-month percent change in the CPI–U (U.S. city average) for the period ending June 30th of the year preceding the update year. The percent change update will be calculated based on the level of precision of the index as published by the Bureau of Labor Statistics and applied based on one decimal place of precision. The annual MDPP services payment update will be published by CMS transmittal.

The proposed methodology to update MDPP performance payments and the bridge payment is included at proposed § 414.84(d). We are inviting public comments on this proposal.

(10) MDPP Supplier Billing and Payment for MDPP Services

(a) Payment for MDPP Services on an Assignment-Related Basis

We are proposing that performance payments and bridge payments to MDPP suppliers for MDPP services would be made only on an assignment-related basis in accordance with § 424.55. As described in Chapter 1, Section 30.3 of the Medicare Claims Processing Manual,[24] CMS identifies a number of supplier and practitioner types who furnish services under the Medicare program and who are required to accept assignment for all Medicare claims for their services. This means that they must accept the Medicare allowed amount as payment in full for their services, regardless of whether the supplier is a participating or non-participating provider in the Medicare program. In these circumstances, the beneficiary's liability is limited to any applicable deductible plus the 20 percent coinsurance if coinsurance applies to the service. CMS currently mandates assignment for claims from multiple types of suppliers and practitioners, including clinical diagnostic laboratory services and physician lab services; physician services to individuals dually entitled to Medicare and Medicaid; and services of physician assistants, nurse practitioners, clinical nurse specialists, nurse midwives, certified registered nurse anesthetists, clinical psychologists, clinical social workers, registered dietitians/nutritionists, anesthesiologist assistants, and mass immunization roster billers. The beneficiary (or the person authorized to request payment on the beneficiary's behalf) is not required to assign the claim to the supplier in order for an assignment to be effective, and when these claims are inadvertently submitted as unassigned, Medicare Administrative Contractors (MACs) process them as assigned.

Consistent with our established requirements for these other types of suppliers, some of whom are similar to MDPP suppliers in that they furnish a limited breadth of Medicare-covered services, we believe it would be appropriate to require all MDPP suppliers, whether they are participating or not participating in Medicare, to accept assignment. We also believe that making performance payments for MDPP services solely on an assignment-related basis is the most appropriate methodology, given the performance-based MDPP payment methodology which is based on the achievement of weight loss and/or attendance performance goals and not based on the MDPP supplier resource expended to furnish individual MDPP services. We further note that as finalized in the CY 2017 PFS final rule (81 FR 80464), MDPP services are additional preventive services under section 1861(ddd) of the Act and, therefore, consistent with section 1833(a)(1)(W) of the Act, are not subject to the Medicare Part B coinsurance or deductible. Under our proposal Medicare would pay 100 percent of the Medicare allowed charge for MDPP services furnished to MDPP beneficiaries, and a beneficiary would have no liability for covered MDPP services. MDPP suppliers would be required to accept the Medicare allowed charge as payment in full and would not be able to bill or collect from the beneficiary any amount.

Finally, to minimize the potential administrative burden on beneficiaries related to payment for MDPP services on an assignment-related basis, we are proposing that for purposes of claims for services submitted by an MDDP supplier, Medicare would deem such claims to have been assigned by the beneficiary (or the person authorized to request payment on the beneficiary's behalf) and the assignment accepted by the MDDP supplier. This proposed treatment of claims from MDPP suppliers in new § 424.55(d) is consistent with the current exception in § 424.55(c) regarding payment to a supplier which specifies that when payment under the Act can only be made on an assignment-related basis or when payment is for services furnished by a participating physician or supplier, the beneficiary (or the person authorized to request payment on the beneficiary's behalf) is not required to assign the claim to the supplier in order for an assignment to be effective.

The proposed assignment-related basis for performance payments and bridge payments MDPP suppliers is included at proposed § 414.84(b) and (c). The proposal to not require the beneficiary to assign the claim for MDPP services to the MDPP supplier in order for assignment to be effective is included at proposed § 424.55(d). We are inviting comments on these proposals.

(b) Requirements for Payment of Bridge Payments and Performance Payments

MDPP suppliers may only submit claims for a performance payment or bridge payment for MDPP services when all of the proposed requirements for the payment are met. Claims for services that do not meet these requirements will not be paid. In accordance with § 424.80, MDPP suppliers are reminded that there are exceptions to the prohibition of reassignment of claims by suppliers for certain arrangements provided the applicable requirements are met. Of specific note, Medicare may pay an agent who furnishes billing and collection services to the supplier if the conditions of § 424.80(b)(5) are met.

[24] Available at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c01.pdf.*

Proposed requirements for performance payments and the bridge payment include that the MDPP services were furnished to a beneficiary eligible for MDPP services as specified at § 410.79(c) and that the MDPP supplier complies with all applicable enrollment and program requirements. In addition, the MDPP services must be furnished by an eligible coach on or after his or her coach eligibility start date and, if applicable, before his or her coach eligibility end date, and the MDPP supplier must submit the National Provider Identifier (NPI) of the coach on MDPP claims. We describe additional details on how eligible coach information would be processed in section III.K.2.d.iii.(10)(d) of this proposed rule. All specific additional proposed requirements for the performance payment or bridge payment, as discussed in sections III.K.2.d.iii.(3) through (6) and III.K.2.d.v. of this proposed rule, must also be met.

In order to submit a claim for a performance payment under the MDPP expanded model, the billing supplier must have documentation in the beneficiary's MDPP record, as specified in proposed § 424.205(g), that all requirements for the payment, including the achievement of the performance goal(s) applicable to the performance payment, have been met. We note that the billing supplier's MDPP record for the beneficiary may include a copy of the beneficiary's MDPP record from a previous MDPP supplier that has been provided to the billing supplier at the request of the MDPP beneficiary. For purposes of an MDPP supplier submitting a claim for an interval performance payment based on attendance at more than one session, this copy of the MDPP record from the previously MDPP supplier may be used as part of the billing supplier's documentation demonstrating that the attendance and weight loss, if applicable, performance goal(s) for the performance payment were achieved. We note that as we finalized at § 424.59(b) in the CY 2017 PFS final rule (proposed to be redesignated and amended at § 424.205(g)), MDPP suppliers are required to maintain and handle any personally identifiable information (PII) and protected health information (PHI) in compliance with HIPAA, other applicable state and federal privacy laws, and CMS standards. Therefore, MDPP suppliers must follow these rules when providing any copies of information from a beneficiary's MDPP records to another MDPP supplier.

We are proposing that any weight loss measurement taken and recorded by an MDPP supplier for the purposes of performance payments must be taken in person during an MDPP core session, core maintenance session, or ongoing maintenance session by the MDPP supplier during the MDPP services period. We believe that in-person measurements are the most feasible method for weight ascertainment at this time for services because the beneficiary would attend regular in-person sessions with the MDPP supplier. Moreover, we believe that self-reported weight loss is not reliable for the purposes of performance payment in the MDPP expanded model. This proposal also would apply to our proposed policy regarding virtual make-up sessions, described in detail in section III.K.2.c.iv.(3) of this proposed rule, meaning that weight loss could not be measured or reported during a virtual make-up session for the purpose of the MDPP supplier submitting a claim for a performance payment. We also are proposing to require that weight loss be measured in person at an MDPP session to align with CDC's DPRP standards, which require for in-person sessions that weight be measured in person at the session.

In addition, we note that the achievement or maintenance of the required minimum weight loss that determines the performance payment amount for a core maintenance session interval and the maintenance of the required minimum weight loss that determines whether a performance payment for an ongoing maintenance session interval is made must be determined by an in-person weight measurement at a session furnished during the applicable interval. Thus, for these interval performance payments, achievement of the performance goal for minimum weight loss does not need to be determined based on attendance at a session furnished by the MDPP supplier billing for that performance payment. However, as discussed previously, if achievement of the performance goal for minimum weight loss was measured at a session furnished by a previous MDPP supplier in the interval, the subsequent supplier must have documentation through a copy of the beneficiary's MDPP record from that previous supplier that the weight loss performance goal was met in the interval to bill for the interval performance payment. Finally, the performance payments for the required minimum and 9 percent weight loss would only be billed by the MDPP supplier furnishing the session at which the weight loss performance goal is met during an in-person session.

Furthermore, we are proposing that the beneficiary must achieve the applicable attendance performance goal for core session, core maintenance session interval, or ongoing maintenance session interval performance payments upon attendance at a session furnished by the MDPP supplier billing for that specific performance payment. An MDPP supplier can only bill for a performance payment on the date the beneficiary has achieved all performance goals associated with that performance payment. We note that in order to bill for an interval performance payment that is based on attendance, the MDPP supplier that furnished the session where the attendance goal is met would bill for the performance payment, even if that supplier did not itself furnish all sessions attended by the MDPP beneficiary during that interval. In these circumstances, as discussed previously, if attendance at a session furnished by a previous MDPP supplier occurred in the interval, the subsequent supplier must have documentation through a copy of the beneficiary's MDPP record from that previous supplier of the session attendance in order to bill for the interval performance payment based on attendance at that session. An MDPP supplier may not bill for an interval performance payment when the MDPP supplier does not furnish the session where the attendance goal is met.

For all interval performance payments, we are proposing that the performance payment would be based on the date the MDPP supplier furnished the session where the interval attendance performance goal is met. Thus, for those intervals where the performance payment is based on MDPP beneficiary session attendance that spans two calendar years, the interval performance payment would be the amount applicable to the later calendar year, reflecting the annual update from the prior year as discussed in section III.K.2.d.iii.(9) of this proposed rule. The proposed conditions for payment by CMS of performance payments and bridge payments to MDPP suppliers are included at proposed § 414.84(b) and (c), as well as at the other provisions in these sections. We are inviting public comments on these proposals.

(c) Reporting HCPCS G-Codes on Claims for MDPP Services

We are proposing to establish 19 unique Healthcare Common Procedure Coding System (HCPCS) G-codes so that MDPP suppliers may submit claims for payment when all the requirements for

billing the codes have been met. Our proposal for the HCPCS G-codes is displayed in Table 33.

We note that each MDPP supplier would be able to bill one of the 18 payable HCPCS G-codes on the date when all the requirements for billing the code have been met, including the session attendance for specific core and ongoing maintenance session intervals and achievement and/or maintenance of weight loss, as applicable to the specific HCPCS G-code. One of the proposed HCPCS G-codes would be nonpayable and assigned a payment amount of $0 because it would only be reported on a claim that also includes a payable HCPCS G-code for MDPP services as described subsequently in this section.

HCPCS G-codes GXXX1 through GXXX3 and GXXX8 through GXX17 may each be paid only once in a beneficiary's lifetime, and the Medicare claims processing system would ensure that no more than one of each specific performance payment per beneficiary reported with these HCPCS G-codes is made. In addition, because only one performance payment may be made for each core maintenance session interval per beneficiary, the claims processing system would also ensure that no more than one unit of HCPCS code GXXX4 or GXXX6 and no more than one unit of HCPCS code GXXX5 or GXXX7 was paid in a beneficiary's lifetime.

Due to these lifetime limitations on payment for certain HCPCS codes for each beneficiary, in the circumstances where two MDPP suppliers furnished sessions during the MDPP services period and both MDPP suppliers met all requirements for billing the same HCPCS G-code, based on our operational processes, we would pay the first valid claim received and deny the second claim. The first valid claim received for a beneficiary for a given HCPCS G-code with a lifetime limitation would be determined through the CMS' Common Working File (CWF), which processes claims for all MACs.

Based on information from the CDC's national DPP, we expect that circumstances where a beneficiary changes MDPP suppliers during the MDPP services period will be uncommon. In addition, in view of the typical structure of DPPs where core sessions are offered weekly for the first 6 months of the core services period, and then offered monthly, we believe it would be rare for more than one MDPP supplier to meet the requirements for billing for the same once-per-lifetime performance payment. However, as an example an MDPP beneficiary could maintain the required minimum weight loss throughout the first core maintenance session interval and attend 3 sessions furnished by one MDPP supplier in the first 1½ months of the first core maintenance interval, and then change to another supplier and attend 3 more core maintenance sessions furnished by a subsequent MDPP supplier before the end of that interval. While both MDPP suppliers would meet the requirements for billing HCPCS code GXXX6, we would only pay the first claim for the HCPCS G-code that was submitted. The second claim for HCPCS code GXXX6 received by us would be denied. We expect that our operational processes will result in MDPP suppliers submitting claims for HCPCS G-codes as soon as the sessions are furnished that meet all of the requirements for billing for the particular performance payment, and that this practice will generally result in the performance payment being made to the MDPP supplier that furnished the first session where the performance goals were met.

Finally, as discussed in section III.K.2.d.v. of this proposed rule, we are not proposing to limit the number of bridge payments, which would be reported with HCPCS code GXX18, that may be paid for an MDPP beneficiary who changes MDPP suppliers during the MDPP services period.

TABLE 33—PROPOSED HCPCS G-CODES FOR MDPP SERVICES

Proposed HCPCS G-code for MDPP services *	Proposed payment amount	Description of MDPP service
GXXX1	$25	1st core session attended.
GXXX2	30	4 total core sessions attended.
GXXX3	50	9 total core sessions attended.
GXXX4	10	3 core maintenance sessions attended in months 7–9 (weight- loss goal not achieved or maintained).
GXXX5	10	3 core maintenance sessions attended in months 10–12 (weight loss goal not achieved or maintained).
GXXX6	60	3 core maintenance sessions attended in months 7–9 and weight loss goal achieved or maintained.
GXXX7	60	3 core maintenance sessions attended in months 10–12 and weight loss goal achieved or maintained.
GXXX8	160	5 percent weight loss from baseline achieved.
GXXX9	25	9 percent weight loss from baseline achieved.
GXX10	50	3 ongoing maintenance sessions attended in months 13–15 and weight loss goal maintained.
GXX11	50	3 ongoing maintenance sessions attended in months 16–18 and weight loss goal maintained.
GXX12	50	3 ongoing maintenance sessions attended in months 19–21 and weight loss goal maintained.
GXX13	50	3 ongoing maintenance sessions attended in months 22–24 and weight loss goal maintained.
GXX14	50	3 ongoing maintenance sessions attended in months 25–27 and weight loss goal maintained.
GXX15	50	3 ongoing maintenance sessions attended in months 28–30 and weight loss goal maintained.
GXX16	50	3 ongoing maintenance sessions attended in months 31–33 and weight loss goal maintained.
GXX17	50	3 ongoing maintenance sessions attended in months 34–36 and weight loss goal maintained.
GXX18	25	Bridge payment—first session furnished by MDPP supplier to an MDPP beneficiary who has previously received MDPP services from a different MDPP supplier.
GXX19	0	MDPP session reported as a line-item on a claim for a payable MDPP services HCPCS G-code for a session furnished by the billing supplier that counts toward achievement of the attendance performance goal for the payable MDPP services HCPCS G-code.

* Illustrative HCPCS G-code numbers are placeholders to allow for comment on this proposed rule. Final HCPCS codes for MDPP services under the MDPP expanded model will be included in the CY 2018 PFS final rule.

We also plan to issue specific billing instructions to MDPP suppliers for those 14 proposed HCPCS G-codes (excluding GXXX1, GXXX8, GXXX9, GXX18, and GXX19) that represent an interval performance payment where attendance

at more than 1 session is required for the performance payment to be made. Suppliers would report the applicable HCPCS G-code as a line-item on the claim on the date the session was furnished where the interval attendance goal was met. On the same claim, suppliers would also report 1 line-item of HCPCS code GXXX19 for each other session furnished by the supplier during the interval that was not previously reported on a claim but that counts toward achievement of the attendance performance goal for the applicable HCPCS G-code.

For example, while beneficiary attendance at the 2nd and 3rd of the 4 core sessions would not result in a separate performance payment, we would instruct MDPP suppliers that the 2nd and 3rd core sessions furnished by the supplier submitting the claim for HCPCS code GXXX2 (4 total core sessions attended) be reported as 2 separate line-items of HCPCS code GXX19 on the claim for the performance payment for 4 core sessions attended. The 4th core session furnished by the billing supplier where the interval attendance goal was met would be represented on the claim line reporting HCPCS code GXXX2. Each of these line-items (one line-item of GXXX2 and 2 line-items of GXX19) would include the date of service and the NPI of the coach associated with that MDPP supplier who furnished the specific session reported as the line-item.

When billing for a HCPCS G-code that represents a cumulative number of MDPP sessions where some sessions already have been reported on a previous claim, only the sessions not previously reported on a claim would be reported by the MDPP supplier. For example, HCPCS code GXXX3 (9 total core sessions attended) would be used to bill for 9 core sessions attended, and the line-item of HCPCS code GXXX3 would represent the 9th core session furnished. Separate line-items of HCPCS code GXX19 would be reported on the same claim only for the 5th through 8th core sessions furnished by the MDPP supplier. Claims for HCPCS codes GXXX1 (1st core session attended) and GXXX2 (4 core sessions attended) would already have been submitted, and those claims would have included line-items for the 1st core session, and for the 2nd, 3rd, and 4th core sessions.

We believe that instructing MDPP suppliers to report a line-item for each session on a single claim submitted for an interval performance payment would simplify the tracking and administrative activities of MDPP suppliers and the reporting of the coach NPI on claims for MDPP services furnished to beneficiaries as discussed in section III.K.2.d.iii.(10)(d) of this proposed rule. We further believe that there should be no significant administrative burden for MDPP suppliers to include information on all sessions they furnished on interval performance payment claims for two reasons. First, the documentation requirements for MDPP sessions at § 424.205(g), including the beneficiary's eligibility, specific session topics attended, the NPI of the coach who furnished the session attended, the date and place of service of sessions attended, and weight, would require the MDPP supplier to document and retain this information.

Therefore, MDPP suppliers would have documentation of the date of each session and the NPI of the furnishing coach for reporting on each line-item on the claim for the interval performance payment. Second, MDPP suppliers would be instructed not to submit separate claims for each session represented in an interval performance payment. All sessions would be reported on the single claim that would be submitted for the interval performance payment.

In the case of an MDPP supplier submitting a claim for an interval performance payment where the billing supplier did not furnish all the sessions attributable to the interval because another supplier had furnished some of the first sessions in the interval, the billing supplier would report on the claim only the sessions it furnished. However, the supplier would need to maintain MDPP records documenting that all requirements, including session attendance and achievement or maintenance of weight loss, if applicable, for billing the HCPCS G-code for the interval for the beneficiary were met. Any sessions covered by the interval performance payment HCPCS G-code but not furnished by the supplier submitting the claim for that interval would not be reported as separate line-items on the claim. However, the billing supplier would need to maintain in the beneficiary's MDPP record a copy of his or her MDPP record from the previous supplier in order to consider sessions furnished by the previous supplier in determining that the performance goal(s) for the interval performance payment were met.

Although the NPIs of the coaches who furnished such sessions that would not be reported as separate line-items would also not be recorded on the claim, the billing supplier would still be required to maintain documentation in the beneficiary's MDPP record of the NPI of each coach who furnished each session through a copy of the beneficiary's MDPP record about those sessions from the previous supplier. Therefore, upon medical review, CMS and its contractors would be able to review and assess the remaining coaches who furnished sessions to Medicare beneficiaries associated with a claim submitted for a given interval performance payment HCPCS G-code, but who do not have an NPI reported on the claim. Because we expect it to be uncommon for suppliers not to furnish all sessions attributable to an interval and due to the administrative burden that could result from a requirement that an MDPP supplier report specific information on sessions on a claim that the particular supplier did not itself furnish, we believe the program integrity risk associated with the limitation in the completeness of information from administrative claims data under this scenario is low. However, we will monitor the completeness of reporting line-items on claims for interval performance payments and may consider revising our billing instructions in the future if we determine that we lack information from administrative claims on a significant number of sessions furnished to MDPP beneficiaries.

We are inviting public comments on the proposal to create 19 HCPCS G-codes for billing for the performance payments and bridge payment and reporting additional session line-items on claims for MDPP services. We also are inviting public comment on matters related to billing instructions for MDPP suppliers that we plan to issue so that information on the date and furnishing coach NPI for all sessions furnished by the billing supplier would be submitted on claims. However, we note that we intend to provide additional claims submission instructions in guidance.

(d) Reporting the Coach National Provider Identifier (NPI) on Claims

In the CY 2017 PFS final rule, we established the policy that coaches will not enroll in Medicare for purposes of furnishing MDPP services, but that they will be required to obtain NPIs. Further details on these policies are described in section III.K.2.e.iii. of this proposed rule.

According to Chapter 26, Section 10.4 of the Medicare Claims Processing Manual,[25] the NPI of the rendering provider is to be reported as Item 24J on the line-item for each service reported on the CMS–1500 claim form. Our proposal in section III.K.2.d.iii.(10)(c) of

[25] Available at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c26.pdf.*

this proposed rule would require that, in the circumstances of a claim for an interval performance payment for MDPP services, each session furnished by the billing supplier be reported as a separate line-item on the claim. In addition, we are proposing to require MDPP suppliers to report the NPI of the coach who furnished the session as Item 24J on the line-item for each session reported on claims for performance payments for MDPP services. Under our proposal, the coach who furnished the session would be the rendering provider for purposes of reporting on the CMS–1500 claim form.

While only MDPP suppliers, not coaches, would be subject to potential Medicare administrative actions related to payments the suppliers may receive, we believe that our proposal to require the NPI of the coach who furnished the session to be reported as the rendering provider for each line-item HCPCS G-code on a claim for MDPP services would provide us with a number of program integrity protections, including the ability to monitor MDPP coach activity to identify suspected fraud or other improper payments and to determine the need for medical review or investigation as appropriate. We would only process claims for payment of MDPP services when all of the coach NPIs reported on the claim are associated with eligible coaches who have been submitted on the coach roster in the MDPP supplier's enrollment application, and when all of the coaches have successfully completed Medicare's screening processes. We would also only process claims for payment of MDPP services furnished by a coach on or after his or her coach eligibility start date, and, if applicable, prior to his or her coach eligibility end date, as the definitions of these terms are included in proposed § 424.205(a).

Without such program integrity protections, we would lack a sufficient method to verify that payment is being made for services furnished by a coach who has met the requirements outlined in section III.K.2.e.iii. of this proposed rule. This verification will help protect both Medicare beneficiaries and the Medicare Trust Funds. Including coach NPIs on claims may also encourage accuracy in reporting on the achievement of beneficiary attendance and/or weight loss performance goals because both CMS and MDPP suppliers would be able to identify on the claim in question which coaches furnished the sessions attributable to the performance payment. In addition, because the accuracy of information reported on the claim is ultimately the MDPP supplier's responsibility, and the MDPP supplier attests to the accuracy of each claim submitted, including the relevant coach NPIs on the claim may assist the MDPP supplier when conducting internal monitoring of claim accuracy.

These proposed requirements for reporting the coach NPI as the rendering provider on session line-items included on claims for performance payments and bridge payments to MDPP suppliers are included at proposed § 414.84(b) and (c). We are inviting public comments on these proposals.

iv. Comparison of Supplier Requirements for Furnishing the Set of MDPP Services and Supplier Payment

As in the DPP model test under section 1115A(b) of the Act, MDPP services are based on a CDC-approved DPP curriculum and, therefore, MDPP suppliers must offer sessions in accordance with that curriculum. We are proposing to apply a performance-based payment methodology to MDPP services, which ties most payments to outcomes—in this case, weight loss and session attendance—to help incentivize suppliers to be engaged in their beneficiaries' weight loss efforts. Given this proposed methodology, we recognize that there would be an inherent amount of supplier financial risk, and that coverage of sessions and supplier requirements and payment would not always align. This section aims to clarify how we are proposing that these elements would fit together in the MDPP expanded model, as displayed in Table 34.

TABLE 34—SET OF MDPP SERVICES AND PAYMENT

MDPP services	MDPP beneficiary eligibility for coverage	MDPP supplier must offer	MDPP supplier payment
Core sessions (months 1 to 6 of the MDPP services period).	An eligible beneficiary has Medicare coverage of core sessions in the first 6 months of the MDPP core services period, regardless of attendance or weight loss. * *Note:* To start the MDPP services period, the beneficiary attends his or her first core session, which begins the beneficiary's MDPP services period timeline of a maximum of 36 months.	At least 16 core sessions, furnished no more frequently than once per week, over the first 6 months of the beneficiary's MDPP services period.	• $25 performance payment for beneficiary attendance at the first core session. • $30 interval performance payment after the beneficiary has attended a total of 4 core sessions. • $50 interval performance payment after the beneficiary has attended a total of 9 core sessions. * *Note:* All payments for core sessions are independent of beneficiary weight loss.
Core maintenance sessions (months 7 to 12 of the MDPP services period).	Beneficiary has coverage of core maintenance sessions in months 7 to 12 of the MDPP services period, regardless of attendance or weight loss.	At least 1 core maintenance session per month in months 7 to 12 of the MDPP services period.	• $10 payment if a beneficiary attends 3 sessions within a 3-month core maintenance session interval but does not achieve or maintain the required minimum weight loss at least once within that 3-month core maintenance session interval; *or* • $60 if a beneficiary attends 3 sessions *and* achieves or maintains the required minimum weight loss at least once within that 3-month core maintenance session interval. * *Note:* There are two consecutive core maintenance session intervals.

TABLE 34—SET OF MDPP SERVICES AND PAYMENT—Continued

MDPP services	MDPP beneficiary eligibility for coverage	MDPP supplier must offer	MDPP supplier payment
Ongoing maintenance sessions (months 13 to 36 of the MDPP services period).	Beneficiary has coverage of ongoing maintenance sessions in the first ongoing maintenance session interval (months 13 to 15 of the MDPP services period) if: • He or she attended at least 1 session during the final core maintenance session interval (months 9 to 12 of the MDPP services period) and had weight measured. • He or she achieved or maintained the required minimum weight loss at least once during the final core maintenance session interval (months 10 to 12 of the MDPP services period). A beneficiary has coverage of a subsequent ongoing maintenance session interval (for up to 21 months after the end of the first ongoing maintenance session interval), if he or she attended at least 3 sessions and maintained the required minimum weight loss from baseline at least once during the previous ongoing maintenance session interval.	At least 1 ongoing maintenance session per month for up to 24 months, if the beneficiary maintains eligibility to have coverage of ongoing maintenance sessions.	• $50 payment if a beneficiary attends 3 sessions and maintains the required minimum weight loss from baseline at least once within a 3-month ongoing maintenance session interval. * *Note:* There are up to eight consecutive ongoing maintenance session intervals.

Once an MDPP supplier enrolls in Medicare to furnish MDPP services, it must offer the set of MDPP services in accordance with the MDPP supplier standards (noted in section III.K.2.e.iv.(4) of this proposed rule and at § 424.205(d), including that it must offer at least 16 core sessions, furnished no more frequently than once per week, over the first 6 months of the MDPP core services period; at least 1 core maintenance session per month over months 7 to 12 of the MDPP core services period; and at least 1 ongoing maintenance session per month for up to 24 additional months (months 13 through 36 of the MDPP services period), if the beneficiary maintains eligibility for coverage of ongoing maintenance sessions. We recognize that beneficiaries might not attend these sessions. However, they must be made available, in accordance with CDC's DPRP standards, to beneficiaries as long as they are eligible for coverage of MDPP sessions. We further note that the set of MDPP services must be furnished in compliance with all applicable federal laws and regulations.

Although a beneficiary is not required to use MDPP services at all, the MDPP services period is initiated by the beneficiary attending his or her first core session, which begins the MDPP services period timeline. To qualify for coverage of ongoing maintenance sessions, a beneficiary would also need to attend at least 1 session during the final core maintenance session interval where in-person weight measurement is performed that demonstrates the achievement or maintenance of the required minimum weight loss.

All of the proposed performance payments except for the weight loss performance payments require the achievement of an attendance performance goal, and if a beneficiary does not achieve attendance performance goals, an MDPP supplier would not be paid a performance payment that relies on achieving those goals. For example, if a beneficiary does not attend 3 sessions in the first core maintenance session interval, a supplier would not be paid a performance payment for the interval that spans months 7 to 9 of the MDPP core services period. However, a supplier must offer at least 1 core maintenance session per month to the beneficiary to ensure that the beneficiary has the opportunity to attend. Furthermore, while the proposed weight loss performance payments are based solely on the achievement of the required minimum or 9 percent weight loss, we note that all weight loss measurements must be obtained in person at a session so that if a beneficiary does not attend a session where weight loss can be measured and compared to baseline, the MDPP supplier would not be paid a performance payment that relies on achieving a weight loss performance goal.

v. Payment Policies When a Beneficiary Changes MDPP Suppliers

In the CY 2017 PFS final rule (81 FR 80470), we confirmed that a beneficiary may change MDPP suppliers at any time. However, we deferred specific policies regarding attribution of beneficiaries who change MDPP suppliers as related to payment to future rulemaking. We are making proposals for payment policies when a beneficiary changes MDPP suppliers during the MDPP services period in this section.

At proposed § 414.84(a)(1), we are proposing to define ''bridge payment'' as a one-time payment to an MDPP supplier for furnishing its first MDPP services session to an MDPP beneficiary who has previously received one or more MDPP services from a different MDPP supplier. We use this definition in the proposed MDPP payment policies for the circumstances when a beneficiary changes MDPP suppliers for any reason during the MDPP services period after the beneficiary has attended at least the first core session.

In cases where the beneficiary changes MDPP suppliers, there is a shift in accountability for offering the set of MDPP services for which the beneficiary is eligible for coverage from one MDPP supplier to a subsequent MDPP supplier. Similar to our proposal for a performance payment to an MDPP supplier that furnishes the first core session to an MDPP beneficiary who initiates the MDPP services period as discussed in section III.K.2.d.iii.(3) of this proposed rule, we are proposing that an MDPP supplier would be paid a bridge payment of $25 for furnishing its first session to an MDPP beneficiary who has previously received MDPP services from a different MDPP supplier, regardless of whether the MDPP

supplier is paid any performance payments for that beneficiary. A subsequent MDPP supplier would be paid this bridge payment after furnishing the first session to a beneficiary and billing the appropriate HCPCS G-code only if the supplier did not furnish the first core session to the MDPP beneficiary.

We believe that making a bridge payment that is the same amount as the proposed performance payment for the first core session discussed in section III.K.2.d.iii.(3) of this proposed rule is appropriate because we expect the MDPP supplier's resources used to be similar under both of these circumstances. The subsequent supplier would expend resources for furnishing a first session to a beneficiary, including collecting administrative information on the beneficiary who is not already known to the supplier, regardless of whether the beneficiary goes on to receive further MDPP sessions from that supplier.

We are proposing that the bridge payment would be paid to the subsequent MDPP supplier any time a beneficiary changes suppliers during the MDPP services period, regardless of when during the core services period or ongoing services period the beneficiary changes MDPP suppliers. The bridge payment is not intended to be a performance payment, which could be paid to the subsequent MDPP supplier in addition to the bridge payment if a beneficiary achieves a performance goal while receiving MDPP services from that the subsequent supplier. Rather, the bridge payment accounts for the financial risk a subsequent MDPP supplier takes on by furnishing services to a beneficiary changing MDPP suppliers during the MDPP services period.

We believe that when suppliers furnish MDPP services to MDPP beneficiaries in these circumstances, they generally do not have the same opportunity for performance payments that they would have if the beneficiary had been receiving MDPP services from the supplier from the beginning of the MDPP services period because certain performance goals, such as the required minimum weight loss, might already have been achieved by the beneficiary. The proposed bridge payment policy would play an important role in ensuring access to MDPP services and freedom of choice of MDPP suppliers for those beneficiaries who either choose to or must change suppliers during the MDPP services period.

If we were to only make performance payments for MDPP services as proposed in sections III.K.2.d.iii.(3) through (6) of this proposed rule and not make a bridge payment to a subsequent supplier when an MDPP beneficiary changes suppliers during the MDPP services period, access problems could result due to the number of scenarios where subsequent MDPP suppliers offering and furnishing MDPP services would be paid no performance payment for the sessions furnished. The following examples illustrate such scenarios.

- A beneficiary changes from MDPP supplier A to MDPP supplier B after attending core session 4; attends core sessions 5 to 8 with supplier B; and then decides not to attend any more MDPP sessions. Supplier B does not meet the requirements for billing for the performance payment for the 9th core session because only 8 core sessions were attended, despite supplier B offering and furnishing core sessions 5 to 8.
- A beneficiary who has not met the required minimum weight loss performance goal changes from MDPP supplier A to MDPP supplier B after completing the first 3-month core maintenance session interval; attends 2 core maintenance sessions in months 9–12 with supplier B; and then fails to attend the 3rd core maintenance session in this interval. Supplier B does not meet the requirements for billing for the performance payment for the second core maintenance session interval despite offering and furnishing core maintenance sessions and the beneficiary eligibility for coverage of MDPP services then ends after month 12, the end of the core services period.

We believe that circumstances like these examples where subsequent MDPP suppliers would receive no payment for sessions furnished to MDPP beneficiaries who change suppliers during the MDPP services period in the absence of the bridge payment policy could lead to those MDPP suppliers preferentially seeking to furnish the remaining MDPP services during the MDPP services period to beneficiaries who have either already achieved the required minimum weight loss, or whom they believe will attend sessions and achieve weight loss, because the required minimum weight loss is tied to eligibility for ongoing maintenance sessions and higher performance payment for core maintenance session intervals.

We note that we are proposing in section III.K.2.e.iv.(4) of this proposed rule that MDPP suppliers may not deny access to MDPP services to eligible beneficiaries based on any reason other than the supplier's own capacity limits to furnish MDPP services to additional beneficiaries and on a discretionary basis if a beneficiary significantly disrupts the session for other participants or becomes abusive. However, MDPP suppliers could comply with this access requirement, while still preferentially seeking to furnish the remaining MDPP services in the MDPP services period to MDPP beneficiaries they believe are most likely to achieve the performance goals. To ensure beneficiary freedom of choice of MDPP supplier, including the choice to change suppliers, we believe the proposal to make a bridge payment helps mitigate the likelihood of MDPP suppliers acting on such preferences. The subsequent supplier would be paid a bridge payment for a beneficiary who changes suppliers, even if the beneficiary does not achieve performance goals that result in a performance payment being made to the subsequent supplier.

We considered an alternative policy in which the bridge payment would only be made in circumstances where the subsequent supplier would not be paid a performance payment that is based on attendance at the first session furnished by that supplier. For example, under this alternative if a beneficiary attends the 1st session during the ongoing maintenance session interval for months 13 through 15 at one MDPP supplier and then changes to a subsequent MDPP supplier that furnishes two additional ongoing maintenance sessions within that same interval and the beneficiary maintains the required minimum weight loss, the subsequent supplier would *not* be paid the $25 bridge payment but would be paid the ongoing maintenance session interval performance payment for months 13 through 15. The subsequent supplier would only be paid the $25 bridge payment if the beneficiary did not maintain the required minimum weight loss for the performance payment for that ongoing maintenance session interval. We are not proposing this alternative because we believe it is appropriate to make a bridge payment for the first session furnished by the subsequent supplier that expends resources for furnishing a session to a beneficiary not previously known to that supplier, unrelated to whether or not the beneficiary achieves a performance goal that results in a performance payment being paid to the subsequent supplier.

We are proposing that an MDPP supplier can be paid either one performance payment for furnishing the first core session or one bridge payment per beneficiary, but not both. We are proposing this policy because we

believe that the potential to be paid both a performance payment for the first core session and a bridge payment, or multiple bridge payments, for the same beneficiary, could increase the risk of MDPP suppliers encouraging discontinuous care patterns. Such patterns could hinder the achievement of the required minimum weight loss that leads to a reduction in the incidence of type 2 diabetes and could lead to increased Medicare expenditures for MDPP services. Financial incentives resulting from the potential for multiple bridge payments to a single supplier for one beneficiary could lead MDPP suppliers to encourage beneficiaries to repeatedly change among them between sessions during the MDPP services period so that the suppliers may repeatedly bill for bridge payments. We believe that limiting the bridge payment to one per beneficiary per supplier and making it available for payment only if the performance payment for the first core session was not paid to that same supplier helps mitigate this risk. However, we are not proposing to limit the number of MDPP suppliers that may be paid a bridge payment for a particular beneficiary because we are not proposing to limit beneficiary freedom of choice for MDPP suppliers. We are proposing only to limit the bridge payments that a particular MDPP supplier may be paid for each MDPP beneficiary to one.

While this proposed limit is intended to provide some protection against MDPP suppliers encouraging certain care patterns for the purposes of their financial gain alone, we understand there may be organizations enrolled in Medicare as the same supplier type but under separate MDPP supplier enrollment records that are part of a larger franchise or umbrella organization with shared financial interests. There is some program integrity risk that these organizations could coordinate to bill multiple bridge payments that would ultimately increase total MDPP payments to separately enrolled MDPP suppliers to serve the financial interests of the umbrella organization. This scenario could occur if MDPP suppliers systematically encourage beneficiaries to change suppliers for the purpose of being paid the bridge payment.

Although we believe that organizations under a larger umbrella organization may have a greater financial incentive and opportunity to engage in this behavior, we understand that any two or more MDPP suppliers could coordinate in this way, potentially affecting large numbers of MDPP beneficiaries. To mitigate this risk, we are proposing to prohibit MDPP suppliers and other individuals or entities performing functions or services related to MDPP services on an MDPP supplier's behalf from unduly coercing an MDPP beneficiary's decision to change or not to change to a different MDPP supplier, including through the use of pressure, intimidation, or bribery as described further in section III.K.2.e.iv.(4). of this proposed rule. We will monitor MDPP supplier billing patterns to detect how frequently bridge payments are paid and to determine whether patterns exists that may suggest fraudulent activity regarding bridge payment claim submissions across suppliers, conducting audits, medical reviews, and investigations as appropriate.

In the CY 2017 PFS final rule, we finalized at § 410.79(b) that a beneficiary's baseline weight refers to the MDPP beneficiary's body weight recorded during that beneficiary's first core session. This definition applies to determine weight loss throughout the MDPP services period. Additionally, the once-per-lifetime policy finalized at § 410.79(d)(1) applies if a beneficiary changes MDPP suppliers, and the services furnished by the subsequent supplier would begin where the beneficiary left off with the previous supplier. We recognize these policies may require the beneficiary to request that a copy of his or her MDPP record be provided by the previous supplier to the subsequent supplier so that subsequent supplier can determine whether the beneficiary achieves or maintains the required minimum weight loss and has information about the MDPP services already furnished. We also finalized at § 424.59(b) (proposed to be redesignated and amended as § 424.205(g)) that an MDPP supplier shall maintain documentation that includes services furnished and body weight measurements. Finally, we finalized at § 424.59(b) (proposed to be redesignated and amended as § 424.205(g)) that MDPP suppliers are required to maintain and handle any beneficiary PII and PHI in compliance with HIPAA, other applicable privacy laws and CMS standards. Any sharing of information from a beneficiary's MDPP record between MDPP suppliers must follow these rules.

We are considering ways to streamline the sharing of this information between suppliers, such as through the development of a model tracker that logs the contact information of a beneficiary's previous supplier and/or coach, and the beneficiary's attendance and weight loss. Beneficiaries could take the tracker with them if they change suppliers during the MDPP services period. Such a tracker would not supplant the previous supplier's beneficiary MDPP record which the subsequent supplier would need to have a copy of in order to consider sessions furnished by the previous supplier in determining whether the subsequent supplier could bill for a performance payment that was based in part on those prior sessions as discussed in section III.K.2.d.iii.(10)(b) of this proposed rule. If the subsequent supplier does not have the beneficiary's MDPP record from the previous supplier, the subsequent supplier cannot use information from the sessions furnished by the previous supplier, such as weight or session attendance, to determine that the performance goals for a performance payment were met so that the subsequent supplier can bill for the performance payment. However, it may help facilitate the process for subsequent suppliers to enroll beneficiaries partway through the MDPP services period while the subsequent supplier is coordinating with the previous supplier to obtain a copy of the beneficiary's MDPP record from that supplier. We are inviting public comments on additional ways this data sharing could be streamlined between suppliers.

The proposed bridge payment is included at proposed § 414.84(c). We are inviting public comments on this proposal and the alternative considered.

e. Supplier Enrollment and Compliance

In the CY 2017 PFS final rule, we established MDPP supplier enrollment eligibility and revocation policies at § 424.59. We propose to add subpart I, which includes §§ 424.200, 424.205, and 424.210. This subpart specifies the requirements for Medicare Diabetes Prevention Program suppliers and beneficiary engagement incentives under the Medicare Diabetes Prevention Program expanded model. We propose to redesignate all requirements under § 424.59 to § 424.205. These requirements previously finalized in the CY 2017 PFS final rule created MDPP suppliers as a new Medicare supplier type, and require that any organization seeking to furnish and receive payment for MDPP services must enroll as this supplier type. Given that the set of MDPP services utilizes CDC's DPRP curriculum, in the CY 2017 PFS final rule we established supplier eligibility criteria that closely match CDC's DPRP standards. The CY 2017 PFS final rule provides that any organization that meets full CDC DPRP recognition will be eligible to enroll as an MDPP

supplier. In this proposed rule, we are proposing to build on these eligibility criteria for enrollment, as well as make some changes, as described in further detail later in this section.

The CY 2017 PFS final rule also established other requirements related to MDPP suppliers. For example, we assigned MDPP suppliers to the high-risk screening category under § 424.518. We also established the policy that coaches will not enroll in Medicare for purposes of furnishing MDPP services, but that they would be required to obtain NPIs. We established that MDPP suppliers must submit the active and valid NPIs of all affiliated coaches and provide updates of this information to us within 30 days of a coach beginning or ceasing to furnish MDPP services. We provided that this roster of coach information must include the first and last name, social security number (SSN), and NPI. The proposals outlined in this section seek to build on these requirements.

In the CY 2017 PFS final rule, we acknowledged that many DPP organizations have not yet achieved full CDC DPRP recognition, and that it might take 36 months to meet CDC's performance standards for full recognition. We believe allowing only organizations with full recognition to enroll as an MDPP supplier would limit the number of organizations with demonstrated capacity to furnish MDPP services, and therefore, constrain beneficiary access to these services. However, we deferred to future rulemaking addressing the issue of allowing certain DPP organizations with less than full CDC recognition to enroll in Medicare.

We are proposing an MDPP interim preliminary recognition standard under CMS authority (proposed at § 424.205(c)). We also are proposing that organizations that meet this standard would be eligible to enroll in Medicare as an MDPP supplier.

i. Preliminary Recognition

The current CDC 2015 Diabetes Prevention Recognition Program (DPRP) Standards do not have standards for preliminary recognition. In the CY 2017 PFS final rule, we indicated that we would align the CDC's DPRP and the set of MDPP services, to the extent possible. It will not be possible for CMS to permit DPP organizations to enroll as MDPP suppliers based on achievement of any new CDC standard through this rulemaking because any updates to the CDC Standards are not expected to go into effect until 2018.

However, our intent is to allow organizations that do not yet have full recognition, but have demonstrated a capacity to furnish DPP services, to enroll in Medicare as of the effective date of the enrollment policies proposed in this rule. We believe this will increase access to MDPP services. For this reason, we are proposing, at § 424.205(c), to establish an MDPP interim preliminary recognition standard to permit DPP organizations who meet this standard to enroll in Medicare even if they do not have full CDC recognition. This MDPP interim preliminary recognition standard will be hereafter referred to as ''interim preliminary recognition.'' As we stated in CY 2017 PFS final rule, our intent with this policy is to bridge the gap until such time as any CDC preliminary recognition standards are established. Once we have established the transition process with CDC, we would expect DPP organizations that seek to enroll into Medicare to obtain CDC preliminary recognition, but MDPP suppliers who have enrolled in Medicare with interim preliminary recognition would maintain their enrollment eligibility as an MDPP supplier.

(1) MDPP Interim Preliminary Recognition Standard

We are proposing, at § 424.205(c)(2)(ii), that DPP organizations with pending CDC recognition that meet the following additional criteria would meet the interim preliminary recognition standard:

- The organization must continue to follow the current 2015 CDC DPRP Standards for data submission and submit a full 12 months of performance data to CDC on at least one completed cohort (see Appendix D, 2015 CDC DPRP Standards, *https://www.cdc.gov/diabetes/prevention/pdf/dprp-standards.pdf*). For this purpose, a completed cohort is a set of at least five participants that entered into a lifestyle change program that has a fixed first and last session and runs for 12 months. An organization can have multiple cohorts running at the same time:
- The 12-month data submission to CDC includes at least 5 participants who attended at least 3 sessions in the first 6 months, and whose time from first session attended to last session of the lifestyle change program was at least 9 months; and
- Of the participants eligible for evaluation in the first criterion, at least 60 percent attended at least 9 sessions in months 1 through 6 and at least 60 percent attended at least 3 sessions in months 7 through 12.

All proposed data requirements reflect current reporting requirements to progress from pending recognition to full recognition through CDC's DPRP; no new data collection would be required. To implement the proposed interim preliminary recognition standard, DPP organizations with pending recognition would submit data following CDC's typical recognition process. For the current standards, this includes data submission every 12 months, during the month of the anniversary of the effective date. The organization's data submission should include: (1) Data for all sessions attended by participants from the approval date to the day before the first anniversary of the effective date, (if the organization has a 2016 effective date; this should include at least 6 months of participant data) *or* data for all sessions attended by participants from the last anniversary of the effective date to the day before the next anniversary of the effective date (if an organization's effective date is before 2016); and (2) one record for each session attended by each participant during the preceding year. CDC would perform a new assessment, interim preliminary recognition, on our behalf. Our interim preliminary recognition will be evaluated by CDC based on those data submissions that use the timetables and submission deadlines that currently apply for CDC recognition. For interim preliminary recognition governed under this regulation, CDC would provide us with its recommendation as to which organizations have met the recognition standards for interim preliminary recognition, but we, using our authority, would make the final decision. CMS would not make any determination for recognition status governed under current or future CDC DPRP recognition processes. We believe that such an approach would minimize burden for DPP organizations, promote consistency in the application of the standards, and allow for a smooth transition if and when CDC adopts preliminary recognition standards. We intend to release additional guidance on the details of this process once the CDC 2018 Standards are released.

(2) MDPP Supplier Enrollment Under the MDPP Interim Preliminary Recognition Standard

Our regulations at § 424.59 (proposed to be redesignated and amended at § 424.205 in this proposed rule) specify that a DPP organization with full CDC recognition is eligible for enrollment as an MDPP supplier if it also meets all of the other conditions for enrollment in § 424.59(a) (proposed to be redesignated and amended at § 424.205(b) in this

proposed rule). We are proposing that organizations that meet the MDPP interim preliminary recognition standard, as proposed in section III.K.2.e.i.(1) of this proposed rule, and meet all other enrollment conditions would also be eligible to enroll as an MDPP supplier.

We also are proposing that DPP organizations would be eligible to enroll as an MDPP supplier if they meet CDC DPRP Standards for preliminary recognition, once any such standards go into effect (proposed § 424.205(c)(2)(i)). We anticipate that CDC's preliminary recognition standards will be established on or after January 1, 2018. After the effective date of any updated CDC standards, we are proposing that MDPP suppliers who have enrolled in Medicare with MDPP interim preliminary recognition would continue to be eligible for MDPP enrollment (assuming they continue to meet all other requirements for enrollment, described in proposed § 424.205(b)).

We intend to ensure that any transition an MDPP supplier may make from interim preliminary recognition to CDC preliminary recognition does not disrupt its status as an MDPP supplier. We will address possible transition issues in future rulemaking or guidance, as appropriate.

We considered an alternative to wait until new CDC DPRP standards are effective to allow organizations other than those with full recognition to enroll as MDPP suppliers. However, as indicated in the CY 2017 PFS final rule, based on CDC data we believe that waiting until the new DPRP standards are effective would limit the number of organizations with demonstrated capacity to furnish the set of MDPP services from enrolling in Medicare when enrollment starts and offering MDPP services once they become effective. We are inviting public comments on this proposed MDPP interim preliminary recognition standard, including performance standards, and the use of this standard as a condition for enrollment in Medicare, and the alternative considered.

ii. Enrollment and Billing Effective Dates

(1) Date MDPP Suppliers May Begin Enrollment

As described in section III.K.2.a. of this proposed rule, we are proposing to change the start date of the MDPP expanded model to April 1, 2018. All other policies not related to the furnishing or billing of MDPP services would, if finalized, be effective January 1, 2018. Thus, although MDPP suppliers would not be able to begin furnishing MDPP services on January 1, 2018, MDPP supplier enrollment would begin on January 1, 2018, if these proposals are finalized. In the CY 2017 PFS final rule, we established that any organization wishing to furnish MDPP services must enroll as an MDPP supplier, regardless of any existing enrollment in Medicare. As indicated in section J.4. of the CY 2017 PFS final rule, we believe that including an effective date for enrollment that precedes the implementation date for MDPP services is necessary to allow organizations sufficient time to enroll as MDPP suppliers. Thus, MDPP services would only become available after there is sufficient time to enroll MDPP suppliers that will furnish those services.

(2) Effective Date of MDPP Suppliers' Billing Privileges

Under § 424.502, the definition of enroll/enrollment means ''the process that Medicare uses to establish eligibility to submit claims for Medicare-covered items and services, and the process that Medicare uses to establish eligibility to order or certify Medicare-covered items and services.'' Thus, the purpose of enrollment is to establish billing privileges in Medicare. In accordance with our proposal that MDPP services will be available beginning on April 1, 2018, we propose that MDPP suppliers may not have an effective date of billing privileges that precedes the date that MDPP services become available (proposed at § 424.205(e)(2). Given that it typically takes an enrollment application 45–60 days to process, if an MDPP supplier submitted its application in January, the application may be approved prior to when MDPP services become available. For this reason, we are specifying a proposal that, under no circumstances would an MDPP suppliers have an effective date for billing privileges for MDPP services prior to April 1, 2018.

We propose that for MDPP supplier enrollment applications that are submitted and subsequently approved, the effective date for billing privileges would be the date the application was submitted. However for applications submitted and subsequently approved prior to April 1, 2018, we propose that the effective date for billing privileges would be April 1, 2018. This proposal is consistent with other suppliers like physicians, non-physician practitioner organizations, ambulance suppliers, and independent diagnostic testing facilities (IDTFs). However, unlike physicians, non-physician practitioner organizations, and ambulance suppliers, MDPP suppliers would not be permitted to retrospectively bill for services rendered prior to their effective date for billing privileges. Given that MDPP suppliers do not furnish services with immediate impacts on health like the aforementioned Part B suppliers, we chose to utilize the approach of IDTFs. We have established MDPP supplier standards as a condition of enrollment, as described in section III.K.2.e.iv of this proposed rule (proposed at § 424.205(d)), and MDPP suppliers are required to certify in their enrollment application that they are in compliance and will continue to remain in compliance with all MDPP supplier standards. Therefore, generally, an MDPP supplier could begin furnishing services on the date the application was submitted, with the goal of having their application subsequently approved. However, payment for those services would depend upon whether the enrollment application is subsequently approved.

We propose that for any enrollment application that is denied under § 424.530(a)(1) for non-compliance, but then subsequently approved due to the submission of a corrective action plan (CAP), the effective date of enrollment would be the date of the CAP submission. This proposal is also consistent with practices for existing suppliers, and institutes an appropriate safeguard for Medicare beneficiaries and the program at-large by prohibiting services from being furnished from suppliers who are not compliant. We acknowledge, however, that if a supplier began furnishing services the date it submitted its application, but was then denied enrollment, it would not be paid for any services it furnished prior to the date it submitted the CAP, if approved. However, as described in section III.K.2.e.iv of this proposed rule (proposed at § 424.205(d)), upon submitting its enrollment application, an MDPP supplier certifies that—to its knowledge—it meets and agrees to continue to meet the following MDPP supplier standards, and all other applicable Medicare requirements. Thus, at the time the MDPP supplier applicant submits its application, it should believe that its enrollment application will be approved. Examples of actions the MDPP supplier could take to improve its certainty and increase the probability that the application will be approved may include reviewing any MDPP supplier supporting documentation to fully understand MDPP supplier enrollment requirements and accompanying CMS guidance or

supplier support materials, confirming compliance with the MDPP supplier standards in this rule (including conducting background checks for those who would be screened by CMS during the enrollment process as required under § 424.518(c) and proposed § 424.205(d)(3)), and conducting a thorough review of the enrollment application to ensure no mistakes exist in the submitted application.

We also propose that if an MDPP supplier adds a new administrative location (defined and discussed further section III.K.2.e.iii.(2) of this section of the proposed rule) that resulted in a new enrollment record or Provider Transaction Access Number (PTAN), the effective date for billing privileges would be the date the MDPP supplier began its MDPP operations at that location. We believe that this proposal is appropriate given that it follows a similar approach for an effective date that applies to when physician organizations, non-physician practitioner organizations, ambulance suppliers, and Independent Diagnostic Testing Facilities (IDTFs) add a new practice location to an existing enrollment record. Though the definition of administrative location differs from that of practice location, it provides a similar function. We seek comments on these proposals.

iii. Enrollment Application

(1) Enrollment Application Type Applicable to MDPP Suppliers

We are proposing to require the use of a new, CMS-approved enrollment application specific to MDPP suppliers. We believe that the creation of a new application will be more easily navigated by and reduce the burden on new, non-traditional suppliers because the new enrollment application will only solicit information relevant to the MDPP supplier type. As this new enrollment application is being created specifically for the MDPP expanded model, we have determined that this new enrollment application is exempt from the Paperwork Reduction Act in accordance with section 1115A(d)(3) of the Act. Further, this enrollment application would be considered an ''enrollment application'' for purposes of part 424 subpart P, and therefore, all existing regulations and administrative guidance that govern the CMS–855 enrollment applications would apply to this new form, unless otherwise specified. We also considered an alternative option to amend the current CMS–855B Medicare Enrollment Application for Clinics/Group Practices and Certain Other Suppliers (CMS–855B) for MDPP supplier enrollment, but we determined that the existing length and complexity of the CMS–855B enrollment application and its applicability to other non-MDPP suppliers may add burdens or unnecessary confusion to MDPP suppliers given that many sections of the current CMS–855B enrollment application would not apply to MDPP suppliers. In addition, we would need to add new sections to solicit information specific to MDPP suppliers, which would only further increase the length of the CMS–855B enrollment application. We invite public comments on this proposal.

(2) Information on MDPP Enrollment Application

On the new MDPP enrollment application, we intend to solicit information specific to MDPP suppliers, as well as information consistent with existing reporting requirements applicable to all suppliers who enroll through the CMS–855B enrollment application, while excluding all reporting requirements that do not apply to MDPP suppliers. As a Medicare supplier enrolling under part 424 subpart P, MDPP suppliers are required to provide complete and accurate information on the MDPP enrollment application, or be subject to enrollment denial under § 424.530(a)(4) or revocation under § 424.535(a)(4). This requirement would include all information solicited on the MDPP-specific enrollment application. The MDPP-specific enrollment application is under development and will be available prior to its use, if this proposal is finalized. While the application is being developed, we wish to indicate some of the information we intend to include on the MDPP enrollment application, as further described in this section.

As finalized in the CY 2017 PFS final rule, § 424.59(a)(5) requires that MDPP suppliers submit the active and valid NPIs of all coaches who will furnish services on the supplier's behalf, as well as their first name, last name, and SSN (in this proposed rule, § 424.59(a)(5) is proposed to be redesignated and amended at § 424.205(b)(4)). We are proposing, at § 424.205(b)(4), to require that MDPP suppliers provide this identifying information of the coaches directly through the enrollment application. This information will be used to complete background checks of the coaches. To accompany the coach identifying information, we propose to require MDPP suppliers to provide an eligibility start and end date, if applicable, for each coach on the supplier's roster. Coach eligibility start and end dates are described at length in section III.K.2.e.iv.(2). As described in more detail in section III.K.2.e.iv., the background checks would be used to prevent MDPP suppliers from allowing coaches to furnish MDPP services when certain adverse histories may indicate potential to harm Medicare beneficiaries or undermine program integrity. We outline further details on our proposed enforcement of this provision in section III.K.2.e.iv. of this proposed rule.

To enable us to conduct background checks of coaches, we are proposing that MDPP suppliers also submit to CMS the date of birth of all coaches who will furnish MDPP services (proposed § 424.205(b)(4)). Combined with other identifying information, date of birth plays a critical role in validating an individual's identity. By collecting date of birth, we would be able to more accurately screen coaches, including accurately conducting a background check, and distinguishing them in the Provider Enrollment, Chain and Ownership System (PECOS). In addition, we want to ensure that we have the capability to most accurately identify individuals reported on the form. To mitigate potential confusion or error found when individuals have common names, we are proposing to collect coach's middle initial (if applicable) on the enrollment application (proposed § 424.205(b)(4)). We believe that this proposal will help to lessen the possibility that CMS or its contractors misattribute the background of one individual for another.

We are proposing, at § 424.205(d)(4), that MDPP suppliers would identify their administrative location(s) by reporting these location(s) on their enrollment application. We are proposing, at § 424.205 (a), to define administrative location as the physical location associated with the supplier's operations, from where coaches are dispatched or based, and where MDPP services may or may not be furnished. We are proposing that an MDPP supplier must have at least one such administrative location, and report any additional administrative locations of the supplier, if MDPP services are either furnished at these locations and/or if the location reflects from where coaches are dispatched or based. For example, if an MDPP supplier operated 2 locations, but only 1 of the 2 locations associated with the entity offered MDPP, only the location offering MDPP would be considered an administrative location. If coaches began offering MDPP in community settings (described in the subsequent paragraph and proposed to be defined at § 424.205(a), but were

dispatched and/or based out of the other non-administrative location, then this location would then be considered under the definition of an administrative location, and would need to be reported on the MDPP enrollment application within 90 days of the change. Given that MDPP suppliers are categorized as high risk under § 424.518, these administrative locations may be subject to site visits prior to approval of an enrollment application. Collecting information on the MDPP supplier's administrative location (regardless whether they furnish services in this location) is important because we may utilize this information to verify that the organization is operational per requirements under proposed § 424.205(d)(4) and (6), discussed in detail in section III.K.2.e.iii.(3) of this proposed rule.

While we recognize that many suppliers furnish MDPP services outside of their administrative locations in community settings, we are proposing to only require enrollment of the administrative locations. In proposed § 424.205(a), we define ''community setting'' as a location where the MDPP supplier furnishes MDPP services outside of their administrative locations. A community setting is a location open to the public, not primarily associated with the supplier. Community settings may include, for example, church basements or multipurpose rooms in recreation centers. When determining whether a location is considered an administrative location or a community setting, MDPP suppliers should consider whether their organizational entity is the primary user of that space and whether coaches are based or dispatched from this location. If so, the location would be considered an administrative location, even if this location dually serves as a community setting. In comparison, community settings are locations not primarily associated with the supplier where many activities occur, including MDPP services.

We seek public comments on these proposals.

(3) Updating Information on MDPP Enrollment Application

We are proposing, at § 424.205(d)(5), that MDPP suppliers must update their enrollment application within 30 days of any changes of ownership, changes to the coach roster, or new final adverse action history of any individual or entity required to report such information on the enrollment application. We are proposing that MDPP suppliers report all other changes to information required on the enrollment application within 90 days of the reportable event. Timely reporting and updating of information plays a critical role in our ability to protect Medicare beneficiaries and protect the integrity of the Medicare program and Trust Funds. We believe that these requirements are fair and consistent with existing reporting requirements for other Medicare suppliers.

All suppliers are required to report changes of ownership and new adverse action history within 30 days. Adding the requirement that any changes to the coach roster be reported within 30 days is consistent with IDTFs requirements at § 410.33(g)(2). Although IDTFs differ from MDPP suppliers in many ways, IDTFs must report a roster of supervising physicians who serve functions on the supplier's behalf and must also report changes to this roster within 30 days. Given this similarity with IDTFs, we modeled our approach after this process. However, we note that while MDPP suppliers would be required to submit changes to the coach roster within 30 days, we would encourage them to submit such changes as soon as possible, due to reasoning explained further in section III.K.2.e.iv.(2) of this proposed rule.

We invite public comments on these proposals.

(4) Enrollment Application Fee

In the CY 2017 PFS final rule, we finalized that MDPP suppliers would enroll in Medicare. We solicited comments on, but did not propose or finalize, an applicable application fee associated with the MDPP supplier's enrollment. In this proposed rule, we propose to amend the definition of ''institutional provider'' as defined under § 424.502, to include MDPP suppliers such that, § 424.514, which governs the application fee, would similarly apply to MDPP suppliers. ''Institutional providers'' that are initially enrolling in Medicare, revalidating their enrollment, or adding a new Medicare practice location are required to submit a fee with their enrollment application. We would like to highlight that while we are proposing to include MDPP suppliers as an institutional provider, MDPP suppliers utilize administrative locations, not practice locations, and therefore the fee would not apply when adding a new administrative location to an existing enrollment record. The application fee is adjusted annually, and additional information about how the adjustment is calculated may be found in the November 7, 2016 **Federal Register** notice establishing the calendar year 2017 application fee (81 FR 78159). For calendar year 2017, the application fee is $560. Section 6401(a) of the Patient Protection and Affordable Care Act (as amended by section 10603 of the Affordable Care Act, amended section 1866(j)(2)(C) of the Act to require the Secretary to impose a fee on each institutional provider of medical or other items or services or supplier. This fee would be used for program integrity efforts including to cover the cost of screening and to carry out the provisions of sections 1866(j) and 1128J of the Act. Given that section 10603 of the Affordable Care Act excludes individual practitioners, such as physicians and nurse practitioners, from paying an enrollment application fee, we have previously determined that an ''institutional provider'' to include any provider or supplier that submits a paper Medicare enrollment application using the CMS–855A, CMS–855B (not including physician and non-physician practitioner organizations), CMS–855S or associated Internet-based PECOS enrollment application.[26] MDPP suppliers are entities, and not individual practitioners. We believe that they would similarly qualify as a ''provider of medical or other items or services'' used to define institutional providers. Taken together, we believe that the definition of institutional provider would also apply to MDPP suppliers. Given that the CY 2017 PFS final rule established that MDPP suppliers would be screened under high categorical risk (codified at § 424.59(a)(3), proposed to be redesignated as § 424.205(b)(3)(i)), the application fee would play an important role in executing particular aspects of the high-risk screening. As we noted in the CY 2017 PFS final rule, any organization that faces financial difficulty related to the application fee may apply for a hardship exception. For more information on the hardship exemption, see *https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLN MattersArticles/downloads/MM7350.pdf.* We are soliciting comments on this proposal.

iv. MDPP Supplier Standards

We are proposing to establish standards that MDPP suppliers must meet and remain in compliance with to be eligible to receive payment for an MDPP service (proposed § 424.205(d)). These supplier standards would build on the conditions for enrollment established under existing § 424.59(a) (which in this proposed rule is

[26] See CMS–6028–FC for further discussion, 76 FR 5862 and 5907 through 5908 (Feb. 2, 2011).

proposed to be redesignated and amended at paragraph § 424.205(b)), as well as any existing Medicare requirements that apply to all suppliers. We are proposing that an MDPP supplier wishing to participate in MDPP must adhere to current Medicare MDPP supplier requirements as outlined in § 424.59 (proposed to be redesignated as § 424.205), as well as all other requirements that apply to Medicare providers and suppliers. MDPP suppliers may choose to utilize a third party administrator, billing agent, or other entity to comply with the requirements of § 424.59 (proposed to be redesignated as § 424.205). Regardless of any use of such entities, any failure to comply with the standards of § 424.205(d) or other relevant Medicare requirements, may result in an enrollment denial under § 424.530(a)(1), revocation of the MDPP supplier for non-compliance under § 424.535(a)(1) or other revocation authority, as appropriate (as proposed in § 424.205(g)). Consistent with existing regulations, we are proposing that MDPP suppliers would have appeal rights under part 498.

We believe that the standards outlined in this section are generally consistent with standards established for other Medicare suppliers while adding safeguards to help ensure compliance with MDPP rules and regulations specific to this expanded model. Because this expanded model would pay MDPP suppliers based on a beneficiary's achievement of performance goals, we believe that it is prudent to include additional requirements consistent with the Office of the Inspector's General's compliance guidance,[27] to promote adherence to applicable statutes, regulations, and program requirements and help reduce fraud, waste, and abuse. In addition to the proposed standards, the MDPP expanded model will be routinely monitored for compliance with supplier standards, consistent with section 1893 of the Act (42 U.S.C. 1395ddd). Although we recognize that these standards may be new for MDPP suppliers and would, if finalized, impose additional requirements on these organizations that they may not otherwise face, both individually and collectively, these standards play an important role in ensuring the integrity of the Medicare program and the safety of our beneficiaries. Therefore, given the goals of these proposed standards to mitigate fraud, waste, or abuse to the Medicare program and its beneficiaries, we believe that they are appropriate for governing MDPP suppliers and do not place an undue burden on suppliers. We are inviting public comments on our proposed approach, as well as any unintended consequences or burdens that we may have not considered.

(1) Medicaid Terminations

In addition to establishing standards for MDPP suppliers with respect to their delivery of MDPP services, we also are proposing standards for MDPP suppliers' general eligibility to furnish services to Medicare beneficiaries. These standards would establish program integrity safeguards that would protect both Medicare beneficiaries and the Medicare program. We are proposing that MDPP suppliers must not currently have their billing privileges terminated for-cause from any State Medicaid program or be excluded from any State Medicaid program (proposed § 424.205(d)(2)). If a supplier's Medicaid billing privileges are currently terminated from or the supplier is excluded from any State Medicaid program, we do not believe that supplier should be able to furnish Medicare services. We believe that this proposal is warranted given that a supplier's improper behavior in another Federal health care program may be duplicated in Medicare. We believe that this proposed requirement would mitigate the MDPP expanded model's susceptibility to fraud, waste, and abuse. Consistent with all standards in this section, any MDPP supplier who does not meet this requirement would be subject to a Medicare enrollment denial or revocation. We believe that this proposed standard would serve to ensure continuity of safeguards across Federal health care programs, and will help preserve the integrity of the Medicare program and protect beneficiaries by prohibiting suppliers found to be noncompliant in one Federal health care program from enrolling in and furnishing services in another.

We seek comments on this proposal.

(2) Ineligible Coaches: Individuals Prohibited From Furnishing MDPP Services to Medicare Beneficiaries

We are proposing, at § 424.205(d)(3), that the MDPP supplier must report coach information on its enrollment application and the MDPP supplier must only permit MDPP services to be furnished by individual coaches who meet the eligibility criteria. We propose, at § 424.205(e)(1) that MDPP coach eligibility criteria require that a coach must not:

- Currently have his or her Medicare billing privileges revoked and whose reenrollment bar has not yet expired. We believe that this proposed supplier standard would protect beneficiaries from receiving MDPP services from individuals already prohibited from furnishing other Medicare services. If an individual is precluded from maintaining enrollment in Medicare for a non-MDPP service, we believe that it is prudent that they similarly not furnish MDPP services.
- Currently have his or her Medicaid billing privileges terminated for-cause or is excluded from any State Medicaid Agency (proposed at § 424.205(e)(1)(ii)). We believe that this proposed supplier standard is warranted given that an individual's improper behavior in another Federal health care program may be duplicated in Medicare. We do not believe that we should permit MDPP suppliers to allow coaches with current for-cause terminations or exclusions in Medicaid to furnish MDPP services to Medicare beneficiaries.
- Currently be excluded from any other Federal health care program, as defined in § 1001.2 of this chapter, in accordance with section 1128, 1128A, 1156, 1842, 1862, 1867 or 1892 of the Act. This includes, but is not limited to, the Office of Inspector General (OIG)'s List of Excluded Individuals and Entities (LEIE). We are proposing this supplier standard for similar reasons we are proposing not to permit coaches with revocations from Medicare or current exclusions from Medicaid to furnish MDPP services.
- Currently be debarred, suspended, or otherwise excluded from participating in any other Federal procurement or non-procurement program or activity in accordance with the Federal Acquisition Streamlining Act implementing regulations and the Department of Health and Human Services non-procurement common rule at 45 CFR part 76. We note that this includes individuals who have an active status on the General Service Administration's System for Award Management list. We may also utilize the Bureau of the Fiscal Service, U.S. Department of the Treasury's Do Not Pay (DNP) List as a resource for determining which individuals fall under this category. The Improper Payments Elimination and Recovery Improvement Act (IPERIA) of 2012 established the DNP to support Federal agencies with their efforts to prevent and detect improper payments by aggregating various data sources for pre-award, pre-payment eligibility verification. Data sources included in this list include Credit Alert System,

[27] *https://oig.hhs.gov/compliance/compliance-guidance/.*

Death Master File, LEIE, Office of Foreign Assets Control (OFAC), System for Award Management (SAM) Entity Registration Records, and SAM Exclusion Records. We believe that we may utilize the DNP as a method of determining whether a coach is excluded from participating in any other federal procurement or nonprocurement programs. Although coaches will not directly be receiving payment from us for furnishing MDPP services, we do not believe that payment should be made to MDPP suppliers for services furnished by individuals excluded from federal procurement or nonprocurement programs, particularly given that MDPP payments rely on beneficiary's achievement of performance goals that the coaches will document. Although the MDPP supplier is ultimately responsible for attesting to all claims submitted for MDPP services, we do not believe that it would be prudent to permit MDPP suppliers to allow coaches excluded from other federal procurement programs to furnish MDPP services.

• Have, in the previous 10 years, one of the following state or federal felony convictions:

++ Crimes against persons, such as murder, rape, assault, and other similar crimes for which the individual was convicted, as defined under 42 CFR 1001.2, had a guilty plea or adjudicated pretrial diversion.

++ Financial crimes, such as extortion, embezzlement, income tax evasion, insurance fraud and other similar crimes for which the individual was convicted, as defined under 42 CFR 1001.2, had a guilty plea or adjudicated pretrial diversion.

++ Any felony that placed the Medicare program or its beneficiaries at immediate risk, such as a malpractice suit that results in the individual being convicted, as defined under 42 CFR 1001.2, having a guilty plea or having adjudicated pretrial diversion of criminal neglect or misconduct.

++ Any felonies that for which the individual was convicted, as defined under 42 CFR 1001.2, had a guilty plea or adjudicated pretrial diversion that would result in mandatory exclusion under section 1128(a) of the Act.

We propose that CMS will screen each individual identified on the roster of coaches included with the supplier's enrollment application to verify that the individual coach does not meet any of these conditions and that the coach can provide MDPP services on behalf of an MDPP supplier (proposed at § 424.205(e)(2)). We are proposing these requirements as a means to ensure the integrity and safety of the Medicare program and the beneficiaries whom we serve. We have selected these types of felony convictions based on the risk we believe they could pose to the Medicare program and our beneficiaries. Additionally, it is consistent with existing criteria that we use to determine felonies that are detrimental to the best interest of the program and its beneficiaries as described in § 424.535(a)(3)(ii). While we selected these criteria to be consistent with how we evaluate other individuals, we also sought to create a more definite list such that MDPP suppliers would have the ability to conduct background checks on coaches prior to, as well as potentially after enrolling in Medicare, to avoid receiving an enrollment denial or revocation due to failure to meet this standard. While coaches are not directly enrolled, and therefore, not directly receiving payment, we believe that it is prudent to prohibit MDPP suppliers from utilizing individuals convicted of certain felonies to furnish services to Medicare beneficiaries. Because coaches will be directly interacting with beneficiaries, recording their attendance and weight loss, we believe that a coach's trustworthiness is vital. Consequentially, we do not believe that such coaches should have a criminal history such as those described in § 424.535(a)(3)(ii).

Coaches that meet any of these criteria would be considered ineligible to furnish MDPP services, and therefore, could not be on an MDPP supplier's roster. Coaches whose information was submitted in an MDPP supplier's enrollment application, screened, and determined as not meeting any of these criteria would be considered eligible coaches. Although the MDPP supplier is the entity that is enrolled in Medicare and submits claims, coaches furnish MDPP services, directly interacting with the beneficiary and documenting attendance and weight loss. Therefore, we believe that precluding individual coaches who meet any of the ineligibility criteria from directly furnishing MDPP services to Medicare beneficiaries would both help reduce fraud, waste, and abuse that could occur in the MDPP expanded model, as well as protect beneficiaries from harm.

If after screening, CMS or its contractors determine that a coach is eligible to furnish MDPP services, the coach would be assigned an eligibility start date, similar to a supplier's enrollment effective date. We are proposing to define coach eligibility start date as follows: The start date indicated by the MDPP supplier when submitting an eligible coach's information on the MDPP enrollment application (proposed at 424.205(a)). On the enrollment application, the MDPP supplier will include a date indicating when the coach began furnishing MDPP services. Consistent with proposals at § 424.205(d)(5), the MDPP supplier must report changes to the coach roster on its enrollment application, including any new coaches added, within 30 days of such a change. Thus, the start date associated with any new coach information must be within 30 days of the date the MDPP supplier actually reports the change on its application. If the coach has not yet begun furnishing MDPP services, the MDPP supplier should indicate the date the supplier is reporting the information. Though the date reflects either when the coach began furnishing services or when the coach could ultimately be determined as eligible to begin furnishing services, after the enrollment application was submitted, CMS must still determine whether the coach is eligible (proposed at § 424.205(e)(2)). If we determine the coach to be eligible, then his or her eligibility start date would be the date the MDPP supplier indicated on its enrollment application. As described in III.K.2.d.(10)(d), payment can be made for services furnished by this coach on or after his or her eligibility start date.

However, if a coach was determined to be ineligible at the onset, the coach would have its eligibility start and end date on the same date, effectively never being eligible to furnish MDPP services. If the coach later became ineligible, he or she would be assigned an eligibility end date. Consistent with proposals at 414.84, payment for MDPP services is made only if such services are furnished by an eligible coach, on or after his or her coach eligibility start date and, if applicable, before his or her coach eligibility end date, to an MDPP beneficiary. This could pose a situation in which an MDPP supplier could submit an updated coach roster that includes a new coach, and allow him or her to begin furnishing services based on the belief that he or she is eligible. Should, after screening, CMS or its contractors determine that the coach is ineligible, the MDPP supplier could be revoked for non-compliance. Though the MDPP supplier would have an opportunity to submit a corrective action plan that removes the ineligible coach from their enrollment application, any claims for services furnished by the ineligible coach would be denied, and the MDPP supplier would not be paid for such services. For this reason, we encourage suppliers to report changes to the coach roster as soon as possible. If the MDPP supplier submits a claim that

includes a coach NPI for a coach we have not yet determined to be an eligible coach for furnishing MDPP services as of the date of service, the claim will be rejected, and the supplier will need to refile the claim with the same information once CMS has made the eligibility determination. If at that time, CMS determined the coach to be ineligible, the claim for the service provided by the coach will be denied, as described in section III.K.2.d.iii.(10)(d).

We believe that the majority of the coach ineligibility criteria described in this section is crafted in such a way that the MDPP supplier could, with reasonable certainty, conduct an independent background check on the coach, to determine whether he or she meets the ineligibility criteria. If the MDPP supplier has any uncertainty about whether the coach meets the ineligibility criteria, they may wish to preclude the coach from furnishing services to Medicare beneficiaries until CMS determines that the coach is eligible. This would avoid a potential situation of a coach furnishing services for which the MDPP supplier could not get paid. If the MDPP supplier believes the coach is eligible and wishes to allow the coach to furnish services prior CMS determining his or her eligibility, then the MDPP supplier would assume the risk not receiving payment for claims for serviced rendered by the ineligible coach.

If a coach no longer provides MDPP services for an MDPP supplier, the supplier must remove that coach from its roster and indicate the date of such event to designate an eligibility end date for that coach. If the MDPP supplier voluntarily terminates its Medicare enrollment or is revoked, CMS will automatically reflect the date of this action as the coach's eligibility end date for that MDPP supplier. We are proposing to define coach ineligibility end date as follows, the end date indicated by the MDPP supplier in submitting a change to the supplier's MDPP enrollment application that removed the coach's information, or the date the supplier itself was revoked from or withdrew its Medicare enrollment as an MDPP supplier.

We are proposing that CMS or its contractors would determine whether coaches submitted on MDPP rosters satisfy the previously stated criteria by using the identifying information MDPP suppliers submit on their enrollment applications (including any changes that MDPP suppliers would be required to report). This information would be checked against internal and publicly available data sources. We are proposing that, upon identification of evidence that a coach met any ineligibility criteria, we may take administrative action to deny or revoke the MDPP supplier's enrollment as appropriate under §§ 424.530(a)(1) and 424.535(a)(1) (proposed at § 424.205(g)(1)(ii)). Consistent with existing enrollment denial and revocation actions, we would notify the prospective or enrolled MDPP supplier via an enrollment denial or revocation notification and include the specific reason for the administrative action. The enrollment denial or revocation notification detailing the findings and the reasoning for the determination would follow requirements under § 488.18. Consistent with similar processes at §§ 424.530(c) and 424.535(e), we are proposing that an MDPP supplier could respond to the enrollment denial or revocation by submitting a corrective action plan (CAP) that would include the removal of the coach from its roster within 30 days of receiving the enrollment denial or revocation notification, and therefore, come into compliance and enroll or maintain its enrollment status. If MDPP suppliers believe that the decision was made in error, they could exercise existing appeal rights under part 498.

We also are proposing that if we determine that an MDPP supplier has continued to allow an ineligible coach to furnish MDPP services after having submitted a CAP removing the coach from its roster to enroll or maintain enrollment in Medicare, we would revoke the MDPP supplier without the opportunity for additional corrective action. This authority, outlined in proposed § 424.205(h)(1)(v), would allow us to revoke an MDPP supplier for knowingly using an ''ineligible coach'' to furnish MDPP services. ''Knowingly,'' in this context, means that the supplier received an enrollment denial or revocation notice based on failing to meet supplier standards at § 424.205(d)(3) (related to ineligible coaches), was provided notice by CMS or contractors working on its behalf of this action including the reason(s) for the administrative action, submitted a CAP to remove the coach, but continued to allow the coach to provide MDPP services in violation of the CAP. We are proposing to define an ''ineligible coach'' in § 424.205(a) as an individual whom CMS has screened and has determined ineligible to furnish MDPP services on behalf of an MDPP supplier based on the standard specified in § 424.205(e), and we are proposing in the same paragraph to define ''eligible coach'' in § 424.205(a) as an individual who CMS has screened and has determined can furnish MDPP services on behalf of an MDPP supplier based on the standard specified in proposed § 424.205(e).

While any individual may be eligible to become a DPP coach, provided that they meet requirements and trainings as dictated by the CDC's DPRP Standards, an individual can only become an eligible coach for purposes of furnishing MDPP services after having their required identifying information submitted on an MDPP supplier's enrollment application, being screened by CMS or its contractors, and as a result, being determined to be eligible to furnish MDPP services on behalf of an MDPP supplier. If CMS or its contractors deem a coach ineligible, this would apply only to the furnishing of MDPP services and would not preclude the DPP organization from continuing to allow this individual to furnish administrative services or DPP sessions to non-Medicare beneficiaries. However, serving as a coach for Medicare beneficiaries would be prohibited and would be subject the MDPP supplier to this revocation authority.

We are proposing this new revocation authority due to the novel program integrity risks that would be posed by MDPP suppliers who knowingly continue to permit ineligible coaches to furnish MDPP services to Medicare beneficiaries. We believe that this new basis for revocation is necessary because coaches are not enrolled in Medicare, even though they will undergo background checks by CMS or its contractors and must meet specified criteria. While we considered using existing revocation authorities under § 424.535(a)(1) (related to noncompliance), § 424.535(a)(4) (related to false or misleading information), and § 424.535(a)(9) (related to failure to report), we determined that these authorities were too general for purposes of specifically addressing MDPP coaches who become ineligible to furnish MDPP services. We are proposing that this revocation authority would follow similar requirements under § 424.535(c), (g), and (h). We do not believe that § 424.535(e) (related to reversal of the revocation) should apply in this case, given that the MDPP supplier already had an opportunity to remove the coach from their roster by submitting a CAP, but continued to allow the ineligible coach to furnish MDPP services. The proposals that we would apply from the provisions of § 424.535 stated in this section are as follows:

- The revocation becomes effective 30 days after CMS or the CMS contractor

mails notice of its determination to the MDPP supplier;

- For the revocation authority, MDPP suppliers are barred from participating in the Medicare program from the date of the revocation until the end of the re-enrollment bar, which begins 30 days after CMS or its contractor mails notice of the revocation and lasts a minimum of 1 year, but not greater than 3 years, depending on the severity of the basis for revocation; and
- A revoked MDPP supplier must, within 60 calendar days after the effective date of revocation, submit all claims for items and services furnished before the date of the revocation letter.

We believe that these proposals would appropriately govern this proposed new revocation authority, given the consistency with existing revocation authorities. Given these consistencies, we do not believe that this proposal places an undue burden on MDPP suppliers, and any burden established would be warranted given the violation of the supplier standards that jeopardize both the integrity of the Medicare program and the safety of its beneficiaries.

We are inviting public comments on these proposals.

(3) Ensuring MDPP Suppliers Are Legitimate, Operational Organizations

We are proposing a number of requirements that would help ensure that MDPP suppliers are operational, have the resources necessary to furnish MDPP services, and are in compliance with MDPP supplier standards. At § 424.205(d)(4), we are proposing that, regardless of whether the MDPP supplier furnishes services solely in community settings, it must maintain at least one administrative location. All administrative locations maintained by the MDPP supplier must be on an appropriate site available to the public and must be reported on the CMS-approved enrollment application. We are proposing that this administration location may not be a private residence. We are proposing that an appropriate site must have signage posted on the exterior of the building, as well as be open for business and have employees, staff, or volunteers present during operational hours. For the purposes of this requirement, such signage may include, for example, the MDPP supplier's legal business name or its ''doing business as'' (DBA) name, as well as hours of operation. This proposal seeks to utilize measurable objective indicators to determine that organizations are legitimately operating and able to furnish MDPP services to Medicare beneficiaries. We believe that, regardless of whether the MDPP supplier furnishes services at its administrative location, establishing a physical location is necessary for associated requirements for furnishing MDPP services, including recordkeeping requirements, training facilities, and storage for any educational materials distributed during sessions.

We are proposing, at § 424.205(d)(6), that a MDPP supplier must maintain a primary business telephone number listed under the name of the organization in public view. Public view could signify, for example, that the phone number is listed on a Web site, on flyers and materials. This proposed policy would require that calls must not automatically go to the answering machine or utilize an answering service during posted business hours. The purpose of this proposed requirement is to help verify that the organization is a legitimate organization and not simply posing as an organization and seeking to bill Medicare fraudulently.

We are further proposing, at § 424.205(d)(7), that an MDPP supplier must not knowingly sell to or allow another individual or entity to use its billing number, consistent with § 424.535(a)(7). We are including this proposal to avoid a situation in which another entity uses an existing MDPP supplier's billing number. We believe that this proposal plays an important role in ensuring that payments are only being made to the intended recipient who has met all of the supplier and compliance standards and that we continue to hold entities responsible for maintaining compliance. Otherwise, we risk making payments to suppliers potentially engaging in fraudulent or potentially harmful behavior.

We believe that the proposed requirements in this section would not pose an undue burden on MDPP suppliers as they are minimum requirements for any functional, operational organization. By establishing these requirements, we believe that we would ensure that MDPP suppliers that do not meet the baseline requirements for an operational organization would not be permitted to furnish MDPP services to or receive payment for such services. We are proposing, at § 424.205(d)(15), that an MDPP supplier must permit CMS or its agents to conduct onsite inspections to ascertain the supplier's compliance with these standards. While we believe that any operational business that truly furnishes MDPP services would be able to meet these requirements, we are inviting public comments on any aspects of these proposed standards.

(4) Beneficiary Access

We are proposing, at § 424.205(d)(8), that MDPP suppliers may not deny access to MDPP services to eligible beneficiaries based on any reason other than the supplier's own self-determined and published capacity limits to furnish MDPP services to additional people and, on a discretionary basis, if a beneficiary significantly disrupts the session for other participants or becomes abusive. Given that we do not yet currently have data on optimal class size for MDPP services, we are currently allowing MDPP suppliers to self-determine any upper limitation on class size. Should they establish such a limit and intent to turn beneficiaries away once the capacity limit is reached, the MDPP supplier must have previously made this limit publicly available; for example, denoting the limit in any brochures, Web sites, or other materials that outline their MDPP services. We are proposing that MDPP suppliers must maintain a record of the number of eligible Medicare beneficiaries turned away for each of these reasons, as well as the date the beneficiary was informed. We are further proposing that if an MDPP supplier denies a Medicare beneficiary access citing disruptive or abusive behavior, details of the occurrence(s), including date(s) of the behavior, any remediation efforts taken by the supplier, and final action (for example, dismissal from an MDPP session or denial from future sessions) must be documented in the beneficiary's MDPP records and adhere to documentation requirements outlined in § 424.205(g). We note that one supplier's decision to dismiss a beneficiary for this purpose would not limit that beneficiary from switching to another MDPP supplier.

We will seek to monitor compliance with this requirement, and investigate further if necessary, based on beneficiary complaints, rates of access denials citing capacity limits in comparison to estimated capacity based on claims submitted, as well as monitoring claims for success rates for achieving performance goals that are higher than what would be expected for a typical Medicare population. Illustrative examples of capacity limits could include that the MDPP supplier has met its self-determined and published class size maximum, or that the supplier is providing MDPP sessions in cohorts and does not have a new or upcoming cohort at the time the beneficiary is seeking MDPP services. Furnishing MDPP services in a cohort means that the DPP curriculum is delivered among a single group, or

cohort, from start to finish with sessions furnished in a specific order, therefore, not allowing any new individuals to join once the cohort has begun.

Given that our proposed payment structure for MDPP services relies on the achievement of weight loss and attendance goals, there may be incentives for MDPP suppliers to seek to serve only those beneficiaries for which they are more likely to earn performance payments. This, in turn, could result in discriminatory treatment of beneficiaries. Through this proposed supplier standard, we would expressly prohibit MDPP suppliers from conditioning access to MDPP services on the basis of a beneficiary's weight or health status (except as provided in our proposed regulations). We also would prohibit MDPP suppliers from conditioning access to MDPP services on the basis of a beneficiary's achievement of performance goals, except where the beneficiary becomes ineligible for additional sessions as a result of not meeting those goals, as proposed elsewhere in this proposed rule. We believe that it is appropriate to prohibit suppliers from denying access to MDPP services except in certain limited circumstances. If a supplier were to deny access to a beneficiary citing lack of capacity, but then furnish MDPP services to a different beneficiary, this may signal a violation of such standards. In addition, and for the same reasons, we are proposing to prohibit MDPP suppliers, which includes any coaches or entities performing functions or furnishing services related to MDPP services on their behalf, from unduly coercing a beneficiary's decision to change or not change to a different or specific MDPP supplier, including through the use of pressure, intimidation, or bribery in proposed § 424.205(d)(9). Information that may result in a beneficiary changing to a different MDPP supplier provided in response to a beneficiary's request for information would not violate this provision.

At § 424.79, the CY 2017 PFS final rule established the set of services included in the expanded model, but did not stipulate that once a supplier began furnishing such services to a beneficiary, that it must continue to offer them to the beneficiary as a part of the MDPP expanded model. We are proposing, at § 424.205(d)(10), that MDPP suppliers must offer and provide beneficiary access to the *entire set* of MDPP services for which beneficiaries are eligible. This includes the requirement that suppliers offer at least 16 in-person core sessions, no more frequently than once per week, over the first 6 months of the core services period and offer at least 6 core maintenance sessions, at least once per month, over months 7 through 12 of the core services period (proposed at § 410.79(c)(2)(i)). For beneficiaries to whom the supplier has begun furnishing MDPP services, and who meet the eligibility requirements for ongoing maintenance sessions described in proposed § 410.79(c)(1)(ii) and (iii), MDPP suppliers are required to offer 24 ongoing maintenance sessions, furnished at least once per month over the course of months 13 through 36 of the MDPP services period, in 3-month consecutive increments. These requirements would also apply to any MDPP supplier who gains a beneficiary at some point during their receipt of MDPP services. Should this MDPP supplier begin furnishing services to a beneficiary at any point during the 3-year MDPP services period, it must continue to offer the services for which the beneficiary is eligible but has not yet received. For example, if a beneficiary changed suppliers after the core sessions in month 6, the subsequent supplier would be required to offer core maintenance sessions for months 7 through 12, and ongoing maintenance sessions should the beneficiary remain eligible for these services.

We also are soliciting public comments on a potential future policy to require a specific class size limit for MDPP sessions. While we acknowledge that MDPP services may be successfully furnished in group settings, we believe that it is important to ensure that the group's size is appropriately set such that each beneficiary gains the necessary interaction with the coach furnishing the session to properly learn the curriculum. We considered different mechanisms to ensure this program objective, and are requesting public comments on considerations to date. The mechanism that currently seems most viable would require a limitation on the number of total attendees in a given session taught by an individual coach. Based on CDC's experience with the DPP program and review of the literature on appropriate class sizes for educational settings, we considered including a class size limitation of 30 participants per coach in a given session (including Medicare beneficiaries). Given that limited data currently exist on this type of requirement among DPP sessions, we are soliciting public comments on what an appropriate class size limitation would be, including any evidence to support such a proposal.

Furthermore, we are soliciting public comments on how MDPP suppliers who furnish sessions in no specific sequential order and allow drop ins would balance the requirement of providing beneficiary access with a class size requirement for a given session. For example, if a supplier offers classes multiple times a week and gives beneficiaries flexibility regarding when to participate, we questioned whether a certain class size limitation could force a supplier to turn away a beneficiary seeking to attend a session at a time when attendance is high, and in so doing potentially discourage continued use of the set of MDPP services. In addition, we are unsure of any implications that would result from establishing a class size restriction for MDPP services while acknowledging that MDPP beneficiaries may participate in DPP sessions with non-Medicare beneficiaries who may not face the same class size limitation. Given these considerations, we are soliciting public comments on how we could structure this proposal in the future that would achieve the programmatic goals of effectively furnishing the DPP curriculum to Medicare beneficiaries in a manner and setting that contributes to positive behavioral changes and ultimately less progression to type 2 diabetes. In providing comments on this approach, we encourage the submission of data and evidence to justify what specific class size would be appropriate for MDPP suppliers.

(5) Disclosure

We are proposing, at § 424.205(d)(11), that MDPP suppliers must provide information about the MDPP expanded model to each beneficiary to whom it furnishes MDPP services as specified by CMS. This includes detailed information on coverage for the set of MDPP services, the once-per-lifetime limit, on eligibility requirements, and the MDPP supplier standards. We recognize that many aspects of the MDPP expanded model are novel for both beneficiaries and suppliers, and we desire that both parties are well informed. Therefore, we believe that requiring the supplier to fully disclose information about the MDPP expanded model, coverage, and the MDPP supplier standards will help inform all parties. We intend to provide a specific template for the MDPP supplier to use to disclose this information to the beneficiaries. For this reason, we do not believe that requiring this type of disclosure places a significant burden on the supplier. While we believe that this approach will help to address the policy goals of the MDPP expanded model, we are inviting public comments on this approach, particularly upon the provision of a standard CMS disclosure

notification as compared to CMS providing MDPP suppliers with information they could use to their own disclosure notification materials. Along these lines, we would like to highlight that we also intent to publish information on MDPP in the 2019 Medicare & You Handbook.

We invite public comments on these proposals.

(6) Beneficiary Complaints

We are proposing that MDPP suppliers must answer Medicare beneficiaries' questions about MDPP services and respond to MDPP related complaints within a reasonable timeframe in proposed § 424.205(d)(12). We also are proposing that MDPP suppliers implement a complaint resolution protocol and maintain documentation of all beneficiary contact regarding such complaints, including the name and Medicare Beneficiary Identifier of the beneficiary, a summary of the complaint, related correspondences, notes of actions taken, and the names and/or NPIs of individuals who took such action on behalf of the MDPP supplier. We are proposing that this information must be kept at a supplier's administrative location and made available to CMS or its contractors upon request. These records would adhere to the same recordkeeping requirements in § 424.205(g), and therefore, would need to be maintained for 10 years. While other records are typically required to be held only for 7 years (per § 424.516(f)), given that the MDPP expanded model includes beneficiary engagement incentive (described further in section III.K.2.f.v.) which typically requires an extended documentation requirement, we considered it important to align all recordkeeping requirements for the MDPP expanded model. As noted earlier in this section, we are proposing at § 424.205(d)(15) that an MDPP supplier must allow CMS or its agents to conduct recordkeeping reviews to ascertain the supplier's compliance with these standards, as well as documentation requirements as outlined in § 424.205(g).

We believe our proposal that MDPP suppliers must answer, respond to, and document beneficiary complaints and resolutions establishes a tracking mechanism to determine whether or not suppliers are adequately addressing beneficiary concerns. We find this requirement particularly important given that complaint procedures provide a good way to ensure best practices by suppliers. Moreover, DMEPOS supplier standards contain a requirement regarding maintaining complaint procedures. Although we acknowledge that this method requires the MDPP suppliers to self-attest to complaints, requiring such documentation as a required Medicare standard can help to build accountability to following through with complaint resolution. Additionally, mandating that suppliers take and maintain records of complaints may help to address situations where beneficiaries raise issues directly to us after failing to receive resolution from the supplier directly.

We believe that requiring this documentation would provide an additional mechanism for us to ensure that the supplier is fully disclosing information pertinent to the supplier standards, specifically those regarding beneficiary access, and other concerns. As an additional benefit of this policy, if a beneficiary is denied access, the MDPP supplier would be required to demonstrate the reasoning behind this approach, and we could have an opportunity to review if this reasoning complied with the proposed standard under § 424.205(d)(8).

This approach is consistent with supplier standards for other Medicare suppliers, including those for Durable Medical Equipment Prosthetics, Orthotics, and Supplies (DMEPOS) suppliers. Given that CMS has imposed similar standards regarding supplier responsibility for addressing beneficiaries' complaints among other supplier types, we do not believe that requiring a similar such requirement poses an undue burden on MDPP suppliers. Rather, we believe that this approach can facilitate beneficiary satisfaction with the services suppliers furnish by requiring that beneficiary complaints are acknowledged, resolved, and tracked appropriately. We believe that this approach will help ensure that the supplier is meeting beneficiaries' needs as they relate to the MDPP expanded model. In addition, we believe that this will help ensure the integrity of the MDPP expanded model.

We invite public comments on these proposals.

(7) MDPP Expanded Model Evaluation Compliance

In the CY 2017 PFS final rule, we finalized a requirement for MDPP suppliers to maintain and submit to CMS a crosswalk file that documented how the beneficiary identifiers submitted to CMS for billing and the beneficiary identifiers submitted to CDC for session-level performance data linked to the same beneficiary as a documentation retention and provision requirement (existing § 424.59(b), proposed to be redesignated and amended as § 424.205(e) in this proposed rule). CMS will use this crosswalk for evaluation purposes so CMS can review session level data that MDPP suppliers provide to CDC to supplement the claims data we receive directly from MDPP suppliers. We indicated that we would provide additional information on format and frequency of this reporting requirement in future rulemaking or administrative guidance as appropriate. We are proposing the maintenance and submission of the crosswalk as an MDPP supplier standard and are providing additional details regarding the format and frequency. We are proposing that the crosswalk file would contain Medicare Health Insurance Claims Numbers or Medicare Beneficiary Identifiers and the unique participant identifier assigned by the organization, for the purposes of CDC performance data reporting, for each beneficiary receiving MDPP services (proposed § 424.205(d)(13)). Beneficiaries for whom at least one Medicare claim was submitted by an MDPP supplier would be required to be included in the crosswalk. We are proposing that the crosswalk be supplied to CMS, or our contractor, beginning 6 months after the organization begins furnishing MDPP services, and quarterly thereafter. The crosswalk would be maintained in a spreadsheet (for example, an Excel file or a CSV file), in a form and manner as specified by CMS. We are inviting public comments on this approach.

Additionally, to enable evaluation of MDPP services for a beneficiary's entire MDPP services period (that is, up to 3 years), we are proposing that MDPP suppliers must submit performance data for any beneficiaries who attend ongoing maintenance sessions in a manner and form as specified by CMS (proposed § 424.205(d)(14)). This proposal serves to ensure that MDPP suppliers provide session-level data for ongoing maintenance sessions that are consistent with the data they are already providing to CDC for the core MDPP services period. This requirement is necessary given that session-level performance data plays a critical role in the Innovation Center's evaluation of the entirety of the MDPP expanded model. Without such data, the Innovation Center would lack any streamlined method of obtaining session-level data for ongoing maintenance sessions furnished to MDPP beneficiaries. We are proposing that this performance data must align with the performance date elements as

required by CDC for the DPRP standards. We are soliciting public comments on this approach.

v. MDPP Supplier Revalidation

In the CY 2017 PFS final rule, we specified that newly enrolling MDPP suppliers as high categorical risk in accordance with § 424.518(c), but we did not address the risk level of MDPP suppliers upon revalidation. Section 6401(a) of the Affordable Care Act established that all Medicare suppliers must revalidate their enrollments as a program integrity measure. Upon revalidation, suppliers are screened for their continued enrollment in Medicare. While MDPP suppliers enroll at the high risk level, we are proposing, at § 424.205(b)(3)(ii), that MDPP suppliers would revalidate under a moderate risk level in accordance with § 424.518(b). We believe that this approach is appropriate, given that fingerprint-based criminal history record checks through the Federal Bureau of Investigation's Integrated Automated Fingerprint Identification System requirement for ''high'' categorical risk and will have already been completed upon initial enrollment. In addition, we believe that this approach is appropriate, given its consistency with other providers and suppliers who initially enroll under ''high'' categorical risk, but revalidate under ''moderate'' categorical risk, such as DMEPOS suppliers and Home Health Agencies. We also are proposing, at § 424.205(b)(6), as a condition of enrollment, that MDPP suppliers must agree to revalidate their enrollment every 3 years, consistent with DMEPOS suppliers who are initially screened under ''high'' categorical risk screening level. While we believe that this approach is appropriate for MDPP suppliers, we welcome public comments on these proposals. Interested parties can learn more information on revalidation available on the CMS Web site at *https://www.cms.gov/medicare/provider-enrollment-and-certification/medicareprovidersupenroll/revalidations.html.*

We invite comment on the proposed risk level upon revalidation, as well as the frequency with which MDPP suppliers must revalidate their enrollment.

vi. Documentation Retention and Provisions Requirements

We are proposing that the following requirements would apply to records related to a MDPP supplier's compliance with the MDPP expanded model (codified at § 424.59(b), redesignated as amended at § 424.205(g)). We believe that these proposals will increase supplier recordkeeping accuracy, and clarify documentation retention requirements. Specifically, we are proposing that an MDPP supplier must:

- Provide to CMS or its contractors, the OIG, and the Comptroller General or their designee(s) scheduled and unscheduled access to all books, contracts, records, documents, and other evidence sufficient to enable the audit, evaluation, inspection, or investigation of the supplier's compliance with MDPP requirements, including the MDPP expanded model requirements for in-kind beneficiary incentive engagements found in § 424.210 in the event that the MDPP supplier chooses to offer such incentives to any MDPP beneficiary.
- Maintain all such books, contracts, records, documents, and other evidence for a period of 10 years from the last day of the MDPP beneficiary's receipt of MDPP services furnished by the MDPP supplier or from the date of completion of any audit, evaluation, inspection, or investigation, whichever is later, unless—

++ CMS determines that there is a special need to retain a particular record or group of records for a longer period and notifies the MDPP supplier at least 30 calendar days before the normal disposition rate; or

++ There has been a dispute or allegation of fraud or similar fault, as defined at § 405.902, against the MDPP supplier, in which case the records must be maintained for an additional 6 years from the date of any resulting final resolution of the dispute or allegation of fraud or similar fault.

We believe these modifications increase the likelihood of operationalizing MDPP program integrity strategies that include audits, evaluations, inspections, or investigations, and that they provide additional clarity on documentation retention for ongoing program integrity. In addition, in the CY 2017 PFS established supplier requirements for documentation and recordkeeping (codified at § 424.59(b), proposed to be redesignated and amended at § 424.205(g). In this proposed rule, we are modifying these requirements to improve clarity. We are proposing at § 424.205(g)(1) and (g)(2) to require that documentation must be established contemporaneous to the furnished MDPP services, which we believe is important for accuracy. We are also proposing that for the initial core session, these records must include the following organizational information:

- The organizational name, CDC DPRP organization number, and organizational NPI;
- Basic beneficiary information including but not limited to beneficiary name, HICN, and age; and
- Evidence that each such beneficiary satisfied the eligibility requirements under § 410.79(c) at the time of service.

For each additional session, we propose that these records must include:

- Documentation of the type of session, whether a core session, a core maintenance session, an ongoing maintenance session, an in-person make-up session, or a virtual make-up session.
- Identification of which CDC-approved DPRP curriculum was associated with each session.
- The NPI of the coach who furnished the session.
- The date and place of service of the session.
- Each MDPP's beneficiary's weight and date weight taken, in a form and manner as specified by CMS.

We believe that this information will play an important role in documenting the provision of MDPP services and fidelity to the requirements established for the expanded model. Finally, at § 424.205(g)(3), we are proposing that MDPP suppliers must maintain and handle any beneficiary Personally Identifiable Information (PII) and Personal Health Information (PHI) in compliance with HIPAA, other state and federal privacy laws, and CMS standards. We believe these proposals will improve supplier recordkeeping accuracy and lessen the possibility of incomplete records and supplier recordkeeping variations.

We are inviting public comments on our proposed documentation and maintenance of records requirements, including whether additional or different requirements may provide better program integrity safeguards.

f. Beneficiary Engagement Incentives Under the MDPP Expanded Model

We believe that the MDPP expanded model would encourage MDPP suppliers to furnish high quality and engaging health behavior change services to MDPP beneficiaries that lead to improved beneficiary health and reductions in Medicare spending. We further believe that one mechanism that may be useful to the MDPP suppliers in achieving these goals would be allowing MDPP suppliers to furnish certain in-kind items and services to their MDPP beneficiaries during the core services period and ongoing services period (described at proposed § 410.79(c)(2)). Under such an approach, the costs of these beneficiary engagement incentives would be borne by the MDPP supplier. However, we believe that certain

conditions on these incentives are necessary to ensure that they would be furnished solely for the purpose of achieving the MDPP goal of engaging beneficiaries in making sustainable, healthy behavior changes to reduce their risk of type 2 diabetes.

We are proposing to establish the rules governing the furnishing of beneficiary engagement incentives to MDPP beneficiaries under the MDPP expanded model at new § 424.210. As discussed in section III.K.2.a. of this proposed rule, we are proposing that MDPP services would be available beginning on April 1, 2018. Therefore, because there would be no MDPP beneficiaries who could receive beneficiary engagement incentives from MDPP suppliers until on or after April 1, 2018, we are proposing that the effective date of § 424.210 would be April 1, 2018.

i. Definitions Specific to Beneficiary Engagement Incentives

We are proposing that if an MDPP supplier offers an in-kind beneficiary engagement incentive, the item or service offered as an incentive must be furnished by an MDPP supplier to a MDPP beneficiary during the engagement incentive period. An engagement incentive period would begin when an MDPP supplier furnishes any MDPP service to an MDPP beneficiary. As proposed at § 424.210(a), the term ''engagement incentive period'' means the period of time during which an MDPP supplier may furnish in-kind beneficiary engagement incentives to a given MDPP beneficiary to whom the MDPP supplier is furnishing MDPP services. The engagement incentive period would end upon the earliest of the following: The beneficiary's MDPP services period ends (as specified in proposed § 410.79(c)(3)) for any reason; the MDPP supplier knows the MDPP beneficiary will no longer be receiving MDPP services from the MDPP supplier; or the MDPP supplier has not had direct contact, either in person, by telephone, or via other telecommunications technology, with the MDPP beneficiary for more than 90 consecutive calendar days during the MDPP services period.

We are proposing that items and services may only be furnished as in-kind beneficiary engagement incentives during the engagement incentive period. This is to ensure that the flexibilities that MDPP suppliers would be afforded under these proposed regulations to furnish free items and services to Medicare beneficiaries only apply while the beneficiary is an MDPP beneficiary being offered MDPP services by that MDPP supplier. Once the MDPP beneficiary's engagement incentive period ends with an MDPP supplier, all existing laws and regulations would apply to the furnishing of free items and services to a Medicare beneficiary by the entity that is an MDPP supplier. Limiting the furnishing of beneficiary engagement incentives under the MDPP expanded model to the engagement incentive period with a particular MDPP supplier serves as a safeguard against the furnishing of free items and services to Medicare beneficiaries to steer them toward particular providers, suppliers, or other services, rather than to engage MDPP beneficiaries in healthy behavior changes that reduce their incidence of type 2 diabetes.

During the course of the MDPP services period, an MDPP beneficiary may begin and end multiple engagement incentive periods, and, to the extent feasible, the MDPP beneficiary would not be in more than one engagement incentive period at the same time. For example, where, after receiving MDPP services from MDPP supplier A, an MDPP beneficiary notifies MDPP supplier A that he or she has chosen to receive MDPP services from MDPP supplier B and subsequently receives MDPP services from MDPP supplier B, the first engagement incentive period ends when MDPP supplier A is told by the MDPP beneficiary that he or she will no longer attend MDPP services with MDPP supplier A. A new engagement incentive period begins when the MDPP beneficiary receives his or her first MDPP service from MDPP supplier B. Additionally, where an MDPP beneficiary begins an engagement incentive period with an MDPP supplier and the engagement incentive period has ended because the MDPP supplier has not had direct contact, either in person, by telephone, or via other telecommunications technology, with the MDPP beneficiary for 90 consecutive days during the MDPP services period, should that MDPP beneficiary receive MDPP services from that MDPP supplier on day 100, a new engagement incentive period would begin.

These proposals for the definitions specific to beneficiary engagement incentives are included at proposed § 424.210(a). We are inviting public comments on these proposed definitions specific to furnishing in-kind beneficiary engagement incentives.

ii. General Conditions for Beneficiary Engagement Incentives

We are proposing, at § 424.210(b), that an MDPP supplier may choose to furnish items or services as in-kind beneficiary engagement incentives to an MDPP beneficiary only during the engagement incentive period, subject to a number of additional conditions as program safeguards. Under this proposal, the in-kind items and services furnished as beneficiary engagement incentives under the MDPP expanded model would not be Medicare-covered items or services.

We are proposing that the engagement incentive must be furnished directly by an MDPP supplier or by an agent of the MDPP supplier under the MDPP supplier's direction and control, such as a coach, to an MDPP beneficiary. As established in the § 410.79(b) in the CY 2017 PFS final rule, coach refers to an individual who furnishes MDPP services on behalf of an MDPP supplier as an employee, contractor, or volunteer. We considered whether this policy on beneficiary engagement incentives should extend to entities other than MDPP suppliers and their agents that may refer to or furnish MDPP services during an engagement incentive period.

However, given that MDPP suppliers maintain the responsibility to ensure the integrity of MDPP programs and would be best positioned to comply with beneficiary engagement incentive documentation and technology retrieval requirements proposed at § 424.210(e) and (c), respectively, we believe that they are best suited to furnished beneficiary engagement incentives. We are proposing that the item or service furnished as a beneficiary engagement incentive must be reasonably connected to the CDC-approved curriculum taught by an MDPP supplier to an MDPP beneficiary during a core session, a core maintenance session, or an ongoing maintenance session. For example, under this proposal, an MDPP supplier could furnish beneficiary engagement incentives such as gym memberships to reduce barriers associated with beneficiary achievement of physical activity recommended as part of the CDC-approved curriculum, but they could not furnish theater tickets, which would bear no reasonable connection to the CDC-approved curriculum. Similarly, MDPP suppliers may offer incentives such as onsite child care when the MDPP beneficiary attends MDPP services or transportation vouchers to the site of MDPP services that may reduce barriers to beneficiary attendance at MDPP services, but they could not furnish attendance awards such as movie tickets or retail gift cards, which would have no reasonable connection to the CDC-approved curriculum. Likewise, this proposal would allow MDPP suppliers to furnish equipment that is reasonably necessary for the curriculum being taught to the

beneficiary, such as digital scales to track and document patient weight or pedometers to track physical activity, but not broadly used technology that is more valuable to the beneficiary, such as a smartphone. If an MDPP supplier were to furnish a smartphone at no cost to an MDPP beneficiary, a reasonable inference arises that the technology would not be reasonably connected to the curriculum being taught to the beneficiary. Among other things, this safeguard precludes incentives that might serve to induce beneficiaries inappropriately to receive other services than MDPP services from the MDPP supplier.

We also are proposing that the beneficiary engagement incentive must be a preventive care item or service, or an item or service that advances a clinical goal for an MDPP beneficiary as described in section III.K.2.f.iv. of this proposed rule by engaging him or her in better managing his or her own health. This ensures that a relationship between the incentive and the goals of the MDPP expanded model exists so that the beneficiary engagement incentive is necessary for testing the expanded MDPP model. Under this proposed condition, we note that beneficiary engagement incentives may not be offered to an MDPP beneficiary as a reward for achievement of a specified outcome, such as losing weight or attending a certain number of sessions, unless the beneficiary engagement incentive meets all the proposed conditions, including that it is reasonably connected to the CDC-approved DPP curriculum furnished to the MDPP beneficiary during a core session, a core maintenance session, or an ongoing maintenance session by the MDPP supplier and that it is a preventive care item or service or it advances a clinical goal for an MDPP beneficiary by engaging him or her in better managing his or her own health. Furnishing in-kind patient engagement incentives upon achievement of an outcome may not advance a clinical goal for an MDPP beneficiary by engaging him or her in better managing his or her own health unless there are clinical goals that the incentive itself can continue to advance. We are further proposing that the item or service furnished as a beneficiary engagement incentive must not be tied to the receipt of items or services outside the MDPP services, and that the item or service must not be tied to the receipt of items or services from a particular provider, supplier, or coach. These provisions provide safeguards against the furnishing of in-kind beneficiary engagement incentives to steer beneficiaries toward certain providers, suppliers, or coaches for services outside MDPP services.

We note that in some circumstances, an item or service may be linked to an MDPP supplier and be offered to the MDPP supplier's MDPP beneficiaries as part of the CDC-approved curriculum that must be furnished during the MDPP services period, rather than being offered to steer the MDPP beneficiary to a particular provider, supplier, or coach. In these situations, we believe the item or service may be furnished as a beneficiary engagement incentive without violating the requirement that the item or service not be tied to the receipt of the items or services from a particular provider, supplier, or coach. For instance, where an MDPP supplier offers a gym membership as a beneficiary engagement incentive, we understand that the gym membership must be tied to a particular supplier of services so that the beneficiary can use the membership. However, in this case, the gym membership would be linked to the MDPP supplier that, in compliance with the curriculum that must be furnished during the MDPP services period, is teaching MDPP beneficiaries how to utilize a physical fitness regime to meet the MDPP goal of reducing an MDPP beneficiary's risk of developing diabetes, rather than being furnished to steer the MDPP beneficiary to a particular supplier. Therefore, we believe that gym memberships may be furnished as a beneficiary engagement incentive without violating the requirement that the item or service not be tied to the receipt of items or services from a particular provider, supplier, or coach as long as the gym membership is reasonably connected to the CDC-approved curriculum and not being furnished to steer the MDPP beneficiary to a particular supplier.

We are proposing that, in general, the availability of the items or services furnished as beneficiary engagement incentives must not be advertised or promoted as in-kind beneficiary engagement incentives available to an MDPP beneficiary receiving MDPP services from the MDPP supplier. However, an MDPP beneficiary may be made aware of the availability of the items or services at the time the MDPP beneficiary could reasonably benefit from them during the engagement incentive period. This condition provides a safeguard against the advertisement of in-kind patient engagement incentives to beneficiaries based on their perceived ability to meet the performance goals of attendance and weight loss as described at proposed § 414.84(a) and associated with the MDPP performance payments proposed at § 414.84(b). The proposed payment structure for MDPP services largely relies on the achievement of these performance goals. Therefore, advertising patient engagement incentives to encourage participation of MDPP-eligible beneficiaries most likely to meet the attendance and weight loss performance goals could produce financial gain for MDPP suppliers that is not related to the quality and efficacy of the MDPP supplier's MDPP services.

In addition, prohibiting the advertisement or promotion of in-kind beneficiary engagement incentives available to an MDPP beneficiary receiving MDPP services from the MDPP supplier except that an MDPP beneficiary may be made aware of the availability of the items or services at the time the MDPP beneficiary could reasonably benefit from them during the engagement incentive period provides a safeguard against using the incentive to steer a beneficiary toward a particular MDPP supplier. Beneficiaries would not be made aware of the availability of beneficiary engagement incentives until the MDPP beneficiary was in an engagement incentive period, which would begin when an MDPP supplier furnished its first MDPP service to the beneficiary. At that point in time, the beneficiary would have already selected that MDPP supplier to furnish his or her MDPP services so the incentive could not be used to steer the beneficiary to that MDPP supplier. We note that we do not intend for beneficiary engagement incentives proposed for the MDPP expanded model to alter an MDPP supplier's market share for an MDPP or non-MDPP item or service.

Finally, we are proposing that the cost of the items or services offered as in-kind beneficiary engagement incentives must not be shifted to another Federal health care program, as defined at section 1128B(f) of the Act. This requirement affirms that the cost of any beneficiary engagement incentive offered by an MDPP supplier is the sole responsibility of the MDPP supplier, and the furnishing of a beneficiary engagement incentive, for instance, must not result in increased payments to the MDPP supplier by Federal health care programs for other items or services.

These proposals for the general conditions for in-kind beneficiary engagement incentives are included at proposed § 424.210(b). We are inviting public comments on these proposed general conditions for furnishing beneficiary engagement incentives. In addition, we are inviting public

comments on additional or alternative program integrity safeguards.

iii. Technology Furnished to a MDPP Beneficiary

In some cases, items or services involving technology may be useful as beneficiary engagement incentives because they can advance a clinical goal of the MDPP expanded model by engaging an MDPP beneficiary in managing his or her health. However, we believe specific enhanced safeguards are necessary for these items and services to prevent abuse.

First, we are proposing that items or services involving technology furnished by an MDPP supplier to its MDPP beneficiary may not, in the aggregate, exceed $1,000 in retail value for any one MDPP beneficiary. We believe that this proposed limit is appropriate, in conjunction with our proposed enhanced requirements for items of technology with a retail value greater than $100 as discussed subsequently in this section. The proposed $1,000 limitation would allow sufficient MDPP supplier flexibility to furnish items or services involving technology as beneficiary engagement incentives to improve the likelihood of the beneficiary's achievement and maintenance of the required minimum weigh loss. The proposed limitation would not allow the furnishing of items of technology that in the aggregate constitute an excessively high value to the beneficiary that could increase the risk that the items of technology would not be in compliance with all of the proposed requirements for beneficiary engagement incentives.

For example, under this proposal, an MDPP beneficiary who begins receiving MDPP services from an MDPP supplier and who, after receiving MDPP services from that MDPP supplier, is furnished items or services of technology with a total retail value of $1,000 may not receive additional items or services of technology from that MDPP supplier. Therefore, an MDPP beneficiary may receive from a MDPP supplier a tablet valued at $700 that is preloaded with weight loss and fitness tracking apps that would support the beneficiary's weight loss goals under the MDPP expanded model and also receive from the same MDPP supplier a fitness tracking watch valued at $200 that uploads and monitors fitness data to the tablet, but he or she could not then receive additional items of technology from the MDPP supplier with an aggregate retail value greater than $100 as this would exceed the $1,000 limit.

In addition, if the same MDPP beneficiary chooses to receive MDPP services from another MDPP supplier, the subsequent supplier is under no obligation to determine the value of any items or services of technology furnished to the MDPP beneficiary by other MDPP suppliers, and may furnish items or services of technology to the MDPP beneficiary so long as those items or services furnished by the subsequent supplier are the minimum necessary to advance a clinical goal for the MDPP beneficiary, are furnished during the engagement incentive period, and do not, in aggregate, exceed $1,000 in retail value. We note that, while items of technology must be furnished to the MDPP beneficiary during an engagement incentive period, the $1,000 limit for items of technology that may be furnished to any one MDPP beneficiary by any one MDPP supplier is not otherwise affected by the engagement incentive period. For example, if an MDPP beneficiary begins and ends multiple engagement incentive periods with the same MDPP supplier as described in section III.K.2.f.i. of this proposed rule, the $1,000 limit for items of technology would not ''reset'' at the beginning of a new engagement incentive period with that MDPP supplier.

We are further proposing that items or services involving technology furnished to an MDPP beneficiary must be the minimum necessary to advance a clinical goal for MDPP beneficiaries as discussed in section III.K.2.f.iv. of this proposed rule.

We are proposing enhanced requirements for items of technology exceeding $100 in retail value as an additional safeguard against misuse of these items as beneficiary engagement incentives. We believe it would be inappropriate for MDPP suppliers to furnish items of technology with a retail value of over $100 for beneficiaries' permanent use because the high value of these items could unduly influence the beneficiary to continue to receive MDPP services from that supplier, or to receive items or services from the supplier other than MDPP services. Therefore, we are proposing that items of technology with a retail value of over $100 would remain the property of the MDPP supplier and be retrieved from the MDPP beneficiary at the end of the engagement incentive period. We do not believe that this requirement would substantially increase the administrative burden on MDPP suppliers because a central facilitator of the success of an MDPP beneficiary in meeting MDPP performance goals is the MDPP supplier's ability to maintain contact with the MDPP beneficiary and engage him or her in MDPP services. We note that items of technology with a retail value of $100 or less could be furnished as beneficiary engagement incentives and would remain the property of the beneficiary. In the case of these items of a technology with a lower retail value, we believe the administrative burden of retrieving these items would outweigh the program integrity benefits of retrieval.

We are further proposing that the MDPP supplier must document all technology retrieval attempts, including the ultimate date of retrieval. However, because we understand that MDPP suppliers may not always be able to retrieve these items, such as when a beneficiary dies or moves to another geographic area, documented, diligent, good faith attempts to retrieve items of technology would be deemed to meet the retrieval requirement.

Our proposals for enhanced requirements for technology furnished to MDPP beneficiaries as beneficiary engagement incentives under the MDPP expanded model are included at proposed § 424.210(c). We are inviting public comments on our proposed requirements for beneficiary engagement incentives that involve technology and welcome comments on additional or alternative program integrity safeguards for this type of beneficiary engagement incentive, including whether the financial thresholds proposed in this section are reasonable, necessary, and appropriate.

iv. Clinical Goals of the MDPP Expanded Model

As established at § 410.79(b) in the CY 2017 PFS final rule, MDPP services furnished to MDPP beneficiaries must follow a CDC-approved curriculum, which outlines required and recommended topics for structured health behavior change sessions offered as MDPP services with the goal of preventing diabetes through long-lasting health behavior change. MDPP suppliers seeking recognition under the CDC's DPRP must furnish either the CDC-preferred curriculum, based on the current evidence base, or may develop their own curriculum. MDPP suppliers who wish to develop their own curriculum must submit it to the CDC for approval. This requirement ensures that all curricula furnished to MDPP beneficiaries meet the DPRP's curriculum content requirements and are based on evidence from efficacy and effectiveness trials consistent with the current evidence base. To be consistent with the current evidence base, all curricula offered by MDPP suppliers must furnish MDPP services focused on the overarching goal of preventing type

2 diabetes in persons at high risk for diabetes because they have prediabetes. This requires MDPP suppliers to emphasize the need to make lasting health behavior changes, rather than simply completing a one-time set of MDPP services that result in the required minimum weight loss during the MDPP services period. MDPP services must also emphasize long-term improvements in nutrition and physical activity that contribute to beneficiaries sustaining weight loss. Therefore, we believe that in-kind patient engagement incentives may appropriately be furnished to support and motivate MDPP beneficiaries in achieving dietary and health behavior change and to teach MDPP beneficiaries to problem-solve strategies to overcome challenges to maintaining weight loss and healthy behaviors, as well as to assist MDPP beneficiaries in meeting the attendance and weight loss performance goals of the MDPP expanded model.

Therefore, we are proposing that the following would be the clinical goals of the MDPP expanded model, which may be advanced through beneficiary engagement incentives:

- Beneficiary attendance at MDPP core sessions, core maintenance sessions, or ongoing maintenance sessions during the MDPP services period.
- Beneficiary weight loss.
- Long-term dietary change for the beneficiary.
- Beneficiary adherence to long-term health behavior changes.

We note that under this proposal, the MDPP supplier may not furnish multiple free meals or meal replacement services to an MDPP beneficiary over a substantial portion of the engagement incentive period because such a practice would not advance a clinical goal for an MDPP beneficiary by engaging him or her in better managing his or her own health.

When a beneficiary engagement incentive does not qualify as a preventive care item or service, our proposals for the clinical goals of the MDPP expanded model that a beneficiary engagement incentive must be intended to advance are included at proposed § 424.210(d). We are inviting public comments on our proposed clinical goals of the MDPP, as well as whether the advancement of additional or different clinical goals through beneficiary engagement incentives may better advance the overarching goals of the MDPP expanded model, while maintaining appropriate program integrity safeguards.

v. Documentation of Beneficiary Engagement Incentives

As a program safeguard against misuse of beneficiary engagement incentives under the MDPP expanded model, we are proposing that, in addition to the documentation requirements for MDPP suppliers at proposed § 424.205(g), MDPP suppliers must maintain documentation of items and services furnished as beneficiary engagement incentives that individually exceed $25 in retail value. We recognize that an MDPP beneficiary could receive many incentives that are each of low dollar value but in the aggregate constitute an excessively high value to the beneficiary. Therefore, we believe it is important to incorporate a documentation threshold at a modest level for all beneficiary incentives in order to monitor compliance with the proposed conditions for furnishing these items and services. Moreover, we believe the proposed $25 retail value threshold strikes an appropriate balance between beneficiary and program protections and MDPP supplier administrative burden.

In addition, we are proposing to require that the documentation must be established contemporaneously with the furnishing of the items and services and must include at least the date the incentive was furnished; the identity of the beneficiary to whom the item or service was furnished; the agent of the supplier who furnished the item or service if applicable; a description of the item or service; the retail value of the beneficiary engagement incentive; and documentation establishing that the item or service was furnished to the MDPP beneficiary during the engagement incentive period.

In addition to the proposed requirements in the previous paragraph, we are further proposing that the documentation regarding items or services furnished to the MDPP beneficiary for use on an ongoing basis during the engagement incentive period, including items of technology exceeding $100 in retail value, must also include contemporaneous documentation establishing that the MDPP beneficiary is in the engagement incentive period throughout the time period that the MDPP beneficiary possesses or has access to the item or service furnished by the MDPP supplier. For example, if an MDPP supplier furnishes a gym membership to an MDPP beneficiary, the MDPP supplier must maintain contemporaneous documentation establishing that the MDPP beneficiary is in the engagement incentive period throughout the time period that the MDPP beneficiary has access to the gym via the membership furnished by the MDPP supplier.

In addition to the above requirements, we are further proposing that the documentation regarding items of technology exceeding $100 in retail value that MSPP suppliers are required to retrieve from the MDPP beneficiary must also include contemporaneous documentation of any attempts to retrieve the item of technology furnished by the MDPP supplier from the MDPP beneficiary as required at proposed § 424.210(c)(3)(ii). We reiterate that under our proposal documented, diligent, good faith attempts to retrieve items of technology would be deemed to meet the retrieval requirement.

Finally, we are proposing that the MDPP supplier must retain and provide access to the required documentation in accordance with proposed § 424.205(g).

Table 35 summarizes the proposed documentation requirements for beneficiary engagement incentives under the MDPP expanded model.

TABLE 35—PROPOSED BENEFICIARY ENGAGEMENT INCENTIVE DOCUMENTATION REQUIREMENTS

Beneficiary Engagement Incentive	Documentation requirement
Item or service with retail value greater than $25	• Contemporaneous documentation that includes at least: ▪ The date the incentive was furnished. ▪ The identity of the MDPP beneficiary to whom the item or service was furnished. ▪ Documentation establishing that the item or service was furnished to the MDPP beneficiary during the engagement incentive period. ▪ The agent of the supplier who furnished the item or service, if applicable. ▪ A description of the item or service. ▪ The retail value of the item or service. • Documentation regarding items or services that are furnished to the MDPP beneficiary for use on an ongoing basis during the engagement incentive period, including items of technology exceeding $100 in retail value, must also include contemporaneous documentation establishing that the MDPP beneficiary is in the engagement incentive period throughout the time period that the MDPP beneficiary possesses or has access to the item or service furnished by the MDPP supplier. • The documentation regarding items of technology exceeding $100 in retail value must also include contemporaneous documentation of any attempt to retrieve the technology.* • The MDPP supplier must retain and provide access to the documentation.

* = Items of technology with a retail value greater than $100 remain the property of the MDPP supplier and must be retrieved from the MDPP beneficiary at the end of the engagement incentive period.

Our proposals for the documentation requirements for beneficiary engagement incentives under the MDPP expanded model are included at proposed § 424.210(e). We are inviting public comments on our proposed documentation requirements, including whether additional or different documentation requirements may provide better program integrity safeguards.

vi. Compliance With Fraud and Abuse Laws

Certain arrangements between MDPP suppliers and beneficiaries may implicate the civil monetary penalty (CMP) law (sections 1128A(a)(5), (b)(1) and (b)(2) of the Act), or the Federal Anti-kickback statute (section 1128B(b)(1) and (2) of the Act). In many cases, arrangements that implicate these laws can be structured to comply with them by using existing safe harbors and exceptions. Section 1115A(d)(1) of the Act authorizes the Secretary to waive certain specified fraud and abuse laws as may be necessary solely for purposes of testing of models under section 1115A(b) of the Act. A waiver is not needed for an arrangement that does not implicate the fraud and abuse laws or that implicates the fraud and abuse laws, but either fits within an existing exception or safe harbor, as applicable, or does not otherwise violate the law. Accordingly, pursuant to section 1115A(d)(1) of the Act, the Secretary will consider whether waivers of certain fraud and abuse laws are necessary for the MDPP expanded model. Such waivers, if any, would be promulgated separately from this proposed regulation by OIG (as to sections 1128A and 1128B of the Act), to which the respective authorities have been delegated.

The requirements in the final rule for the MDPP expanded model will bear on the need for and scope of any fraud and abuse waivers that might be granted for the model. Because of the close nexus between the final regulations governing the structure and operations of the MDPP expanded model and the development of any fraud and abuse waivers necessary to carry out the provisions of the model, CMS and OIG may, when considering the need for or scope of any waivers, consider comments submitted in response to this proposed rule and the provisions of the final rule.

3. Virtual DPP and the MDPP Expanded Model

The CDC's DPRP standards allow evidence-based DPP curricula to be furnished through a variety of modes, including through remote technologies. Similar to the description noted in section III.K.2.c.iv.3 with respect to virtual make-up sessions, virtual DPP refers to any modality, or method of furnishing MDPP services, that is not in person. This includes, but is not limited to:

(1) Furnishing services online where the behavior change program is furnished 100 percent online, with participants accessing course resources and lifestyle coach via a computer, laptop, tablet, smart phone, or other device with internet access. This modality requires an internet connection to participate in all aspects of the DPP;

(2) Furnishing services online with other means of support by a coach (for example, telecommunications, video conferencing). This modality requires an internet connection for some aspects of the DPP, but not all; and

(3) Distance learning, where a coach is present in one location and participants are calling, video-conferencing, or otherwise using telecommunications technology to access the coach from another location. This modality does not require any internet connection for any of the aspects of the DPP.

These types of delivery modes are hereafter referred to as ''virtual,'' and DPP furnished *exclusively* through these modes with no in-person delivery is hereafter referred to as ''virtual DPP.''

We acknowledge that the public comments in response to the MDPP expanded model in the CY 2017 PFS proposed rule supported the inclusion of virtual DPP in the MDPP expanded model. Many commenters stated that this proposal would increase access to MDPP services, referenced emerging evidence that suggests virtual DPP may be as effective as DPP furnished in a community setting, and stated that virtual delivery may be preferable to some beneficiaries. In the CY 2017 PFS final rule, we deferred policies pertinent

to virtual DPP to future rulemaking. While we propose to allow a limited number of virtual make-up sessions in the MDPP expanded model (discussed in section III.K.2.c.iv.3), we do not propose to include virtual DPP services (that is, DPP furnished *exclusively* through remote technologies with no in-person delivery) . We considered including virtual DPP services in the MDPP expanded model, however, the DPP model test that was used to make the statutorily required determination for expansion did not include virtual DPP services. Instead, we are considering a separate model under CMS's Innovation Center authority to test and evaluate virtual DPP services. Our intention is that any separate model test of virtual DPP services would run in parallel with the MDPP Expanded Model. Consistent with our regular practice for Innovation Center models, we would release details on the model test for virtual DPP services separately.

We note that some DPP suppliers currently offer DPP services through a combination of in-person and virtual delivery. We only propose to allow this combination of delivery subject to the requirements on virtual make-up sessions discussed in section III.K.2.c.iv.3. The combined-delivery DPP services that are currently offered are intended to offer a participant DPP services through both online and in-person methods. The MDPP expanded model, in contrast, is intended to offer participants in-person DPP services primarily, but allows a limited number of virtual make-up sessions on an individual basis. As discussed in section III.K.2.c.iv.3., there is substantial research on the effectiveness of DPP furnished virtually, and emerging evidence on DPP delivered virtually suggests that virtual delivery can show similarly successful participant weight loss and health benefits to DPP delivered in other settings, including among Medicare-age participants. However, since the DPP model test only included in-person delivery, we propose to limit the number of virtually-delivered make-up sessions to the limits discussed in section III.K.2.c.iv.3.

An organization may furnish separate DPPs where some participants receive only in-person DPP services, others receive only virtual DPP services, and others receive a combination program where some sessions are offered in person and others virtually. If an organization that offers multiple distinct DPPs through different delivery modes enrolls as an MDPP supplier, we propose that only DPP services furnished in person will be paid in the MDPP expanded model, with the exception of virtual make-up sessions as discussed in section III.K.2.c.iv.3 of this proposed rule.

We invite public comments on these policies.

4. Evaluation

We intend to evaluate the MDPP expanded model using a combination of encounter and claims data to analyze the long-term utilization of services by beneficiaries who have received the MDPP benefit. As discussed in the CY 2017 PFS final rule, we will continue to assess whether the MDPP expanded model is expected to improve the quality of care without increasing spending, reduce spending without reducing the quality of care, or improve the quality of care and reduce spending, and we will terminate or modify the MDPP expanded model if the expanded model is not expected to meet these criteria.

Among other possible questions we might explore, our analysis will specifically look at long-term utilization and expenditures that might suggest subsequent treatment of diabetes. We intend to use beneficiary-level encounter data and program data furnished by CDC and will match these data to Medicare claims using the crosswalk finalized at § 424.59(b)(3) of the CY 2017 PFS final rule (proposed to be redesignated and amended at § 424.205(d)(13)). As with other Innovation Center model evaluation reports (which are currently published online at *https://innovation.cms.gov/Data-and-Reports/index.html*), we intend to publish the MDPP evaluation annual reports publicly on a CMS Web site. We refer readers to the supplier requirements discussed under section III.K.2.e.iv.(7) of this proposed rule for the proposal regarding supplier compliance with this requirement, as well as specifications on the timing and format of the crosswalk.

L. Request for Information on CMS Flexibilities and Efficiencies

CMS is committed to transforming the health care delivery system—and the Medicare program—by putting an additional focus on patient-centered care and working with providers, physicians, and patients to improve outcomes. We seek to reduce burdens for hospitals, physicians, and patients, improve the quality of care, decrease costs, and ensure that patients and their providers and physicians are making the best health care choices possible. These are the reasons we are including this Request for Information in this proposed rule.

As we work to maintain flexibility and efficiency throughout the Medicare program, we would like to start a national conversation about improvements that can be made to the health care delivery system that reduce unnecessary burdens for clinicians, other providers, and patients and their families. We aim to increase quality of care, lower costs improve program integrity, and make the health care system more effective, simple and accessible.

We would like to take this opportunity to invite the public to submit their ideas for regulatory, subregulatory, policy, practice, and procedural changes to better accomplish these goals. Ideas could include payment system redesign, elimination or streamlining of reporting, monitoring and documentation requirements, aligning Medicare requirements and processes with those from Medicaid and other payers, operational flexibility, feedback mechanisms and data sharing that would enhance patient care, support of the physician-patient relationship in care delivery, and facilitation of individual preferences. Responses to this Request for Information could also include recommendations regarding when and how CMS issues regulations and policies and how CMS can simplify rules and policies for beneficiaries, clinicians, physicians, providers, and suppliers. Where practicable, data and specific examples would be helpful. If the proposals involve novel legal questions, analysis regarding CMS' authority is welcome for CMS' consideration. We are particularly interested in ideas for incentivizing organizations and the full range of relevant professionals and paraprofessionals to provide screening, assessment and evidence-based treatment for individuals with opioid use disorder and other substance use disorders, including reimbursement methodologies, care coordination, systems and services integration, use of paraprofessionals including community paramedics and other strategies. We are requesting commenters to provide clear and concise proposals that include data and specific examples that could be implemented within the law.

We note that this is a Request for Information only. Respondents are encouraged to provide complete but concise responses. This Request for Information is issued solely for information and planning purposes; it does not constitute a Request for Proposal (RFP), applications, proposal abstracts, or quotations. This Request for Information does not commit the U.S.

Government to contract for any supplies or services or make a grant award. Further, CMS is not seeking proposals through this Request for Information and will not accept unsolicited proposals. Responders are advised that the U.S. Government will not pay for any information or administrative costs incurred in response to this Request for Information; all costs associated with responding to this Request for Information will be solely at the interested party's expense. We note that not responding to this Request for Information does not preclude participation in any future procurement, if conducted. It is the responsibility of the potential responders to monitor this Request for Information announcement for additional information pertaining to this request. In addition, we note that CMS will not respond to questions about the policy issues raised in this Request for Information. CMS will not respond to comment submissions in response to this Request for Information in the FY 2018 PFS final rule. Rather, CMS will actively consider all input as we develop future regulatory proposals or future subregulatory policy guidance. CMS may or may not choose to contact individual responders. Such communications would be for the sole purpose of clarifying statements in the responders' written responses. Contractor support personnel may be used to review responses to this Request for Information. Responses to this notice are not offers and cannot be accepted by the Government to form a binding contract or issue a grant. Information obtained as a result of this Request for Information may be used by the Government for program planning on a nonattribution basis. Respondents should not include any information that might be considered proprietary or confidential. This Request for Information should not be construed as a commitment or authorization to incur cost for which reimbursement would be required or sought. All submissions become U.S. Government property and will not be returned. CMS may publically post the public comments received, or a summary of those public comments.

IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. chapter 35), we are required to publish a 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval.

To fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our burden estimates.
- The quality, utility, and clarity of the information to be collected.
- Our effort to minimize the information collection burden on the affected public, including the use of automated collection techniques.

We are soliciting public comment on each of the required issues under section 3506(c)(2)(A) of the PRA for the following information collection requirements (ICRs): (1) The Medicare Diabetes Prevention Program (MDPP) Expanded Model, (2) the Physician Quality Reporting System (PQRS), (3) appropriate use criteria for advanced diagnostic imaging services, and (4) the Medicare Shared Savings Program.

A. Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2016 National Occupational Employment and Wage Estimates for all salary estimates (*http://www.bls.gov/oes/current/oes_nat.htm*). In this regard, Table 36 presents the mean hourly wage, the cost of fringe benefits and overhead (calculated at 100 percent of salary), and the adjusted hourly wage.

TABLE 36—NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

Occupation title	Occupation code	Mean hourly wage ($/hr)	Fringe benefits and overhead costs ($/hr)	Adjusted hourly wage ($/hr)
Family and General Practitioner	29–1062	96.54	96.54	193.08

As indicated, we are adjusting our employee hourly wage estimates by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Nonetheless, there is no practical alternative and we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

B. Proposed Information Collection Requirements (ICRs)

1. ICRs Regarding the Medicare Diabetes Prevention Program (MDPP) Expanded Model

In §§ 410.79, 414.84, 424.200, 424.205, 424.210, 424.502, 424.516, 424.518 and 424.55 of this proposed rule, we discuss our proposals to further implement the Medicare Diabetes Prevention Program (MDPP) Expanded Model, which is aimed at preventing the onset of type 2 diabetes among Medicare beneficiaries with prediabetes. Section 1115A(d)(3) of the Act exempts Innovation Center model tests and expansions, which include the MDPP expanded model, from the provisions of the PRA. Specifically, this section provides that the provisions of the PRA shall not apply to the testing and evaluation of Innovation Center models or expansions of such models.

2. ICRs Regarding the Physician Quality Reporting System (PQRS) (§ 414.90)

While this rule proposes to revise our PQRS reporting criteria for the 2016 reporting period to avoid the 2018 payment adjustment, we are not proposing to accept any additional data for the 2016 reporting period. In this regard this rule does not set out any new or revised burden or requirements that would trigger the requirements of the PRA.

3. ICRs Regarding Appropriate Use Criteria for Advanced Diagnostic Imaging Services (§ 414.94)

This rule proposes to revise § 414.94(i)(3) by reiterating the availability of a significant hardship exception for ordering professionals who demonstrate a significant hardship consistent with the criteria listed under § 495.102(d)(4)(i), (d)(4)(iii), (d)(4)(iv)(A) or (d)(4)(iv)(B). Consistent with a final rule that published on November 14,

2016 (81 FR 79865 through 79866) the hardship exception process involves the completion of an application which imposes no burden beyond the provision of identifying information and attesting to the applicable information. In this regard, the application is not ''information'' as defined under 5 CFR 1320.3(h), and therefore, is exempt from requirements of the PRA.

Consistent with section 1834(q)(4)(A) of the Act (as amended by section 218(b) of the PAMA), § 414.94(j) proposes to require that ordering professionals consult specified applicable AUC through a qualified clinical decision support mechanism (CDSM) for applicable imaging services ordered on or after January 1, 2019. We propose a one-time burden associated with a possible 6-month voluntary consulting period beginning sometime in 2018, as well as a mandatory annual burden beginning January 1, 2019. Because general practitioners are the largest group of practitioners who order applicable imaging services and would be required to consult AUC under this program we use ''family and general practitioner'' for our estimates below.

During the 6-month voluntary participation period, we estimate 3,410,000 responses in the form of consultations based on market research from current applicants for the qualification of their CDSMs for advanced diagnostic imaging services. Based on feedback from CDSMs with experience in AUC consultation as well as standards recommended by the Office of the National Coordinator (ONC) and the Healthcare Information Management Systems Society (HIMSS), we estimate it would take 2 minutes at $193.08/hr for a family and general practitioner to use a qualified CDSM to consult specified applicable AUC. Per consultation, we estimate 2 minutes (0.033 hr) at a cost of $6.37 (0.033 hr × $193.08/hr). In aggregate, we estimate a one-time burden of 112,530 hours (0.033 hr × 3,410,000 consultations) at a cost of $21,727,292.40 (112,530 hr × $193.08/hr).

Annually, we estimate 37,510 hours (112,530 hr/3 yr) at a cost of $7,242,430.80 ($21,727,292.40/3 yr). We are annualizing the one-time burden (by dividing our estimates by OMB's 3-year approval period) since we do not anticipate any additional burden after the 6-month voluntary participation period ends.

Beginning January 1, 2019, we anticipate 43,181,818 responses in the form of consultations based on the aforementioned market research, as well as Medicare claims data for advanced diagnostic imaging services. As noted above, we estimate it would take 2 minutes (0.033 hr) at $193.08/hr for a family and general practitioner to use a qualified CDSM to consult specified applicable AUC. In this regard, we estimate 0.033 hours per consultation at a cost of $6.37 (0.033 hr × $193.08/hr). In aggregate, we estimate an annual burden of 1,425,000 hours (0.033 hr × 43,181,818 consultations) at a cost of $275,139,000 (1,425,000 hr × $193.08/hr).

The consultation requirements and burden will be submitted to OMB for approval under control number 0938-New (CMS–10654).

Consistent with section 1834(q)(4)(B) of the Act, we are also proposing to implement a one-time 6-month voluntary reporting period beginning sometime in 2018, as well as a mandatory annual reporting requirement beginning January 1, 2019. Specifically, § 414.94(k) proposes to require that furnishing professionals report on the Medicare claims for advanced diagnostic imaging services, paid for under an applicable payment system (as defined in § 414.94(b)) and ordered on or after January 1, 2019, the following information: (1) Identify which qualified CDSM was consulted by the ordering professional; (2) identify whether the service ordered would adhere to specified applicable AUC, would not adhere to specified applicable AUC, or whether specified applicable AUC was not applicable to the service ordered; and (3) identify the NPI of the ordering professional (if different from the furnishing professional). The proposed reporting requirement would not have any impact on any Medicare claim forms because the forms' currently approved data fields, instructions, and burden are not expected to change. Consequently, there is no need for review by OMB under the authority of the PRA.

The timing and implementation of the voluntary consultation and reporting period is dependent on the readiness of the Medicare claims systems to accept and process claims including AUC consultation information. Currently, 99 percent of all Medicare claims are submitted electronically as a result of The Administrative Simplification Compliance Act amendment to section 1862(a) of the Act, which prescribes that no payment may be made under Part B of the Medicare Program for any expenses incurred for items or services for which a claim is received in a non-electronic form. Consequently, absent an applicable exception, paper claims received by Medicare will not be paid. Continued developments in the deployment of CDSMs has produced research [28] and best practices [29] [30] [31] supporting our position that any such changes made to respondent IT systems would be a usual and customary business practice whose burden is exempt from the requirements of the PRA under 5 CFR 1320.3(b).

4. ICRs Regarding the Medicare Shared Savings Program (Part 425)

Section 1899(e) of the Act provides that chapter 35 of title 44 of the U.S. Code, which includes such provisions as the PRA, shall not apply to the Shared Savings Program.

C. Summary of Annual Burden Estimates for Proposed Requirements

TABLE 37—PROPOSED ANNUAL REQUIREMENTS AND BURDEN

Regulation section(s)	OMB control number	Respondents	Responses	Burden per response (hours)	Total annual burden (hours)	Labor cost of reporting ($/hr)	Total cost ($) *
§ 414.94(j) (voluntary consultations)	0938-New	3,410,000	1,136,666.67 (3,410,000/3)	0.033	37,510	193.08	7,242,431
§ 414.94(j) (mandatory consultations)		43,181,818	43,181,818	0.033	1,425,000	193.08	275,139,000

[28] CDC Health Information Innovation Consortium, May 17 2016, available at *https://www.cdc.gov/ophss/chiic/forums/2016-05-17_index.html.*

[29] ONC eCQI resource for process improvement: *bit.ly/oncecqicds.*

[30] CMS CDS tipsheet: *bit.ly/cmscdstips.*

[31] HIMSS CDS Guidebook Series: *www.himss.org/cdsguide.*

TABLE 37—PROPOSED ANNUAL REQUIREMENTS AND BURDEN—Continued

Regulation section(s)	OMB control number	Respondents	Responses	Burden per response (hours)	Total annual burden (hours)	Labor cost of reporting ($/hr)	Total cost ($) *
Total		46,591,818	44,318,485	0.033	1,462,510	193.08	282,381,431

* With respect to the PRA, this rule would not impose any non-labor costs.

D. Submission of PRA-Related Comments

We have submitted a copy of this proposed rule to OMB for its review of the rule's information collection and recordkeeping requirements. These requirements are not effective until they have been approved by the OMB.

To obtain copies of the supporting statement and any related forms for the proposed collections discussed above, please visit CMS' Web site at Web site address at *https://www.cms.gov/Regulations-andGuidance/Legislation/PaperworkReductionActof1995/PRAListing.html,* or call the Reports Clearance Office at 410–786–1326.

We invite public comments on these potential information collection requirements. If you wish to comment, please submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule and identify the rule (CMS–1676–P) and where applicable the ICR's CFR citation, CMS ID number, and OMB control number.

See the **DATES** and **ADDRESSES** sections of this proposed rule for further information.

V. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

VI. Regulatory Impact Analysis

A. Statement of Need

This proposed rule makes payment and policy changes under the Medicare PFS and makes required statutory changes under the MACRA, ABLE, PAMA, and the Consolidated Appropriations Act of 2016. This final rule also makes changes to payment policy and other related policies for Medicare Part B, Part D, and Medicare Advantage.

B. Overall Impact

We examined the impact of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (February 2, 2013), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2)), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). We estimate, as discussed in this section, that the PFS provisions included in this final rule would redistribute more than $100 million in 1 year. Therefore, we estimate that this rulemaking is ''economically significant'' as measured by the $100 million threshold, and hence also a major rule under the Congressional Review Act. Accordingly, we prepared an RIA that, to the best of our ability, presents the costs and benefits of the rulemaking. The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals, practitioners and most other providers and suppliers are small entities, either by nonprofit status or by having annual revenues that qualify for small business status under the Small Business Administration standards. (For details see the SBA's Web site at *http://www.sba.gov/content/table-small-business-size-standards* (refer to the 620000 series)). Individuals and states are not included in the definition of a small entity.

The RFA requires that we analyze regulatory options for small businesses and other entities. We prepare a regulatory flexibility analysis unless we certify that a rule would not have a significant economic impact on a substantial number of small entities. The analysis must include a justification concerning the reason action is being taken, the kinds and number of small entities the rule affects, and an explanation of any meaningful options that achieve the objectives with less significant adverse economic impact on the small entities.

Approximately 95 percent of practitioners, other providers, and suppliers are considered to be small entities, based upon the SBA standards. There are over 1 million physicians, other practitioners, and medical suppliers that receive Medicare payment under the PFS. Because many of the affected entities are small entities, the analysis and discussion provided in this section, as well as elsewhere in this final rule is intended to comply with the RFA requirements regarding significant impact on a substantial number of small entities.

For example, the effects of changes to payment rates for practitioners, other providers, and suppliers are discussed in VI.C. of this proposed rule. Alternative options considered to the proposed payment rates are discussed generally in section VI.F of this proposed rule, while specific alternatives for individual codes are discussed throughout this rule, especially in section II.H.

In addition, section 1102(b) of the Act requires us to prepare an RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. We did not prepare an analysis for section 1102(b) of the Act because we

determined, and the Secretary certified, that this final rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits on state, local, or tribal governments or on the private sector before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2017, that threshold is approximately $148 million. This proposed rule will impose no mandates on state, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it issues a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. Since this regulation does not impose any costs on state or local governments, the requirements of Executive Order 13132 are not applicable.

Executive Order 13771, entitled Reducing Regulation and Controlling Regulatory Costs (82 FR 9339), was issued on January 30, 2017. This proposed rule is subject to the requirements of E.O. 13771 because, if finalized as proposed, it is expected to result in regulatory costs.

We prepared the following analysis, which together with the information provided in the rest of this preamble, meets all assessment requirements. The analysis explains the rationale for and purposes of this proposed rule; details the costs and benefits of the rule; analyzes alternatives; and presents the measures we would use to minimize the burden on small entities. As indicated elsewhere in this proposed rule, we are implementing a variety of changes to our regulations, payments, or payment policies to ensure that our payment systems reflect changes in medical practice and the relative value of services, and implementing statutory provisions. We provide information for each of the policy changes in the relevant sections of this proposed rule. We are unaware of any relevant federal rules that duplicate, overlap, or conflict with this proposed rule. The relevant sections of this proposed rule contain a description of significant alternatives if applicable.

C. Changes in Relative Value Unit (RVU) Impacts

1. Resource-Based Work, PE, and MP RVUs

Section 1848(c)(2)(B)(ii)(II) of the Act requires that increases or decreases in RVUs may not cause the amount of expenditures for the year to differ by more than $20 million from what expenditures would have been in the absence of these changes. If this threshold is exceeded, we make adjustments to preserve budget neutrality.

Our estimates of changes in Medicare expenditures for PFS services compare payment rates for CY 2017 with proposed payment rates for CY 2018 using CY 2016 Medicare utilization. The payment impacts in this proposed rule reflect averages by specialty based on Medicare utilization. The payment impact for an individual practitioner could vary from the average and would depend on the mix of services he or she furnishes. The average percentage change in total revenues would be less than the impact displayed here because practitioners and other entities generally furnish services to both Medicare and non-Medicare patients. In addition, practitioners and other entities may receive substantial Medicare revenues for services under other Medicare payment systems. For instance, independent laboratories receive approximately 83 percent of their Medicare revenues from clinical laboratory services that are paid under the Clinical Laboratory Fee Schedule.

The annual update to the PFS conversion factor (CF) was previously calculated based on a statutory formula; for details about this formula, we refer readers to the CY 2015 PFS final rule with comment period (79 FR 67741 through 67742). Section 101(a) of the MACRA repealed the previous statutory update formula and amended section 1848(d) of the Act to specify the update adjustment factors for calendar years 2015 and beyond. For CY 2018, the specified update is 0.5 percent before applying other adjustments.

Section 220(d) of the PAMA added a new paragraph at section 1848(c)(2)(O) of the Act to establish an annual target for reductions in PFS expenditures resulting from adjustments to relative values of misvalued codes. Under section 1848(c)(2)(O)(ii) of the Act, if the net reduction in expenditures for the year is equal to or greater than the target for the year, reduced expenditures attributable to such adjustments shall be redistributed in a budget-neutral manner within the PFS in accordance with the existing budget neutrality requirement under section 1848(c)(2)(B)(ii)(II) of the Act. Section 1848(c)(2)(O)(iii) of the Act specifies that, if the estimated net reduction in PFS expenditures for the year is less than the target for the year, an amount equal to the target recapture amount shall not be taken into account when applying the budget neutrality requirements specified in section 1848(c)(2)(B)(ii)(II) of the Act. We estimate the CY 2018 net reduction in expenditures resulting from adjustments to relative values of misvalued codes to be 0.31 percent. Since this amount does not meet the 0.5 percent target established by the Achieving a Better Life Experience Act of 2014 (ABLE) (Division B of Pub. L. 113–295, enacted December 19, 2014), payments under the fee schedule must be reduced by the difference between the target for the year and the estimated net reduction in expenditures, known as the target recapture amount. As a result, we estimate that the CY 2018 target recapture amount will produce a reduction to the conversion factor of −0.19 percent.

To calculate the proposed conversion factor for this year, we multiplied the product of the current year conversion factor and the update adjustment factor by the target recapture amount and the budget neutrality adjustment described in the preceding paragraphs. We estimate the CY 2018 PFS conversion factor to be 35.9903, which reflects the budget neutrality adjustment, the 0.5 percent update adjustment factor specified under section 1848(d)(18) of the Act, and the −0.31 percent target recapture amount required under section 1848(c)(2)(O)(iv) of the Act and described above. We estimate the CY 2018 anesthesia conversion factor to be 22.0353, which reflects the same overall PFS adjustments, as well as an additional adjustment due to an update to the malpractice risk factor for the anesthesia specialty.

TABLE 38—CALCULATION OF THE PROPOSED CY 2018 PFS CONVERSION FACTOR

Conversion factor in effect in CY 2017		35.8887
Update Factor	0.50 percent (1.0050)	
CY 2018 RVU Budget Neutrality Adjustment	−0.03 percent (0.9997)	

TABLE 38—CALCULATION OF THE PROPOSED CY 2018 PFS CONVERSION FACTOR—Continued

Conversion factor in effect in CY 2017		35.8887
CY 2018 Target Recapture Amount	−0.19 percent (0.9981)	
CY 2018 Conversion Factor		35.9903

TABLE 39—CALCULATION OF THE PROPOSED CY 2018 ANESTHESIA CONVERSION FACTOR

CY 2017 national average anesthesia conversion factor		22.0454
Update Factor	0.50 percent (1.0050)	
CY 2018 RVU Budget Neutrality Adjustment	−0.03 percent (0.9997)	
CY 2018 Target Recapture Amount	−0.19 percent (0.9981)	
CY 2018 Anesthesia Fee Schedule Practice Expense and Malpractice Adjustment	−0.33 percent (0.9967)	
CY 2018 Conversion Factor		22.0353

Table 40 shows the payment impact on PFS services of the proposals contained in this proposed rule. To the extent that there are year-to-year changes in the volume and mix of services provided by practitioners, the actual impact on total Medicare revenues would be different from those shown in Table 40 (CY 2018 PFS Estimated Impact on Total Allowed Charges by Specialty). The following is an explanation of the information represented in Table 40.

- *Column A (Specialty):* Identifies the specialty for which data are shown.
- *Column B (Allowed Charges):* The aggregate estimated PFS allowed charges for the specialty based on CY 2016 utilization and CY 2017 rates. That is, allowed charges are the PFS amounts for covered services and include coinsurance and deductibles (which are the financial responsibility of the beneficiary). These amounts have been summed across all services furnished by physicians, practitioners, and suppliers within a specialty to arrive at the total allowed charges for the specialty.
- *Column C (Impact of Work RVU Changes):* This column shows the estimated CY 2018 impact on total allowed charges of the changes in the work RVUs, including the impact of changes due to potentially misvalued codes.
- *Column D (Impact of PE RVU Changes):* This column shows the estimated CY 2018 impact on total allowed charges of the changes in the PE RVUs.
- *Column E (Impact of MP RVU Changes):* This column shows the estimated CY 2018 impact on total allowed charges of the changes in the MP RVUs, which are primarily driven by the required five-year review and update of MP RVUs.
- *Column F (Combined Impact):* This column shows the estimated CY 2018 combined impact on total allowed charges of all the changes in the previous columns. Column F may not equal the sum of columns C, D, and E due to rounding.

TABLE 40—CY 2018 PFS ESTIMATED IMPACT ON TOTAL ALLOWED CHARGES BY SPECIALTY *

(A) Specialty	(B) Allowed charges (mil)	(C) Impact of work RVU changes (percent)	(D) Impact of PE RVU changes (percent)	(E) Impact of MP RVU changes (percent)	(F) Combined impact ** (percent)
TOTAL	$92,628	0	0	0	0
ALLERGY/IMMUNOLOGY	245	0	−3	0	−3
ANESTHESIOLOGY	2,009	−1	0	0	0
AUDIOLOGIST	66	0	0	−1	−1
CARDIAC SURGERY	311	0	0	−1	−2
CARDIOLOGY	6,671	0	−1	−1	−2
CHIROPRACTOR	772	0	1	0	1
CLINICAL PSYCHOLOGIST	756	0	2	0	2
CLINICAL SOCIAL WORKER	664	0	3	0	3
COLON AND RECTAL SURGERY	166	0	0	−1	−1
CRITICAL CARE	332	0	0	0	0
DERMATOLOGY	3,475	0	0	−1	−1
DIAGNOSTIC TESTING FACILITY	765	0	−6	0	−6
EMERGENCY MEDICINE	3,176	0	0	−1	−1
ENDOCRINOLOGY	477	0	0	0	0
FAMILY PRACTICE	6,307	0	0	0	0
GASTROENTEROLOGY	1,792	0	0	−1	−1
GENERAL PRACTICE	452	0	0	0	0
GENERAL SURGERY	2,154	0	0	0	−1
GERIATRICS	211	0	0	0	1
HAND SURGERY	200	0	0	0	1
HEMATOLOGY/ONCOLOGY	1,802	0	0	0	0
INDEPENDENT LABORATORY	684	0	−1	0	−2
INFECTIOUS DISEASE	651	0	0	1	1
INTERNAL MEDICINE	11,022	0	0	0	0
INTERVENTIONAL PAIN MGMT	830	0	0	0	0

TABLE 40—CY 2018 PFS ESTIMATED IMPACT ON TOTAL ALLOWED CHARGES BY SPECIALTY *—Continued

(A) Specialty	(B) Allowed charges (mil)	(C) Impact of work RVU changes (percent)	(D) Impact of PE RVU changes (percent)	(E) Impact of MP RVU changes (percent)	(F) Combined impact ** (percent)
INTERVENTIONAL RADIOLOGY	357	0	−1	0	−1
MULTISPECIALTY CLINIC/OTHER PHYS	139	0	0	0	0
NEPHROLOGY	2,257	0	0	0	0
NEUROLOGY	1,545	0	0	0	0
NEUROSURGERY	805	0	0	−1	−1
NUCLEAR MEDICINE	50	0	0	0	0
NURSE ANES/ANES ASST	1,238	−1	0	1	−1
NURSE PRACTITIONER	3,541	0	0	0	0
OBSTETRICS/GYNECOLOGY	658	0	0	−1	−1
OPHTHALMOLOGY	5,480	0	0	0	0
OPTOMETRY	1,259	0	0	0	0
ORAL/MAXILLOFACIAL SURGERY	57	0	−2	0	−2
ORTHOPEDIC SURGERY	3,784	0	0	0	0
OTHER	28	0	0	0	0
OTOLARNGOLOGY	1,232	0	−1	0	−2
PATHOLOGY	1,147	0	0	0	−1
PEDIATRICS	63	0	0	0	0
PHYSICAL MEDICINE	1,105	0	0	0	1
PHYSICAL/OCCUPATIONAL THERAPY	3,780	1	1	0	1
PHYSICIAN ASSISTANT	2,232	0	0	0	0
PLASTIC SURGERY	379	0	0	0	0
PODIATRY	1,973	0	1	1	1
PORTABLE X–RAY SUPPLIER	100	0	−1	0	−1
PSYCHIATRY	1,233	0	1	0	1
PULMONARY DISEASE	1,753	0	0	0	0
RADIATION ONCOLOGY AND RADIATION THERAPY CENTERS	1,784	0	1	1	1
RADIOLOGY	4,863	0	−1	0	−1
RHEUMATOLOGY	553	0	0	0	0
THORACIC SURGERY	356	0	0	−1	−1
UROLOGY	1,772	0	−1	0	−1
VASCULAR SURGERY	1,115	0	−1	0	−2

** Column F may not equal the sum of columns C, D, and E due to rounding.

2. CY 2018 PFS Impact Discussion

a. Changes in RVUs

The most widespread specialty impacts of the final RVU changes are generally related to the changes to RVUs for specific services resulting from the Misvalued Code Initiative, including finalized RVUs for new and revised codes. The estimated impacts for some specialties, including behavioral health specialists, physical and occupational therapists, and radiation oncology, reflect increases relative to other physician specialties. These increases can largely be attributed to proposed increases in value for particular services following the American Medical Association Relative Value Update Committee and CMS review, the proposed change in allocation of indirect practice expense RVUs for office-based, face-to-face behavioral health services, and proposed changes based on updated professional liability premium data.

The estimated impacts for several specialties, including diagnostic testing facilities, allergy/immunology, otolaryngology, oral/maxillofacial surgery, and independent laboratories, reflect decreases in payments relative to payment to other physician specialties as a result of proposed revaluation of individual procedures reviewed by the American Medical Association Relative Value Update Committee and CMS, proposed changes based on updated professional liability premium data, proposed decreases in relative payment as a result of proposed updates to prices for particular medical supplies, and continued implementation of previously finalized code-level reductions that are being phased-in over several years. For independent laboratories, it is important to note that these entities receive approximately 83 percent of their Medicare revenues from services that are paid under the Clinical Laboratory Fee Schedule. As a result, the estimated 2 percent reduction for CY 2018 is only applicable to approximately 17 percent of the Medicare payment to these entities.

We often receive comments regarding the changes in RVUs displayed on the specialty impact table, including comments received in response to the proposed rates. We remind stakeholders that although the estimated impacts are displayed at the specialty level, typically the changes are driven by the valuation of a relatively small number of new and/or potentially misvalued codes. The percentages in the table are based upon aggregate estimated PFS allowed charges summed across all services furnished by physicians, practitioners, and suppliers within a specialty to arrive at the total allowed charges for the specialty, and compared to the same summed total from the previous calendar year. They are therefore averages, and may not necessarily be representative of what is happening to the particular services furnished by a single practitioner within any given specialty.

b. Impact

Column F of Table 40 displays the estimated CY 2018 impact on total allowed charges, by specialty, of all the RVU changes. A table shows the estimated impact on total payments for selected high volume procedures of all

of the changes is available under ''downloads'' on the CY 2018 PFS proposed rule Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/.* We selected these procedures for sake of illustration from among the most commonly furnished by a broad spectrum of specialties. The change in both facility rates and the nonfacility rates are shown. For an explanation of facility and nonfacility PE, we refer readers to Addendum A on the CMS Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/.*

D. Effect of Changes in Telehealth List

As discussed in section II.D. of this proposed rule, we are proposing to add several new codes to the list of Medicare telehealth services. Although we expect these changes to have the potential to increase access to care in rural areas, based on recent telehealth utilization of services already on the list, including services similar to the proposed additions, we estimate no significant impact on PFS expenditures from the proposed additions. For example, for services already on the list, they are furnished via telehealth, on average, less than 0.1 percent of the time they are reported overall.

E. Effect of Changes to Payment to Provider-Based Departments (PBDs) of Hospitals Paid Under the PFS

As discussed in section II.G of this proposed rule, for CY 2018, we are proposing a PFS Relativity Adjuster of 25 percent, meaning that nonexcepted items and services furnished by nonexcepted PBDs would be paid under the PFS at a rate that is 25 percent of the OPPS rate. We estimate that this change will result in total Medicare Part B savings of $25 million for CY 2018 relative to maintaining the CY 2017 PFS Relativity Adjuster for CY 2018.

F. Other Provisions of the Proposed Regulation

1. New Care Coordination Services and Payment for RHCs and FQHCs

As discussed in section III.A of this proposed rule, we are proposing the establishment of two new G codes for use by RHCs and FQHCs. The first new G code would be a General Care Management code for RHCs and FQHCs with the payment amount set at the average of the 3 national non-facility PFS payment rates for the CCM and general BHI codes. The second new G code for RHCs and FQHCs would be a Psychiatric CoCM code with the payment amount set at the average of the 2 national non-facility PFS payment rates for psychiatric CoCM services. The payment rate for each code would be updated annually, based on the national non-facility PFS payment rates for each code contained in the G code.

The proposed methodology for payment of care coordination services is consistent with the RHC and FQHC payment principles of not paying for services based on time increments. It does not create additional reporting burden and is expected to promote beneficiary access to comprehensive care management services furnished by RHCs and FQHCs.

Establishment of the RHC and FQHC General Care Management code, which includes all levels of CCM and general BHI services, is projected to increase Medicare spending by $600,000 in CY 2018 and by $7.4 million over 10 years. This estimate is based on the proposed per service allowed charge increase (from approximately $42.71 to $61.37) applied to historical 2016 CCM and BHI volume in RHCs and FQHCs. This volume was adjusted with an assumed 10 percent behavioral volume increase to reflect the increase in allowed charges per service.

Establishment of the RHC and FQHC Psychiatric CoCM code, which includes all levels of psychiatric CoCM services, is projected to increase Medicare spending by approximately $100,000 in CY2018 and $3.7 million over 10 years. Because psychiatric CoCM is not billable currently by RHCs or FQHCs and is also new to practitioners billing under the PFS, this estimate is based on first quarter 2017 PFS psychiatric CoCM claims of 0.03 percent of psychiatric E/M visits, adjusted to an ultimate average rate of 0.16 percent based on the pattern of increase in CCM services in the PFS found in the first two years of implementation. This rate was then applied to the number of 2016 RHC and FQHC mental health visits to get an estimate of CoCM volume, and then projected forward on a per-capita basis. PFS price updates were applied to the initial approximate $135 psychiatric CoCM payment amount to project future costs.

The combined increase in Medicare spending for both new G codes is estimated to be approximately $600,000 in 2018, and approximately $11.1 million over 10 years. While these services are expected to increase quality and improve efficiency over time, the programs are still new and the data is not available yet to demonstrate any cost savings. Therefore, no healthcare cost reductions were assumed as a result of increased care management.

TABLE 42—CALENDAR YEARS 2018–2027 PROJECTED SPENDING IMPACT OF NEW GENERAL CARE MANAGEMENT AND PSYCHIATRIC COCM CODES FOR RHCS AND FQHCS (MILLIONS) [32]

CY	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2018–2027
General Care Management	0.6	0.7	0.7	0.7	0.7	0.8	0.8	0.8	0.8	0.8	7.4
Psychiatric CoCM	0.1	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4	3.7
Total	0.8	1.0	1.1	1.1	1.1	1.1	1.2	1.2	1.2	1.3	11.1

[32] Figures may not sum to totals due to rounding.

As discussed in section III.A. of this proposed rule, we considered 3 other options (for example, allowing any of the 7 codes to be separately added to a claim, bundling all 7 codes into one G code, and developing 3 separate G codes—one each for CCM, BHI, and CoCM services). We estimate that there would be no significant difference in the costs among the options because all of the options considered include the same services paid at the same rate and no data is available to estimate a different rate of billing for each code.

2. Payment for DME Infusion Drugs

As discussed in section III.B. of this proposed rule, we proposed to conform the regulation text at § 414.904(e)(2) to section 5004 of the Cures Act, which transitioned payment for DME infusion drugs from AWP-based pricing to the ASP-pricing methodology on January 1, 2017. Table 43 shows the effect of changes in drug payments to DME suppliers. We estimate adoption of the ASP+6 pricing methodology will result in total Medicare Part B savings ranging over the 10-year period from $40 million in FY 2017 to $110 million in FY 2026 with a 10-year total Medicare Part B savings of $960 million.

TABLE 43—IMPACT OF CURES SECTION 5004 ON PAYMENT FOR INFUSION DRUGS FURNISHED THROUGH AN ITEM OF DMS (IN MILLIONS)

FY	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	5-yr impact 2017–2021	10-yr impact 2017–2026
Benefits	(50)	(110)	(130)	(130)	(130)	(130)	(150)	(150)	(150)	(150)	(550)	(1,280)
Premium Offset	10	30	30	30	30	30	40	40	40	40	130	320
Total Part B	(40)	(80)	(100)	(100)	(100)	(100)	(110)	(110)	(110)	(110)	(420)	(960)

3. Appropriate Use Criteria for Advanced Diagnostic Imaging Services

We are proposing and requesting public comment on the appropriate use criteria (AUC) consulting and reporting requirements and the effective date on which these requirements will begin. We are also proposing modifications to the significant hardship exception to better align these exceptions under the AUC program with those under existing quality programs. In the COI section of this document, we have estimated the proposed consulting requirement to result in an annual burden of 1,425,000 hours at a cost of $275,139,000. Under these proposals, claims for advanced diagnostic imaging services would not be denied in CY 2018, and thus, these proposals would not impact CY 2018 physician payments under the PFS. The Congressional Budget Office estimates that section 218 of the PAMA would save approximately 200 million dollars over 10 years from FY 2014 through 2024, which could be the result of identification of outlier ordering professionals. Because we have not yet proposed a mechanism or calculation for outlier ordering professional identification and prior authorization, we are unable to quantify that impact at this time. We will provide an impact statement when applicable in future rulemaking.

4. Physician Quality Reporting System Criteria for Satisfactory Reporting for Individual EPs

a. Burden Estimate for PQRS Reporting

We previously discussed the burden estimate for PQRS regarding the program year 2016 reporting criteria, which applies to the 2018 payment adjustment in the CY 2016 PFS final rule (see 80 FR 71362 through 71367). The burden estimates for reporting that data have not changed since these data for program year 2016 PQRS have already been reported; therefore, there are no added burden estimates for the proposed policy change in this rule in section III.F.

b. Burden Savings Estimated Based on PQRS Measures Reduction Proposed Policy

Amending the policy to reduce the amount of measures needed to satisfactorily report to avoid the 2018 payment adjustment from 9 measures across 3 NQS domains to 6 measures (see section III.F. of this proposed rule) would increase the amount of satisfactory reporters for the 2016 reporting period, which would decrease those subject to the 2018 payment adjustment. Using data from the 2015 reporting period as the basis for our estimates, there were roughly 525,000 eligible professionals who failed the PQRS reporting requirements for the 2015 reporting period and received a downward payment adjustment in 2017 (see *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/Downloads/2015_PQRS_Experience_Report.pdf*). We estimate that, based on 2015 results, approximately 4.5 percent of EPs that received a downward payment adjustment would be found successful and therefore would avoid the payment penalty. This equates to an estimated 23,625 EPs that would no longer be subject to the 2018 payment adjustment based on PQRS data for the 2015 reporting period.

Based on the estimated average payment adjustment of $937.02 in program year 2015, which was negative 2 percent based on 2015 PFS charges, an estimated ($937.02 × 23,625 = $22,137,097.50) would be the amount EPs would receive as a result of not being subject to the 2018 payment adjustment due to the proposed measure reduction policy in this rule for PQRS program year 2016, which applies to the 2018 payment adjustment.

5. Medicare Shared Savings Program

We are proposing certain modifications to our rules regarding ACO assignment and financial calculations, quality measures and quality validation audits, TIN overlaps, and application requirements. Specifically we are proposing: (1) Modifications to how services furnished by FQHCs and RHCs are used for purposes of beneficiary assignment to an ACO as a result of the 21st Century Cures Act, including reducing reporting burden for ACOs that include FQHCs and RHCs; (2) modifications to the assignment methodology to include new chronic care management and behavioral health integration codes in our definition of primary care services; (3) a policy to improve the quality validation audit process and, absent unusual circumstances, to use the results to proportionally modify an ACO's overall quality score; (4) a policy to address substantive changes to quality measures made under the Quality Payment Program; (5) revisions to our application requirements to reduce burden for ACO applicants seeking to participate in the Shared Savings Program and for ACOs applying to use the SNF 3-Day Rule Waiver; (6) changes to our program rules to address compliance with our ACO participant TIN overlap policies, specifically, to address situations in which overlapping ACO participant TINs begin billing for services that are used in beneficiary assignment during a benchmark or performance year; and (7) a policy to use final beneficiary identifiable non-claims based payments in establishing benchmarks and performing financial reconciliation.

Each of these proposed policies is generally expected to have a minimal impact on affected ACOs. We do not anticipate any overall impact for these proposed policies because potential individual ACO impacts are more likely to offset one another rather than build to a substantial total in terms of costs or savings.

6. Value-Based Payment Modifier and the Physician Feedback Program

Section 1848(p) of the Act requires that we establish a value-based payment modifier (VM) and apply it to specific physicians and groups of physicians the Secretary determines appropriate starting January 1, 2015, and to all physicians and groups of physicians by January 1, 2017. Section 1848(p)(4)(C) of the Act requires the VM to be budget neutral. Budget-neutrality means that, in aggregate, the increased payments to high performing physicians and groups equal the reduced payments to low performing physicians and groups, as well as those physicians and groups that failed to meet the criteria to avoid the PQRS payment adjustment as a group or as individuals.

In the CY 2016 PFS final rule with comment period (80 FR 71277 and 71279), we established that, beginning with the CY 2018 payment adjustment period, the VM will apply to nonphysician EPs who are physician assistants (PAs), nurse practitioners (NPs), clinical nurse specialists (CNSs), and certified registered nurse anesthetists (CRNAs) in groups with 2 or more EPs and to PAs, NPs, CNSs, and CRNAs who are solo practitioners.

In CY 2018, the VM will be waived for groups and solo practitioners, as identified by their TIN, if at least one EP who billed for Medicare PFS items and services under the TIN during 2016 participated in the Pioneer ACO Model, the Comprehensive Primary Care initiative, Next Generation ACO Model, the Oncology Care Model, and the Comprehensive ESRD Care Initiative in 2016 (80 FR 71286 through 71288).

In the CY 2016 PFS final rule with comment period (80 FR 71280), we adopted a two-category approach for the CY 2018 VM based on participation in the PQRS by groups and solo practitioners. For the purposes of the CY 2018 VM, Category 1 represents those groups and solo practitioners subject to

the VM who met the criteria to avoid the 2018 PQRS payment adjustment (a) as a group practice participating in the PQRS GPRO, (b) groups that have at least 50 percent of the group's EPs meet the criteria to avoid the 2018 PQRS payment adjustment for CY 2018 as individuals, (c) solo practitioners that meet the criteria to avoid the CY 2018 PQRS payment adjustment as individuals, and (d) groups and solo practitioners that participated in a Shared Savings Program ACO, if the ACO in which they participate successfully reports quality data as required by the Shared Savings Program. Category 2 represents those groups and solo practitioners that are subject to the CY 2018 VM payment adjustment and do not fall within Category 1.

In section III.I. of this proposed rule, we are proposing to reduce the CY 2018 VM payment adjustment amount for groups and solo practitioners in Category 2. We proposed to reduce the automatic payment adjustment from −4.0 percent to −2.0 percent for Physicians, PAs, NPs, CNSs, and CRNAs in groups with 10 or more EPs and at least one physician and from −2.0 percent to −1.0 percent for Physicians, PAs, NPs, CNSs, and CRNAs in groups of 2 or more EPs, PAs, NPs, CNSs, and CRNAs in groups comprised solely of non-physician EPs and physician and non-physician solo practitioners.

Additionally, in section III.I. in this proposed rule, we are proposing that, under quality-tiering, which is the methodology for evaluating performance on quality and cost measures for the VM, there will be no downward adjustments for groups or solo practitioners in Category 1 for the VM for CY 2018. We are also proposing to reduce the maximum upward adjustment under the quality-tiering methodology in CY 2018 for physicians, PAs, NPs, CNSs, and CRNAs in groups with 10 or more EPs and at least one physician that are Category 1 from four times an adjustment factor (+4.0x) to two times an adjustment factor (+2.0x) for those classified as high quality/low cost and from two times an adjustment factor (+2.0x) to one times an adjustment factor (+1.0x) for those classified as either average quality/low cost or high quality/average cost. This proposal aligns the upward adjustment for groups of 10 or more EPs with those previously finalized for smaller groups and solo practitioners, as well as groups comprised solely of non-physician EPs and provides a smoother transition to MIPS by bringing the incentives in line with those in the first year of the MIPS.

Under the quality-tiering methodology, each group and solo practitioner's quality and cost composites will continue to be classified into high, average, and low categories depending upon whether the composites are at least one standard deviation above or below the mean and statistically different from the mean. We will compare their quality of care composite classification with the cost composite classification to determine their VM adjustment for the CY 2018 payment adjustment period according to the amounts in Table 44.

TABLE 44—PROPOSED CY 2018 VM AMOUNTS UNDER THE QUALITY-TIERING APPROACH FOR PHYSICIANS, PAS, NPS, CNSS, AND CRNAS WHO ARE IN GROUPS OR SOLO PRACTITIONERS

Cost/Quality	Low quality	Average quality	High quality
Low cost	+0.0%	+1.0x *	+2.0x *
Average cost	+0.0	+0.0%	+1.0x *
High cost	+0.0	+0.0	+0.0%

* Groups and solo practitioners eligible for an additional +1.0x if reporting measures and average beneficiary risk score is in the top 25 percent of all beneficiary risk scores, where 'x' represents the upward payment adjustment factor.

Under the quality-tiering methodology, for groups and solo practitioners that participated in a Shared Savings ACO that successfully reports quality data for CY 2016, the cost composite will be classified as ''Average'' and the quality of care composite will continue to be based on ACO-level quality measures. We will compare their quality of care composite classification with the ''Average'' cost composite classification to determine their VM adjustment for the CY 2018 payment adjustment period. For groups and solo practitioners that participate in a Shared Savings Program ACO that did not successfully report quality data for CY 2016 and are Category 1 as a result of quality data reported to the PQRS outside of the ACO, the quality and cost composites will continue to be classified as ''Average''.

To ensure budget neutrality, we first aggregate the automatic downward payment adjustments of −1.0 percent or −2.0 percent for groups and solo practitioners subject to the VM that fall within Category 2. Using the aggregate downward payment adjustment amount, we then calculate the upward payment adjustment factor (x). Additionally, as we have done when calculating the upward payment adjustment factor for the 2017 VM, we will also incorporate adjustments made for estimated changes in physician behavior (that is, changes in the volume and/or intensity of services delivered and shifting of services to TINs that receive higher VM adjustments) and estimated impact of pending PQRS and VM informal reviews. These calculations will be done after the performance period has ended and announced around the start of the payment adjustment year after the informal review period ends.

At the time of this proposed rule, we have not completed the analysis of the impact of the VM in CY 2018 on physicians and non-physicians in groups of 2 or more EPs and physician and non-physician solo practitioners based on performance in 2016. However, preliminary estimates indicate that the implementation of the proposed policies discussed above, would reduce the adjustment factor to below 10 percent. In the CY 2018 PFS final rule, we will present the number of groups and solo practitioners that will be subject to the VM in CY 2018.

7. MACRA Patient Relationship Categories and Codes

We are soliciting comments on these HCPCS codes. Our intention is to collect the codes beginning January 2018, and our plan not to tie the collection of the codes with payment until we are sure clinicians have gained ample experience and education in using these modifiers. Therefore, there is no impact to CY 2018 physician payments under the PFS. There may be a burden associated with clinicians and their administrative staff having to learn which codes to use and how to submit them properly.

8. Effects of Proposals Relating to the Medicare Diabetes Prevention Program Expanded Model

In section III.K of the preamble of this proposed rule, we discuss our proposals to further implement the MDPP expanded model under the authority of section 1115A of the Act, which authorizes the Innovation Center to test innovative payment and service delivery models to reduce program expenditures while preserving or enhancing the quality of care furnished to Medicare, Medicaid and CHIP beneficiaries. The MDPP expanded model was established in the November 15, 2016 MDPP final rule as an additional preventive service with a model effective date of January 1, 2018. Many of the policies for the MDPP expanded model were deferred to future rulemaking and, therefore, are being proposed in this rule. On March 14, 2016, the Office of the Actuary (OACT) published a certification memorandum setting out the conditions for expansion of the Medicare Diabetes Prevention Program (MDPP). Prior to its implementation, OACT is required to review the parameters of the MDPP expansion and provide an updated certification. This regulatory impact assessment is not an updated certification; rather, it is based on estimates of the proposed rule.

Diabetes affects more than 25 percent of Americans aged 65 or older and its prevalence is projected to increase approximately two-fold for all U.S. adults (ages 18–79) by 2050 if current trends continue.[33] Furthermore, the risk of progression to type 2 diabetes in an individual with pre-diabetes is 5–10 percent per year, or 5–20 times higher than in individuals with normal blood glucose.[34] We estimate that Medicare spent $42 billion more in the single year of 2016 on fee-for-service, non-dual eligible, over age 65 beneficiaries with diabetes and related comorbidities than it would have spent if those beneficiaries did not have diabetes, including $20 billion more for Part A, $17 billion more for Part B, and $5 billion more for Part D.[35] The goal of the MDPP expanded model is to reduce the incidence rate of type 2 diabetes among Medicare beneficiaries with prediabetes through a structured behavioral change program where the primary outcome is weight loss. Weight loss is a key indicator of success among persons enrolled in a Diabetes Prevention Program due to the strong association between weight loss and reduction in the risk of type 2 diabetes. In reducing the incidence rate of type 2 diabetes we expect to reduce Medicare spending while improving quality of care for eligible beneficiaries. In this proposed rule, we are proposing a value-based payment structure for the MDPP Expanded Model. Instead of traditional fee-for-service payment, our proposed payment structure shifts risk from Medicare to the rendering supplier by making payments for MDPP services to MDPP suppliers based on the achievement of performance goals.

a. Anticipated Effects

(1) Effects on Beneficiaries

The MDPP expanded model is expected to have a positive impact on beneficiaries' health that will generally lead to reduced beneficiary spending on Part A, Part B, and Part D health care services over time due to a reduced need for Part A, Part B, and Part D services. As a new preventive service, the MDPP services are available to eligible Medicare beneficiaries without cost-sharing. The CDC estimates that approximately 50 percent of adults aged 65 and over living in the United States have prediabetes [36] and that awareness of the condition among those who have it is relatively low—approximately 30 percent for the general population. Therefore, we anticipate that up to 7 million Medicare beneficiaries who are aware of their prediabetes would be eligible for the MDPP services at the start of the MDPP expanded model. This estimate does not take into account any increased beneficiary awareness of their prediabetes due to the availability of MDPP services. We also expect there to be pent-up demand, with the number of beneficiaries utilizing the MDPP services greater in the initial few years (roughly 65,000 to 110,000 per year) but then leveling off afterwards (to a base demand of roughly 50,000 participants per year).

To arrive at our participation estimate we developed projections for pent-up demand and ongoing demand. To develop the projection for pent-up demand we first analyzed data from the CDC National Diabetes Prevention Recognition Program (DPRP). Specifically, we analyzed State-by-State DPRP in-person utilization for ages 65 or older in 2015. Because the Health Care Innovation Award (HCIA) MDPP model test was still serving beneficiaries during this period, and the HCIA DPP suppliers are also part of the DPRP, we used its enrollment data to inform what Medicare beneficiary participation may look like when Medicare pays for MDPP. Given that HCIA participation seemed to drive most of the DPRP participation in an HCIA supplier's region, we determined that a well-defined HCIA region would be a reasonable proxy for the rest of the nation. We found the state with the highest HCIA saturation, and calculated the percentage of fee for service beneficiaries that received services from a DPRP DPP. This percentage was applied to all fee for service beneficiaries nationwide in order to get a national pent-up demand estimate. We added this pent-up demand to a stable level of demand based on the number of new beneficiaries utilizing the obesity management benefit each year. Given the limited nationwide Medicare DPP participation data, there is a great amount of uncertainty in these estimates.

We believe that the eligibility criteria for continued participation in the set of MDPP services incentivizes beneficiaries to lose 5-percent body weight from baseline. Beneficiaries are incentivized to lose weight because continued eligibility for the services benefit after the first 12 months is contingent upon achieving 5-percent weight loss and the set of MDPP services is a once per lifetime set of services. In addition to prevention of type 2 diabetes, we believe participating beneficiaries would likely receive other possible health benefits including prevention of obesity for those who are overweight upon receiving MDPP services, prevention of sleep apnoea, and reduced risk for heart disease, coronary artery disease and stroke.[37]

[33] Centers for Medicare & Medicaid Services, ''Chronic Conditions Among Medicare Beneficiaries, Chartbook: 2012 Edition,'' *Centers for Medicare & Medicaid Services,* 2012, *https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/chronic-conditions/downloads/2012chartbook.pdf.* James Boyle, et al., ''Projection of the Year 2050 Burden of Diabetes in the US Adult Population: Dynamic Modeling of Incidence, Mortality, and Pre-Diabetes Prevalence,'' *Population Health Metrics* 8, no. 29 (2010): 1–12.

[34] X Zhang et al., ''A1C Level and Future Risk of Diabetes: A Systematic Review,'' *Diabetes Care* 33, no. 7 (2010): 1665–1673.

[35] Erkan Erdem and Holly Korda, ''Medicare Fee-For-Service Spending for Diabetes: Examining Aging and Comorbidities,'' *Diabetes & Metabolism* 5, no. 3 (2014); The Boards of Trustees: Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds, ''2016 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds,'' *Centers for Medicare & Medicaid Services,* 2016, *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFu2016.pdf.;* and CMS estimates.

[36] *https://www.cdc.gov/diabetes/pubs/statsreport14national-diabetes-report-web.pdf.*

[37] Orchard, T. J., et al. (2005). ''The effect of metformin and intensive lifestyle intervention on

Continued

Furthermore, we believe the MDPP expanded model could improve mental health and wellbeing by affording beneficiaries social interaction with their peers during sessions and could lead to reduced social isolation.[38] The prevention of type 2 diabetes and these other potential health benefits of MDPP services may result in reduced beneficiary expenditures for health care services over time as services will not be needed to treat health conditions that are avoided.

(2) Effects on the Market

Currently, more than 1,200 organizations nationally are providing DPP services with some level of recognition through the CDC. Service delivery is primarily to individuals with private or employer-sponsored insurance, as well as some Medicare Advantage plans. The majority of existing DPP organizations are not enrolled in the Medicare program. We anticipate that the addition of MDPP services as new preventive services in Medicare would result in growth in the market, including growth in the number of individuals served per year by existing DPP suppliers, as well as the introduction of new suppliers into the market. There are burdens associated with obtaining CDC recognition and enrolling into Medicare as an MDPP supplier. There is also burden associated with submitting claims to Medicare for payment. Below we have provided an estimate of the financial burden to suppliers.

(3) Burden Related to Information Collection Requirements

(a) Wage Estimates

To derive average costs for use throughout the subsequent sections, we used data from the U.S. Bureau of Labor Statistics' May 2015 National Occupational Employment and Wage Estimates for all salary estimates (*https://www.bls.gov/oes/current/oes_nat.htm*). Table 45 presents the mean hourly wage, the cost of fringe benefits and overhead (calculated at 100 percent of salary), and the adjusted hourly wage.

TABLE 45—NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

Occupation title	Occupation code	Mean hourly wage ($/hr)	Fringe benefits and overhead ($/hr)	Adjusted hourly wage ($/hr)
Medical records and health information technician	29–2071	19.93	19.93	39.84
Office and administrative support worker	43–9000	16.31	16.31	32.62
Billing and posting Clerk	43–3011	$18.09	$18.09	$36.18

(b) Interim Preliminary Recognition

Our proposals under proposed § 424.205 would provide that an entity is eligible to enroll in Medicare as an MDPP supplier if it has MDPP interim preliminary recognition, as determined by CMS. In order to receive MDPP interim preliminary recognition, we are proposing that the entity must have pending CDC recognition and must submit a full 12 months of data on at least one completed cohort of participants to CDC. In order to receive pending recognition from CDC, organizations are required to submit an application for recognition to CDC and agree to CDC's curriculum, duration and intensity requirements. CMMI plans to engage CDC's services to assist CMMI in administering its interim preliminary recognition standard, if finalized. CMMI would make the final determination of which entities qualify to receive interim preliminary recognition.

The burden associated with the preceding requirements is the time for MDPP staff to: submit an application for pending recognition to CDC and then collect and submit a full 12 months of data (including session attendance, body weight documentation, physical activity minutes documentation, and weight loss achieved) on at least one completed cohort of participants to CDC for the purposes of being evaluated for interim preliminary recognition.

We estimate that it will take a medical records and health information technician 12 hours, at $38.88/hour to collect and report these data for one cohort of participants, and an office or administrative worker 1 hour, at $31.54/hour, to complete the CDC application for pending recognition. The estimated cost per supplier to achieve interim preliminary recognition is $498.10.

(c) Supplier Standards

Our proposals under proposed revised § 424.59 (proposed in this rule to be redesignated at § 424.205) would require that an MDPP supplier must certify in its enrollment application, which is a new Medicare enrollment application that we are creating specific to MDPP suppliers, and that it meets a set of standards. As this new enrollment application is being created specifically for the MDPP expanded model, we have determined that it is exempt from the Paperwork Reduction Act in accordance with section 1115A(d)(3) of the Act. We estimate that it will take an office or administrative support worker 3 hours, at $31.54/hour, to complete the MDPP supplier enrollment application using the internet-based Provider Enrollment,

the metabolic syndrome: the Diabetes Prevention Program randomized trial.'' *Ann Intern Med* 142(8): 611–619; Orchard, T. J., et al. (2013). ''Long-term effects of the Diabetes Prevention Program interventions on cardiovascular risk factors: a report from the DPP Outcomes Study.'' Diabet Med 30(1): 46–55; Li, G., et al. (2014). ''Cardiovascular mortality, all-cause mortality, and diabetes incidence after lifestyle intervention for people with impaired glucose tolerance in the Da Qing Diabetes Prevention Study: a 23-year follow-up study.'' Lancet Diabetes Endocrinol 2(6): 474–480; Mudaliar, U., et al. (2016). ''Cardiometabolic Risk Factor Changes Observed in Diabetes Prevention Programs in US Settings: A Systematic Review and Meta-analysis.'' PLoS Med 13(7): e1002095; Kuna, S. T., et al. (2013). ''Long-term effect of weight loss on obstructive sleep apnea severity in obese patients with type 2 diabetes.'' Sleep 36(5): 641–649a; Mitchell, L. J., et al. (2014). ''Weight loss from lifestyle interventions and severity of sleep apnoea: a systematic review and meta-analysis.'' Sleep Med 15(10): 1173–1183; Thomasouli, M. A., et al. (2013). ''The impact of diet and lifestyle management strategies for obstructive sleep apnoea in adults: a systematic review and meta-analysis of randomised controlled trials.'' Sleep Breath 17(3): 925–935; U.S. Department of Health and Human Services. *2008 Physical Activity Guidelines for Americans.* Washington (DC): U.S. Department of Health and Human Services; 2008. ODPHP Publication No. U0036. Available at: *http://www.health.gov/paguidelines;* U.S. Department of Health and Human Services and U.S. Department of Agriculture. *2015—2020 Dietary Guidelines for Americans.* 8th Edition. December 2015. Available at *http://health.gov/dietaryguidelines/2015/guidelines/.*

[38] Florez, H., et al. (2012). ''Impact of lifestyle intervention and metformin on health-related quality of life: the diabetes prevention program randomized trial.'' J Gen Intern Med 27(12): 1594–1601; Ackermann, R. T., et al. (2009). ''Changes in health state utilities with changes in body mass in the Diabetes Prevention Program.'' Obesity (Silver Spring) 17(12): 2176–2181; Weinhold, K. R., et al. (2015). ''A Randomized Controlled Trial Translating the Diabetes Prevention Program to a University Worksite, Ohio, 2012–2014.'' Preventing Chronic Disease 12: E210.

Chain and Ownership System (PECOS). In general, provider enrollment fees for Medicare are $560 in 2017. We also note that CMS provides hardship exceptions to the application fee with a written request that describes the need for the hardship exception. CMS determines such exceptions on a case-by-case basis. The estimated cost to complete the MDPP supplier enrollment application, without a hardship exception, is $843.86. If a provider is granted a hardship exception from the enrollment fee, then the estimated cost to complete the enrollment process is $283.86.

We also note that access to the HIPAA Eligibility Transaction System (HETS), which a supplier could use to check factors of eligibility for the MDPP services, including the beneficiary's Part B eligibility and whether the beneficiary has received coverage for end-stage renal disease (ESRD) is free to suppliers, as long as they are active Medicare fee-for-service providers or suppliers in PECOS.

Suppliers also would be required to maintain documentation of all beneficiary contact regarding complaints or questions, as specified in proposed § 424.205(d)(11), and maintain and submit to CMS a crosswalk file which indicates how participant identifications for the purposes of CDC performance data correspond to Medicare Beneficiary Identifiers (that is, beneficiary health insurance claims numbers) for each beneficiary receiving MDPP services. We estimate that creating and maintaining documentation of beneficiary contact regarding complaints or questions will take an office or administrative support worker 1 hour, at $31.54/hour, per complaint or question request to create and maintain documentation of the request. We have no way to estimate how many complaints or questions MDPP suppliers will receive from beneficiaries, and we expect that may differ based on many factors, so have not included an overall cost in this burden estimate. Further, we estimate that it will take an office and administrative support worker approximately 4 hours, at $31.54/hour, to create and submit the crosswalk file for a cohort of 100 beneficiaries participating in the MDPP services, for a total cost of $126.16 per cohort of 100 beneficiaries. The crosswalk is proposed to be submitted quarterly. Therefore, for a year of delivering the set of MDPP services the estimated total cost to create and submit the crosswalk file would be $504.64 per cohort of 100 beneficiaries. We believe the incremental costs to meet this requirement would decrease with the addition of beneficiaries to a cohort, because the work and time to establish the file and submit it would be the same for a cohort of 100 and a cohort of 1000. What would be different is the collection of the information from the beneficiaries, and the addition of these data points to the file. We estimate that, for every additional 100 beneficiaries added to the file, the office and administrative support worker would add 1 hour, at $31.54/hour. We estimate the total incremental cost over 1 year for each additional 100 beneficiaries above the cohort of 100 beneficiaries is $126.16.

Our proposals under proposed § 424.205 also would require that suppliers meet a set of standards that includes maintaining a physical facility on an appropriate site and maintain a primary business telephone that is operating at the appropriate site. Because we have no way to estimate how many beneficiaries each MDPP supplier may provide the set of MDPP services to, and we expect this will differ based on many factors, including but not limited to the size of the supplier, the number of coaches the supplier employs, the physical space the supplier uses to furnish MDPP services, and the supplier's geographic location, we have not included an overall cost for these requirements in this burden estimate.

(d) Payment for MDPP Services

Our proposals under proposed § 414.84 specify the proposed payments MDPP suppliers may be eligible to receive for furnishing MDPP services and meeting performance targets related to beneficiary weight loss and/or attendance. MDPP suppliers would be paid by CMS by submitting claims for MDPP beneficiaries using claim form CMS–1500 (*https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS1500.pdf*), and as a condition for payment, claims submitted by MDPP suppliers must be for services furnished to eligible beneficiaries in accordance with § 414.84(b) and (c). Our proposal under proposed § 424.205 would require MDPP suppliers to include an attestation that the MDPP beneficiary for which it is submitting a claim has met the performance goals laid out in proposed § 424.205. Section 424.205 also proposes to require MDPP suppliers to report the NPI of the coach on MDPP claims as a program integrity safeguard. To meet these requirements for submitting claims, we estimate that it would take a billing and posting clerk 10 minutes per beneficiary to fill out the claim form and submit it to CMS at $33.70/hour. Based on this time and wage, we estimate the total cost per beneficiary per claim to be $5.62. As mentioned previously, we have no way to estimate how many beneficiaries to whom each MDPP supplier may furnish MDPP services. Therefore, we have not included an estimate of the overall cost of submitting claims in the burden estimate.

(4) Effects on the Medicare Program

(a) Estimated 10-Year Impact of MDPP

The set of MDPP services is an optional set of services for beneficiaries who meet the eligibility requirements described elsewhere in the proposed rule. MDPP services will be furnished by a new provider type in Medicare. The CDC recognizes DPPs nationwide; these programs effectively deliver lifestyle-changing services that reduce the incidence of type 2 diabetes. The number of CDC-recognized DPPs is growing rapidly, increasing by nearly 90 percent from September 2015 to March 2017. The historical participation rate suggests that the vast majority of these providers are not serving a significant volume of new participants, aside from those served in the DPP model test.

This estimate is based on the initial methodology used for the estimate of the MDPP expanded model as set out in the certification memorandum, but with differences in several program features including the payment parameters. It also includes the impact of improved longevity among those who participate in the MDPP expanded model. This cost of improved longevity was ignored for certification purposes, as noted in that memorandum.

The model is dependent on the number of eligible participants, the annual take-up rate, and the savings per participant, all of which are uncertain. The methodology determines gross savings as the result of an assumed reduction in the number of beneficiaries transitioning from prediabetes to diabetes and a marginal cost difference between the individuals with diabetes and those that are prediabetic. The Office of the Actuary assumed that the initial savings per beneficiary for avoiding diabetes is $3,000 per year. The progression rate from prediabetes to diabetes absent the intervention is expected to be roughly 5 percent per year. Based on observed results, we assume that the set of MDPP services will reduce the progression rate among those receiving the services by 50 percent in the first year and that the reduction will be 5 percent less in each subsequent year until leveling off at a rate of 10 percent. The program costs in

this estimate include payments to MDPP suppliers in the initial year of the MDPP services period and in the 2 maintenance years. Based on the results of the DPP model test regarding the number of sessions attended and the weight loss achieved, we estimate the average expected Medicare payment per participant to be approximately $320 in the first year and $75 in each of the following 2 years. Overall, the payments under the expanded model would occur in the first 3 years following the beneficiary's first MDPP services, but the expected reduction in medical costs would occur over a long period following the intervention. For the leading cohort of 2018, we would expect savings in excess of costs by 2019 (the second year), with cumulative savings by 2022 (after 4 years). Yearly net savings reduce slightly each subsequent year but do not result in a cost to Medicare during the 10-year projection window.

Table 46 shows the 10-year impact of the MDPP expanded model, net of payments to MDPP providers but gross of any other model costs, based on our expected enrollment per year. The 10-year impact is a savings to Medicare of $186 million. The estimate is expected to cross into a cumulative savings to Medicare in the sixth year of the MDPP expanded model.

TABLE 46—ESTIMATED 10-YEAR IMPACT OF MDPP ON NET CLAIMS COSTS, PAYMENTS TO PROVIDERS, AND NET SAVINGS FOR CYS 2018 THROUGH 2027

[In millions, negative values indicate savings]

Year	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	Total
Net Claim Costs	−$5	−$16	−$29	−$41	−$52	−$60	−$66	−$70	−$72	−$72	−$484
Provider Payments	21	41	40	31	28	26	27	28	28	29	298
Net Savings	16	25	11	−10	−25	−34	−40	−43	−44	−43	−186
Cumulative Net Savings	16	41	52	42	17	−17	−56	−99	−143	−186	.....

(b) Sensitivity Testing

MDPP is a new Medicare expanded model that was tested in the DPP model test using a small percentage of the population. As a result, the estimated impact from the expanded MDPP model is very uncertain. In particular, it is unknown how many beneficiaries will be interested in participating in MDPP and how quickly MDPP suppliers available will be able to serve those individuals. To understand how various participation scenarios would affect the financial results, we have prepared the estimates under two other participation scenarios. The first shows the results if half of the beneficiaries shown in the best estimate participate, and the second uses twice as many beneficiaries. The details are shown in Tables 47 and 48.

TABLE 47—SCENARIO TEST OF MDPP 10-YEAR IMPACT OF HALF THE EXPECTED PARTICIPANTS ON NET CLAIMS COSTS, PAYMENTS TO PROVIDERS, AND NET SAVINGS FOR CYS 2018 THROUGH 2027

Year	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	Total
Net Claim Costs	−$2	−$8	−$15	−$21	−$26	−$30	−$33	−$35	−$36	−$36	−$242
Provider Payments	10	20	20	16	14	13	13	14	14	14	149
Net Savings	8	13	5	−5	−12	−17	−20	−21	−22	−22	−93

TABLE 48—SCENARIO TEST OF MDPP 10-YEAR IMPACT OF DOUBLE THE EXPECTED PARTICIPANTS ON NET CLAIMS COSTS, PAYMENTS TO PROVIDERS, AND NET SAVINGS FOR CYS 2018 THROUGH 2027

Year	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	Total
Net Claim Costs	−$9	−$31	−$58	−$83	−$104	−$121	−$133	−$140	−$144	−$145	−$969
Provider Payments	41	82	80	63	55	52	54	55	56	58	596
Net Savings	32	50	22	−20	−49	−68	−79	−85	−88	−87	−372

b. Alternatives Considered for MDPP

Section III.K. of the preamble of this proposed rule includes a range of proposed policies necessary to implement the MDPP expanded model, including benefit structure, payment, supplier enrollment, and supplier standards. Throughout section III.K., we present descriptions of the relevant statutory provisions; identify those policies when discretion has been exercised in our proposals, present rationale for our proposed policies; and discuss alternative to our proposals that where considered.

We considered alternatives to the MDPP services period that would significantly impact the potential payment. Specifically, we considered limiting the MDPP to a 12-month MDPP services period without any ongoing maintenance sessions available in months 13 through 36. It is estimated that the average payment to suppliers for the maintenance years is $75 per year per beneficiary. We also considered limiting the ongoing maintenance sessions to 12 months, culminating in a total MDPP service period of up to 2 years as opposed to up to 3 years. Either of these alternatives would reduce the total potential payment to MDPP suppliers by 52 percent or 28 percent, respectively, from a maximum of $810 for meeting all attendance and weight loss achievement goals under our proposals. We did not propose these alternatives because weight loss is difficult to achieve and can be more difficult to sustain. Our proposal to allow for up to 2 years of ongoing maintenance sessions for those beneficiaries who have achieved a minimum 5 percent weight loss from baseline during months 1 to 12 of the MDPP services period will allow for reinforcement of the lifestyle changes

needed to maintain weight loss. Finally, a 3-year diabetes prevention program is supported by evidence from the NIH DPP clinical trial.

In this proposed rule, we also considered linking additional outcomes beyond attendance and weight loss to payment in the value-based payment methodology. Specifically, we considered linking hemoglobin A1c level to MDPP payments. However, we did not adopt this alternative because the MDPP expanded model is certified based on the DPP model test, which demonstrated that weight loss was associated with reductions in Medicare expenditures. Although elevated hemoglobin A1c levels were included as part of the beneficiary eligibility criteria in the DPP model test, hemoglobin A1c levels were not evaluated post-intervention in the DPP model test. Therefore, the proposed MDPP payment structure would incentivize MDPP suppliers to prioritize the achievement of beneficiary weight loss by furnishing MDPP services, providing a balance between value-based payments related to weight loss and session attendance.

In conclusion, we estimate that the 10-year impact of the MDPP expanded model, net of payments to MDPP providers but gross of any other program costs, based on our expected enrollment per year would be a savings to Medicare of $186 million. The estimate is expected to cross into a cumulative savings to Medicare in the sixth year of the MDPP expanded model.

F. Alternatives Considered

This proposed rule contains a range of policies, including some provisions related to specific statutory provisions. The preceding preamble provides descriptions of the statutory provisions that are addressed, identifies those policies when discretion has been exercised, presents rationale for our final policies and, where relevant, alternatives that were considered. For purposes of the payment impact on PFS services of the policies contained in this proposed rule, we presented the estimated impact on total allowed charges by specialty. The alternatives we considered, as discussed in the preceding preamble sections, will result in different proposed payment rates, and therefore, result in different estimates than those shown in Table 40 (CY 2018 PFS Estimated Impact on Total Allowed Charges by Specialty).

G. Impact on Beneficiaries

There are a number of changes in this proposed rule that would have an effect on beneficiaries. In general, we believe that many of these changes, including those intended to improve accuracy in payment through revisions to the inputs used to calculate payments under the PFS, would have a positive impact and improve the quality and value of care provided to Medicare beneficiaries.

Most of the aforementioned proposed policy changes could result in a change in beneficiary liability as relates to coinsurance (which is 20 percent of the fee schedule amount, if applicable for the particular provision after the beneficiary has met the deductible). To illustrate this point, as shown in our public use file Impact on Payment for Selected Procedures available on the CMS Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/,* the CY 2017 national payment amount in the nonfacility setting for CPT code 99203 (Office/outpatient visit, new) was $109.46, which means that in CY 2017, a beneficiary would be responsible for 20 percent of this amount, or $21.89. Based on this proposed rule, using the CY 2018 CF, the CY 2018 national payment amount in the nonfacility setting for CPT code 99203, as shown in the Impact on Payment for Selected Procedures table, is $109.77, which means that, in CY 2018, the final beneficiary coinsurance for this service would be $21.95.

H. Estimating Regulatory Familiarization Costs

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this proposed rule, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review the rule, we assume that the total number of unique commenters on last year's proposed rule will be the number of reviewers of this proposed rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this rule. It is possible that not all commenters reviewed last year's rule in detail, and it is also possible that some reviewers chose not to comment on the proposed rule. For these reasons we thought that the number of past commenters would be a fair estimate of the number of reviewers of this rule. We welcome any comments on the approach in estimating the number of entities which will review this proposed rule.

We also recognize that different types of entities are in many cases affected by mutually exclusive sections of this proposed rule, and therefore for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of the rule. We seek comments on this assumption.

Using the wage information from the BLS for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing this rule is $105.16 per hour, including overhead and fringe benefits *https://www.bls.gov/oes/current/oes_nat.htm.* Assuming an average reading speed, we estimate that it would take approximately 8.0 hours for the staff to review half of this proposed rule. For each facility that reviews the rule, the estimated cost is $841 (8.0 hours × $105.16). Therefore, we estimate that the total cost of reviewing this regulation is $4,981,243 ($841 × 5,943 reviewers).

I. Accounting Statement

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf*), in Tables 49 and 50 (Accounting Statements), we have prepared an accounting statement. This estimate includes growth in incurred benefits from CY 2017 to CY 2018 based on the FY 2018 President's Budget baseline.

TABLE 49—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES

Category	Transfers
CY 2018 Annualized Monetized Transfers	Estimated increase in expenditures of $0.3 billion for PFS CF update.
From Whom To Whom?	Federal Government to physicians, other practitioners and providers and suppliers who receive payment under Medicare.

TABLE 50—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED COSTS, TRANSFER, AND SAVINGS

Category	Transfer
CY 2018 Annualized Monetized Transfers of beneficiary cost coinsurance.	$0.1 billion.
From Whom to Whom?	Federal Government to Beneficiaries.

TABLE 51—ESTIMATED COSTS AND COST SAVINGS

Category	Costs	Cost savings
ICR Burden	$282 million	$186 million.
MDPP		
Regulatory Familiarization	$5 million	

J. Conclusion

The analysis in the previous sections, together with the remainder of this preamble, provided an initial Regulatory Flexibility Analysis. The previous analysis, together with the preceding portion of this preamble, provides a Regulatory Impact Analysis. In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 405

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medical devices, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 410

Health facilities, Health professions, Kidney diseases, Laboratories, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 414

Administrative practice and procedure, Biologics, Drugs, Health facilities, Health professions, Kidney diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 424

Emergency medical services, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 425

Administrative practice and procedure, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as set forth below:

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

■ 1. The authority citation for part 405 continues to read as follows:

Authority: Secs. 205(a), 1102, 1861, 1862(a), 1869, 1871, 1874, 1881, and 1886(k) of the Social Security Act (42 U.S.C. 405(a), 1302, 1395x, 1395y(a), 1395ff, 1395hh, 1395kk, 1395rr and 1395ww(k)), and sec. 353 of the Public Health Service Act (42 U.S.C. 263a).

■ 2. Section 405.2413 is amended by revising paragraph (a)(5) to read as follows:

§ 405.2413 Services and supplies incident to a physician's services.

(a) * * *

(5) Furnished under the direct supervision of a physician, except that services and supplies furnished incident to Transitional Care Management, General Care Management, and the Psychiatric Collaborative Care model, can be furnished under general supervision of a physician when these services or supplies are furnished by auxiliary personnel, as defined in § 410.26(a)(1) of this chapter.

* * * * *

■ 3. Section 405.2415 is amended by revising paragraph (a)(5) to read as follows:

§ 405.2415 Incident to services and direct supervision.

(a) * * *

(5) Furnished under the direct supervision of a nurse practitioner, physician assistant, or certified nurse-midwife, except that services and supplies furnished incident to Transitional Care Management, General Care Management, and the Psychiatric Collaborative Care model, can be furnished under general supervision of a nurse practitioner, physician assistant, or certified nurse-midwife, when these services or supplies are furnished by auxiliary personnel, as defined in § 410.26(a)(1) of this chapter.

* * * * *

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

■ 4. The authority citation for part 410 is revised to read as follows:

Authority: Secs. 1102, 1834, 1871, 1881, and 1893 of the Social Security Act (42 U.S.C. 1302, 1395m, 1395hh, 1395rr, and 1395ddd).

■ 5. Section 410.79 is amended by—

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

■ b. Under paragraph (b):

■ i. Revising the definition of ''Baseline weight'';

■ ii. Removing the definition ''Coach'';

■ iii. Revising the definition of ''Core maintenance session'';

■ iv. Adding in alphabetical order a definition for ''Core maintenance session interval;''

■ v. Revising the definition of ''Core session'';

■ vi. Removing the definitions of ''Maintenance of weight loss'' and ''Maintenance session bundle'';

■ vii. Adding in alphabetical order definitions for ''Make-up session'' and ''MDPP beneficiary'';

■ viii. Removing the definitions of ''MDPP core benefit'' and ''MDPP eligible beneficiary'';

■ ix. Revising the definition of ''MDPP services'';

■ x. Adding in alphabetical order definitions for ''MDPP services period'' and ''MDPP session'';

■ xi. Revising the definitions of ''MDPP supplier'' and ''Medicare Diabetes Prevention Program (MDPP)'';

■ xii. Adding in alphabetical order a definition for ''Ongoing maintenance session interval'';

■ xiii. Revising the definition of ''Ongoing maintenance sessions''; and

■ xiv. Adding in alphabetical order definitions for ''Set of MDPP services'' and ''Virtual make-up session''; and

■ c. Revising paragraphs (c) and (d).

The revisions and additions read as follows:

§ 410.79 Medicare Diabetes Prevention Program expanded model: Conditions of coverage.

(a) Medicare Diabetes Prevention Program (MDPP) services will be available beginning on April 1, 2018.

(b) * * *

Baseline weight means the MDPP beneficiary's body weight recorded during that beneficiary's first core session.

* * * * *

Core maintenance session means an MDPP service that—

(i) Is furnished by an MDPP supplier to an MDPP beneficiary during a core maintenance session interval;

(ii) Is approximately 1 hour in length; and

(iii) Adheres to a CDC-approved DPP curriculum for maintenance sessions.

Core maintenance session interval means one of the two consecutive 3-month time periods during months 7 through 12 of the MDPP services period, during which an MDPP supplier offers an MDPP beneficiary at least one core maintenance session per month.

Core session means an MDPP service that—

(i) Is furnished by an MDPP supplier to an MDPP beneficiary during months 1 through 6 of the MDPP services period;

(ii) Is approximately 1 hour in length; and

(iii) Adheres to a CDC-approved DPP curriculum for core sessions.

* * * * *

Make-up session means a core session, a core maintenance session, or an ongoing maintenance session furnished to an MDPP beneficiary when the MDPP beneficiary misses a regularly scheduled core session, core maintenance session, or ongoing maintenance session.

MDPP beneficiary means a Medicare beneficiary who meets the criteria specified in paragraph (c)(1)(i) of this section, who has initiated the MDPP services period by attending the first core session, and for whom the MDPP services period has not ended as specified in paragraph (c)(3) of this section.

MDPP services means structured health behavior change sessions that are furnished under the MDPP expanded model with the goal of preventing diabetes among Medicare beneficiaries with prediabetes, and that follow a CDC-approved curriculum. The sessions provide practical training in long-term dietary change, increased physical activity, and problem-solving strategies for overcoming challenges to maintaining weight loss and a healthy lifestyle.

MDPP services period means the time period, beginning on the date an MDPP beneficiary attends his or her first core session, over which the set of MDPP services is furnished to the MDPP beneficiary, to include the core services period described in paragraph (c)(2)(i) and, subject to paragraph (c)(3) of this section, one or more ongoing maintenance session intervals during the ongoing services period described in paragraph (c)(2)(ii) of this section.

MDPP session means a core session, a core maintenance session, or an ongoing maintenance session.

MDPP supplier means an entity that is enrolled in Medicare to furnish MDPP services as provided in § 424.205 of this chapter.

Medicare Diabetes Prevention Program (MDPP) refers to a model test expanded under section 1115A(c) of the Act that makes MDPP services available to MDPP beneficiaries.

* * * * *

Ongoing maintenance session means an MDPP service that—

(i) Is furnished by an MDPP supplier to an MDPP beneficiary during an ongoing maintenance session interval;

(ii) Is approximately 1 hour in length; and

(iii) Adheres to a CDC-approved DPP curriculum for maintenance sessions.

Ongoing maintenance session interval means one of the up to eight consecutive 3-month time periods during the ongoing services period described in paragraph (c)(2)(ii) of this section, during which an MDPP supplier offers at least one ongoing maintenance session to an MDPP beneficiary per month.

* * * * *

Set of MDPP services means the series of MDPP sessions, composed of core sessions, core maintenance sessions, and subject to paragraph (c)(3) of this section, ongoing maintenance sessions, offered over the course of the MDPP services period.

Virtual make-up session means a make-up session that is not furnished in person and that is furnished in a manner consistent with the DPRP standards for virtual sessions.

(c) Coverage for *MDPP services.*—

(1) *Beneficiary eligibility.* (i) A Medicare beneficiary is eligible for MDPP services offered during the core services period described in paragraph (c)(2)(i) of this section if the beneficiary meets all of the following criteria:

(A) Is enrolled under Medicare Part B;

(B) Attended the first core session within the most recent 12-month time period and, prior to attending this first core session, had not previously received the set of MDPP services in his or her lifetime;

(C) Has, on the date of attendance at the first core session, a body mass index (BMI) of at least 25 if not self-identified as Asian or a BMI of at least 23 if self-identified as Asian;

(D) Has received, within the 12-month time period prior to the date of attendance at the first core session, a hemoglobin A1c test with a value of between 5.7 and 6.4 percent, a fasting plasma glucose test with a value of between 110 and 125 mg/dL, or a 2-hour plasma glucose test (oral glucose tolerance test) with a value of between 140 and 199 mg/dL;

(E) Has, as of the date of attendance at the first core session, no previous diagnosis of diabetes, other than gestational diabetes; and

(F) Does not have end-stage renal disease (ESRD).

(ii) An MDPP beneficiary is eligible for the first ongoing maintenance session interval only if the beneficiary:

(A) Attends at least one in-person core maintenance session during the final core maintenance session interval; and

(B) Achieves or maintains the required minimum weight loss at a minimum of one in-person core maintenance session during the final core maintenance session interval.

(iii) An MDPP beneficiary is eligible for a subsequent ongoing maintenance session interval only if the beneficiary:

(A) Attends at least three ongoing maintenance sessions during the previous ongoing maintenance session interval, including at least one in-person ongoing maintenance session; and

(B) Maintains the required minimum weight loss at a minimum of one in-person ongoing maintenance session furnished during the previous ongoing maintenance session interval.

(iv) Weight measurements used to determine the achievement or maintenance of the required minimum weight loss must be taken in person by an MDPP supplier during an MDPP session.

(2) *MDPP services period.* An MDPP beneficiary's MDPP services period is composed of the following periods and intervals:

(i) The core services period, which is the first 12 months of the MDPP services period, and consists of:

(A) At least 16 core sessions offered at least one week apart during months 1 through 6 of the MDPP services period; and

(B) Two 3-month core maintenance session intervals offered during months 7 through 12 of the MDPP services period.

(ii) Subject to paragraph (c)(3) of this section, the ongoing services period, which consists of up to eight 3-month ongoing maintenance session intervals offered during months 13 through 36 of the MDPP services period.

(3) *Limitations on the MDPP services period.* (i) The MDPP services period ends upon completion of the core services period described in paragraph (c)(2)(i) of this section, unless the MDPP beneficiary qualifies for the first ongoing maintenance session interval, in accordance with paragraph (c)(1)(ii) of this section.

(ii) If the MDPP beneficiary qualifies for the first ongoing maintenance session interval as described in paragraph (c)(3)(i) of this section, the MDPP services period ends upon completion of this first ongoing maintenance session interval or any subsequent ongoing maintenance session interval, unless the beneficiary meets the eligibility requirements under paragraph (c)(1)(iii) of this section.

(iii) Unless sooner ended in accordance with this paragraph (c)(3), the MDPP services period ends automatically upon the completion of the eighth ongoing maintenance session interval.

(d) *Make-up sessions.* (1) An MDPP supplier may offer a make-up session to an MDPP beneficiary who missed a regularly scheduled session. If an MDPP supplier offers one or more make-up sessions to an MDPP beneficiary, each such session must be furnished in accordance with the following requirements:

(i) The curriculum furnished during the make-up session must address the same CDC-approved DPP curriculum topic as the regularly scheduled session that the beneficiary missed;

(ii) The MDPP supplier may furnish to the beneficiary a maximum of one make-up session on the same day as a regularly scheduled session; and

(iii) The MDPP supplier may furnish to the beneficiary a maximum of one make-up session per week.

(2) An MDPP supplier may offer virtual make-up sessions only if consistent with the requirements in paragraph (d)(1) of this section. Virtual make-up sessions are also subject to the following requirements:

(i) Virtual make-up sessions must be furnished in a manner consistent with the DPRP standards for virtual sessions;

(ii) An MDPP supplier may only offer virtual make-up sessions based on an individual MDPP beneficiary's request; and

(iii) An MDPP supplier may offer to an MDPP beneficiary:

(A) No more than 4 virtual make-up sessions within the core services period described in paragraph (c)(2)(i) of this section, of which no more than 2 virtual make-up sessions are core maintenance sessions; and

(B) No more than 3 virtual make-up sessions that are ongoing maintenance sessions during any rolling 12-month time period.

(3) Make-up sessions furnished in accordance with paragraph (d)(1) of this section that an MDPP beneficiary attends in person are counted toward meeting the attendance requirements described in paragraph (c)(1) of this section and toward achieving the performance goals described in § 414.84(b) of this chapter as if the MDPP beneficiary attended a regularly scheduled session. Virtual make-up sessions furnished in accordance with paragraph (d)(2) of this section are also counted toward such attendance requirements and performance goals, subject to the following limitations:

(i) The MDPP beneficiary receives no more than 4 virtual make-up sessions within the core services period described in paragraph (c)(2)(i) of this section, of which no more than 2 virtual make-up sessions may be core maintenance sessions; and

(ii) The MDPP beneficiary receives no more than 3 virtual make-up sessions that are ongoing maintenance sessions during any rolling 12-month period.

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

■ 6. The authority citation for part 414 continues to read as follows:

Authority: Secs. 1102, 1871, and 1881(b)(l) of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395rr(b)(l)).

■ 7. Section 414.84 is added to read as follows:

§ 414.84 Payment for MDPP services.

(a) *Definitions.* In addition to the definitions specified at §§ 410.79(b) and 424.205(a) of this chapter, the following definitions apply to this section.

Bridge payment means a one-time payment to an MDPP supplier for furnishing its first MDDP session to an MDPP beneficiary who has previously received one or more MDPP services from a different MDPP supplier.

Performance goal means an attendance or weight-loss goal that an MDPP beneficiary must achieve during the MDPP services period for an MDPP supplier to be paid a performance payment.

Performance payment means a payment made to an MDPP supplier for furnishing certain MDPP services to an MDPP beneficiary when the MDPP beneficiary achieves the applicable performance goal.

(b) *Performance payment.* CMS makes one or more types of performance payments to an MDPP supplier as specified in this paragraph. Each type of performance payment is made only if the beneficiary achieves the applicable performance goal and only once per MDPP beneficiary. A performance payment is made only on an assignment-related basis in accordance with § 424.55 of this chapter, and MDPP suppliers must accept the Medicare allowed charge as payment in full and may not bill or collect from the beneficiary any amount. CMS will make a performance payment only to an MDPP supplier that complies with all applicable enrollment and program requirements and only for MDPP services that are furnished by an eligible coach, on or after his or her coach eligibility start date and, if applicable, before his or her coach eligibility end date. As a condition of payment, the MDPP supplier must report the NPI of the coach who furnished each session on the claim for the MDPP session. The seven types of performance payments are as follows:

(1) *Performance Goal 1: Attends the first core session that initiates the MDPP services period.* CMS makes a performance payment to an MDPP supplier if an MDPP beneficiary attends the first core session, which initiates the MDPP services period, and that first core session was furnished by that supplier. An MDPP supplier who has been paid this performance payment for an MDPP beneficiary is not eligible to be paid a bridge payment described in paragraph (c) of this section for that MDPP beneficiary. The amount of this performance payment is determined as follows:

(i) For a first core session furnished April 1 through December 31, 2018, the amount of the performance payment is $25.

(ii) For a first core session furnished during a calendar year subsequent to CY 2018. The performance payment amount specified in this paragraph for the prior year, adjusted as specified in paragraph (d) of this section.

(2) *Performance Goal 2: Attends four core sessions.* CMS makes a performance payment to an MDPP supplier if an MDPP beneficiary achieves attendance at the beneficiary's fourth core session upon attendance at

a core session furnished by that supplier. The amount of this performance payment is determined as follows:

(i) For a fourth core session furnished April 1 through December 31, 2018, the amount of the performance payment is $30.

(ii) For a fourth core session furnished during a calendar year subsequent to CY 2018, the performance payment amount specified in this paragraph for the prior year, adjusted as specified in paragraph (d) of this section.

(3) *Performance Goal 3: Attends nine core sessions.* CMS makes a performance payment to an MDPP supplier if an MDPP beneficiary achieves attendance at the ninth core session upon the beneficiary's attendance at a core session furnished by that supplier. The amount of this performance payment is determined as follows:

(i) For a ninth core session furnished April 1 through December 31, 2018, the amount of the performance payment is $50.

(ii) For a ninth core session furnished during a calendar year subsequent to CY 2018, the performance payment amount specified in this paragraph for the prior year, adjusted as specified in paragraph (d) of this section.

(4) *Performance Goal 4: Attends three core maintenance sessions during a core maintenance session interval.* CMS makes a performance payment to an MDPP supplier if an MDPP beneficiary attends three core maintenance sessions in a core maintenance session interval and achieves attendance at that third core maintenance session upon attendance at a core maintenance session furnished by that supplier. CMS makes this performance payment to an MDPP supplier only once per MDPP beneficiary per core maintenance session interval. The amount of this performance payment is determined as follows:

(i) If the beneficiary also achieves or maintains the required minimum weight loss as measured in-person during a core maintenance session furnished during the applicable core maintenance session interval:

(A) For a third core maintenance session furnished April 1 through December 31, 2018, the amount of the performance payment is $60.

(B) For a third core maintenance session furnished during a calendar year subsequent to CY 2018., the performance payment amount specified in this paragraph for the prior year, adjusted as specified in paragraph (d) of this section.

(ii) If the beneficiary does not achieve or maintain the required minimum weight loss as measured in-person during a core maintenance session furnished during the applicable core maintenance session interval:

(A) For a third core maintenance session furnished April 1 through December 31, 2018, the amount of the performance payment is $10.

(B) For a third core maintenance session furnished during a calendar year subsequent to CY 2018, the performance payment amount specified in this paragraph for the prior year, adjusted as specified in paragraph (d) of this section.

(5) *Performance Goal 5: Attends three ongoing maintenance sessions and maintains the required minimum weight loss within an ongoing maintenance session interval.* CMS makes a payment to an MDPP supplier if an MDPP beneficiary attends three ongoing maintenance sessions during an ongoing maintenance session interval, achieves attendance at that third ongoing maintenance session upon attendance at an ongoing maintenance session furnished by that supplier, and achieves or maintains the required minimum weight loss as measured in-person during an ongoing maintenance session furnished during the applicable ongoing maintenance session interval. CMS makes this performance payment to an MDPP supplier only once per MDPP beneficiary per ongoing maintenance session interval. The amount of this performance payment is determined as follows:

(i) For a third ongoing maintenance session furnished April 1 through December 31, 2018, the amount of the performance payment is $50.

(ii) For a third ongoing maintenance session furnished during a calendar year subsequent to CY 2018, the performance payment amount specified in this paragraph for the prior year, adjusted as specified in paragraph (d) of this section.

(6) *Performance Goal 6: Achieves the required minimum weight loss.* CMS makes a performance payment to an MDPP supplier for an MDPP beneficiary who achieves the required minimum weight loss as measured in-person during a core session or core maintenance session furnished by that supplier. The amount of this performance payment is determined as follows:

(i) For a core session or core maintenance session, as applicable, furnished April 1 through December 31, 2018, the amount of the performance payment is $160.

(ii) For a core session or core maintenance session, as applicable, furnished during a calendar year subsequent to CY 2018, the performance payment amount specified in this paragraph for the prior year, adjusted as specified in paragraph (d) of this section.

(7) *Performance Goal 7: Achieves 9-percent weight loss.* CMS makes a performance payment to an MDPP supplier for an MDPP beneficiary who achieves at least a 9-percent weight loss as measured in-person during a core session, core maintenance session, or ongoing maintenance session furnished by that supplier. The amount of this performance payment is determined as follows:

(i) For a core session, core maintenance session, or ongoing maintenance session, as applicable, furnished April 1 through December 31, 2018, the amount of the performance payment is $25.

(ii) For a core session, core maintenance session, or ongoing maintenance session, as applicable, furnished during a calendar year subsequent to CY 2018, the performance payment amount specified in this paragraph for the prior year, adjusted as specified in paragraph (d) of this section.

(c) *Bridge payment.* CMS makes a bridge payment to an MDPP supplier only for a core session, core maintenance session, or ongoing maintenance session furnished to an MDPP beneficiary who has previously received MDPP services from a different MDPP supplier. An MDPP supplier who has previously been paid either a bridge payment or a performance payment for an MDPP beneficiary is not eligible to be paid a bridge payment for that beneficiary. A bridge payment is made only on an assignment-related basis in accordance with § 424.55 of this chapter, and MDPP suppliers must accept the Medicare allowed charge as payment in full and may not bill or collect from the beneficiary any amount. CMS will make a bridge payment only to an MDPP supplier that complies with all applicable enrollment and program requirements, and only for MDPP services furnished by an eligible coach, on or after his or her coach eligibility start date and, if applicable, before his or her coach eligibility end date. As a condition of payment, the MDPP supplier must report the NPI of the coach who furnished the session on the claim for the MDPP session. The amount of the bridge payment is determined as follows:

(1) For a core session, core maintenance session, or ongoing

maintenance session furnished April 1 through December 31, 2018, the amount of the bridge payment is $25.

(2) For a core session, core maintenance session, or ongoing maintenance session furnished during a calendar year subsequent to CY 2018, the bridge payment amount specified in this paragraph for the prior year, adjusted as specified in paragraph (d) of this section.

(d) *Updating performance payments and the bridge payment.* The performance payments and bridge payment will be adjusted each calendar year by the percent change in the Consumer Price Index for All Urban Consumers (CPI–U) (U.S. city average) for the 12-month period ending June 30th of the year preceding the update year. The percent change update will be calculated based on the level of precision of the index as published by the Bureau of Labor Statistics and applied based on one decimal place of precision. The annual MDPP services payment update will be published by CMS transmittal.

■ 8. Section 414.90 is amended by revising paragraphs (j)(8)(i)(A)(*1*)(*i*), (j)(8)(ii)(A)(*1*)(*i*), (j)(8)(ii)(A)(*2*), (j)(8)(iii) and (iv), (j)(9)(ii) through (vi) and (viii), (k)(3) introductory text subject heading, and (k)(5)(i) and by adding (k)(5)(ii) to read as follows:

§ 414.90 Physician Quality Reporting System (PQRS).

* * * * *

(j) * * *

(8) * * *

(i) * * *

(A) * * *

(*1*)(*i*) Report at least 6 measures AND report each measure for at least 50 percent of the eligible professional's Medicare Part B Fee-for-Service patients seen during the reporting period to which the measure applies. If less than 6 measures apply to the eligible professional, the eligible professional must report on each measure that is applicable, AND report each measure for at least 50 percent of the Medicare Part B Fee-for-Service patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate will not be counted (unless they are inverse measures where a lower rate reflects better performance).

* * * * *

(ii) * * *

(A) * * *

(*1*)(*i*) Report at least 6 measures AND report each measure for at least 50 percent of the eligible professional's Medicare Part B Fee-for-Service patients seen during the reporting period to which the measure applies. If less than 6 measures apply to the eligible professional, the eligible professional must report on each measure that is applicable, AND report each measure for at least 50 percent of the Medicare Part B Fee-for-Service patients seen during the reporting period to which the measure applies.

* * * * *

(*2*) Measures with a 0 percent performance rate or measures groups containing a measure with a 0 percent performance rate will not be counted (unless they are inverse measures where a lower rate reflects better performance).

* * * * *

(iii) *Via EHR direct product.* For the 12-month 2018 PQRS payment adjustment reporting period, report 6 measures. If an eligible professional's direct EHR product or EHR data submission vendor product does not contain patient data for at least 6 measures, then the eligible professional must report all of the measures for which there is Medicare patient data. An eligible professional must report on at least 1 measure for which there is Medicare patient data.

(iv) *Via EHR data submission vendor.* For the 12-month 2018 PQRS payment adjustment reporting period, report at least 6 measures. If an eligible professional's direct EHR product or EHR data submission vendor product does not contain patient data for at least 6 measures, then the eligible professional must report all of the measures for which there is Medicare patient data. An eligible professional must report on at least 1 measure for which there is Medicare patient data.

(9) * * *

(ii) *Via qualified registry.* For a group practice of 2 or more eligible professionals, for the 12-month 2018 PQRS payment adjustment reporting period, report at least 6 measures AND report each measure for at least 50 percent of the group practice's Medicare Part B Fee-for-Service patients seen during the reporting period to which the measure applies. If less than 6 measures apply to the group practice, the group practice must report on each measure that is applicable, AND report each measure for at least 50 percent of the Medicare Part B Fee-for-Service patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate would not be counted (unless they are inverse measures where a lower rate reflects better performance).

(iii) *Via EHR direct product.* For a group practice of 2 or more eligible professionals, for the 12-month 2018 PQRS payment adjustment reporting period, report 6 measures. If the group practice's direct EHR product or EHR data submission vendor product does not contain patient data for at least 6 measures, then the group practice must report all of the measures for which there is Medicare patient data. A group practice must report on at least 1 measure for which there is Medicare patient data.

(iv) *Via EHR data submission vendor.* For a group practice of 2 or more eligible professionals, for the 12-month 2018 PQRS payment adjustment reporting period, report 6 measures. If the group practice's direct EHR product or EHR data submission vendor product does not contain patient data for at least 6 measures, then the group practice must report all of the measures for which there is Medicare patient data. A group practice must report on at least 1 measure for which there is Medicare patient data.

(v) *Via a certified survey vendor in addition to a qualified registry.* For a group practice of 2 or more eligible professionals that elects to report via a certified survey vendor in addition to a qualified registry for the 12-month 2018 PQRS payment adjustment reporting period, the group practice must have all CAHPS for PQRS survey measures reported on its behalf via a CMS-certified survey vendor. In addition, the group practice must report at least 3 additional measures using the qualified registry AND report each measure for at least 50 percent of the group practice's Medicare Part B Fee-for-Service patients seen during the reporting period to which the measure applies. If less than 3 measures apply to the group practice, the group practice must report on each measure that is applicable, AND report each measure for at least 50 percent of the Medicare Part B Fee-for-Service patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate would not be counted (unless they are inverse measures where a lower rate reflects better performance).

(vi) *Via a certified survey vendor in addition to a direct EHR product or EHR data submission vendor.* For a group practice of 2 or more eligible professionals that elects to report via a certified survey vendor in addition to a direct EHR product or EHR data submission vendor for the 12-month 2018 PQRS payment adjustment reporting period, the group practice must have all CAHPS for PQRS survey measures reported on its behalf via a CMS-certified survey vendor. In addition, the group practice must report at least 3 additional measures using the

direct EHR product or EHR data submission vendor product. If less than 3 measures apply to the group practice, the group practice must report all of the measures for which there is patient data. Of the additional 3 measures that must be reported in conjunction with reporting the CAHPS for PQRS survey measures, a group practice must report on at least 1 measure for which there is Medicare patient data.

* * * * *

(viii) If the CAHPS for PQRS survey is applicable to the practice, group practices comprised of 100 or more eligible professionals that register to participate in the GPRO may administer the CAHPS for PQRS survey, regardless of the GPRO reporting mechanism selected.

(k) * * *

(3) *Satisfactory participation criteria for individual eligible professionals for the 2016 PQRS payment adjustment.* * * *

* * * * *

(5) * * *

(i) *Individual eligible professional.* For the applicable 12-month reporting period, report at least 6 measures available for reporting under a QCDR AND report each measure for at least 50 percent of the eligible professional's patients seen during the reporting period to which the measure applies. If less than 6 measures apply to the eligible professional, the eligible professional must report on each measure that is applicable, AND report each measure for at least 50 percent of the eligible professional's patients.

(ii) *Group practices.* For the applicable 12-month reporting period, report at least 6 measures available for reporting under a QCDR AND report each measure for at least 50 percent of the group practice's patients seen during the reporting period to which the measure applies. If less than 6 measures apply to the group practice, the group practice must report on each measure that is applicable, AND report each measure for at least 50 percent of the group practice's patients. If a group practice reports the CAHPS for PQRS survey measures, apply reduced criteria as follows: 3 measures, as applicable.

* * * * *

■ 9. Section 414.94 is amended by revising paragraph (i)(3) and adding paragraphs (j) and (k) to read as follows:

§ 414.94 Appropriate use criteria for advanced diagnostic imaging services.

* * * * *

(i) * * *

(3) The significant hardship exception applies to ordering professionals who:

(i) Are granted re-weighting of the advancing care information performance category to zero percent of the final score for the year under MIPS pursuant to § 414.1380(c)(2) due to circumstances that include the criteria listed in § 495.102(d)(4)(i) and (iii) and (d)(4)(iv)(A) and (B) of this chapter. The AUC significant hardship exception is available for the same period the re-weight is applied for purposes of the MIPS payment adjustments, or

(ii) Demonstrate a significant hardship consistent with the criteria listed in § 495.102(d)(4)(i) and (iii) and (d)(4)(iv)(A) or (B) of this chapter. The AUC significant hardship exception may be available for a period no longer than 12 months.

(j) *Consulting.* Ordering Professionals must consult specified applicable AUC through qualified CDSMs for applicable imaging services furnished in an applicable setting, paid for under an applicable payment system and ordered on or after January 1, 2019.

(k) *Reporting.* Furnishing Professionals must report the following information on Medicare claims for advanced diagnostic imaging services furnished in an applicable setting, paid for under an applicable payment system defined in § 414.94(b), and ordered on or after January 1, 2019:

(1) The qualified CDSM consulted by the ordering professional.

(2) Information indicating:

(i) Whether the service ordered would adhere to specified applicable AUC;

(ii) Whether the service ordered would not adhere to specified applicable AUC, or

(iii) Whether the specified applicable AUC consulted was not applicable to the service ordered.

(3) The NPI of the ordering professional who consulted specified applicable AUC as required in paragraph (j) of this section, if different from the furnishing professional.

■ 10. Section 414.904 is amended by revising paragraph (e)(2) to read as follows:

§ 414.904 Average sales price as the basis for payment.

* * * * *

(e) * * *

(2) *Infusion drugs furnished through a covered item of durable medical equipment.* The payment limit for an infusion drug furnished before January 1, 2017, through a covered item of durable medical equipment is calculated using 95 percent of the average wholesale price in effect on October 1, 2003.

* * * * *

■ 11. Section 414.1270 is amended by revising paragraph (d)(1) to read as follows:

§ 414.1270 Determination and calculation of the Value-Based Payment Modifier adjustments.

* * * * *

(d) * * *

(1) A downward payment adjustment of −1.0 percent will be applied to a solo practitioner, a group with two to nine eligible professionals, and a group consisting only of nonphysician eligible professionals subject to the value-based payment modifier and no physicians; and a downward payment adjustment of −2.0 percent will be applied to a group with 10 or more eligible professionals and at least one physician if, during the applicable performance period as defined in § 414.1215, the following apply:

(i) For groups:

(A) Such group does not meet the criteria as a group to avoid the PQRS payment adjustment for CY 2018 as specified by CMS; and

(B) Fifty percent of the eligible professionals in such group do not meet the criteria as individuals to avoid the PQRS payment adjustment for CY 2018 as specified by CMS.

(ii) For solo practitioners, such solo practitioner does not meet the criteria as an individual to avoid the PQRS payment adjustment for CY 2018 as specified by CMS.

* * * * *

■ 12. Section 414.1275 is amended by revising paragraphs (c)(4) and (d)(3)(i) and (ii) to read as follows:

§ 414.1275 Value-based payment modifier quality-tiering scoring methodology.

* * * * *

(c) * * *

(4) The following value-based payment modifier percentages apply to the CY 2018 payment adjustment period, for physicians, physician assistants, nurse practitioners, clinical nurse specialists, and certified registered nurse anesthetists who are solo practitioners or who are in groups of any size:

CY 2018—VALUE-BASED PAYMENT MODIFIER AMOUNTS FOR THE QUALITY-TIERING APPROACH FOR PHYSICIANS, PHYSICIAN ASSISTANTS, NURSE PRACTITIONERS, CLINICAL NURSE SPECIALISTS, AND CERTIFIED REGISTERED NURSE ANESTHETISTS

Cost/quality	Low quality	Average quality	High quality
Low Cost	+0.0%	+*1.0x	+*2.0x
Average Cost	+0.0%	+0.0%	+*1.0x
High Cost	+0.0%	+0.0%	+0.0%

* Eligible for an additional +1.0x if reporting Physician Quality Reporting System quality measures and average beneficiary risk score is in the top 25 percent of all beneficiary risk scores, where 'x' represents the upward payment adjustment factor.

(d) * * *

(3) * * *

(i) Classified as high quality/low cost receive an upward adjustment of +3x (rather than +2x); and

(ii) Classified as either high quality/average cost or average quality/low cost receive an upward adjustment of +2x (rather than +1x).

PART 424—CONDITIONS FOR MEDICARE PAYMENT

■ 13. The authority citation for part 424 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 14. Section 424.55 is amended by adding paragraph (d) to read as follows:

§ 424.55 Payment to the supplier.

* * * * *

(d) For purposes of claims for services submitted by an MDDP supplier (as defined at § 410.79(b)), Medicare deems such claims to have been assigned by the beneficiary (or the person authorized to request payment on the beneficiary's behalf) and the assignment accepted by the MDDP supplier.

§ 424,59 [Removed]

■ 15. Remove § 424.59.

■ 16. Subpart I, consisting of §§ 424.200 through 424.210, is added to read as follows:

Subpart I—Requirements for Medicare Diabetes Prevention Program Suppliers and Beneficiary Engagement Incentives Under the Medicare Diabetes Prevention Program Expanded Model

Sec.
424.200 Scope.
424.205 Requirements for Medicare Diabetes Prevention Program suppliers.
424.210 Beneficiary engagement incentives under the Medicare Diabetes Prevention Program expanded model.

Subpart I—Requirements for Medicare Diabetes Prevention Program Suppliers and Beneficiary Engagement Incentives Under the Medicare Diabetes Prevention Program Expanded Model

§ 424.200 Scope.

This subpart specifies the requirements for Medicare Diabetes Prevention Program suppliers and beneficiary engagement incentives under the Medicare Diabetes Prevention Program expanded model.

§ 424.205 Requirements for Medicare Diabetes Prevention Program suppliers.

(a) *Definitions.* In addition to the definitions specified at §§ 410.79(b) and 414.84(a) of this subchapter, the following definitions apply to this section:

Administrative location means a physical location associated with the MDPP supplier's operations, from where coaches are dispatched or based, and where MDPP services may or may not be furnished.

Coach means an individual who furnishes MDPP services on behalf of an MDPP supplier as an employee, contractor, or volunteer.

Coach eligibility end date means the end date indicated by the MDPP supplier in submitting a change to the supplier's MDPP enrollment application in accordance with paragraph (d)(5) of this section that removed the coach's information, or the date the supplier itself was revoked from or withdrew its Medicare enrollment as an MDPP supplier.

Coach eligibility start date, means the start date indicated by the MDPP supplier when submitting an eligible the coach's information on the MDPP enrollment application.

Community setting means a location where the MDPP supplier furnishes MDPP services outside of their administrative locations. A community setting is a location open to the public not primarily associated with the supplier. Community settings may include, for example, church basements or multipurpose rooms in recreation centers.

Eligible coach means an individual who CMS has screened and has determined can provide MDPP services on behalf of an MDPP supplier in accordance with paragraph (e) of this section.

Ineligible coach means an individual whom CMS has screened and has determined cannot provide MDPP services on behalf of an MDPP supplier in accordance with paragraph (e) of this section.

MDPP interim preliminary recognition means a status that CMS has granted to an entity in accordance with paragraph (c) of this section.

(b) *Conditions for MDPP supplier enrollment.* An entity may enroll as an MDPP supplier only if it satisfies the following requirements and all other applicable Medicare enrollment requirements:

(1) Has either an MDPP preliminary recognition, as defined in paragraph (c)(1) of this section or a full CDC DPRP recognition.

(2) Maintains an active and valid TIN and NPI at the organizational level.

(3) Has passed screening requirements as follows:

(i) Upon initial enrollment, at a ''high'' categorical risk in accordance with § 424.518(c)(2); and

(ii) Upon revalidation, at a ''moderate'' categorical risk in accordance with § 424.518(b)(2).

(4) Maintains, and submits to CMS through the CMS-approved enrollment application, a roster of all coaches who will be furnishing MDPP services on the entity's behalf that includes each coach's first and last names, middle initial (if applicable), date of birth, Social Security Number (SSN), active and valid NPI, coach eligibility start date, and coach eligibility end date (if applicable). This roster must be updated in accordance with paragraph (d)(5) of this section.

(5) Meets and certifies in its CMS-approved enrollment application that it meets and will continue to meet the

supplier enrollment standards described in paragraph (d) of this section.

(6) Revalidates its Medicare enrollment every 3 years after the effective date of enrollment.

(c) *MDPP preliminary recognition.* (1) For the purposes of this section, an MDPP preliminary recognition may include either:

(i) Any preliminary recognition established by CDC for the purposes of the DPRP; or

(ii) An MDPP interim preliminary recognition.

(A) *MDPP interim preliminary recognition application period.* Entities may apply to CDC for CMS' MDPP interim preliminary by submitting information at the time and in the form and manner specified by CMS.

(B) *MDPP Interim preliminary recognition requirements.* An entity may qualify for MDPP interim preliminary recognition if—

(*1*) The entity has pending CDC recognition.

(*2*) The entity submits a full 12 months of performance data to CDC on at least one completed cohort. The 12 month data submission includes at least 5 participants who attended at least 3 sessions in the first 6 months and whose time from first session attended to last session of the lifestyle change program was at least 9 months, at least 60 percent of whom attended at least 9 sessions in months 1 through 6, and at least 60 percent of whom attended at least 3 sessions in months 7 through 12.

(2) [Reserved]

(d) *Medicare Diabetes Prevention Program supplier standards.* An MDPP supplier must meet and must certify in its CMS-approved enrollment application that it meets and will continue to meet the following standards.

(1) The MDPP supplier must have and maintain MDPP preliminary recognition, as defined under paragraph (c)(1) of this section, or a full CDC DPRP recognition.

(2) The MDPP supplier must not currently have its billing privileges terminated for-cause or be excluded by a State Medicaid agency.

(3) The MDPP supplier must not include on the roster of coaches, described in paragraph (b)(4) of this section and updated in accordance with paragraph (d)(5) of this section, nor permit MDPP services to be furnished by any individual coach who meets any of ineligibility criteria outlined in paragraph (e)(1) of this section.

(4) The MDPP supplier must maintain at least one administrative location. All administrative locations maintained by the MDPP supplier must be located at an appropriate site and be reported on the CMS-approved enrollment application. An appropriate site for such an administrative location would include all of the following characteristics:

(i) Signage posted on the exterior of the building. Such signage may include, for example, the MDPP supplier's legal business name or DBA, as well as hours of operation.

(ii) Open for business during stated operational hours.

(iii) Employees, staff, or volunteers present during operational hours; and

(iv) Not a private residence.

(5) The MDPP supplier must update its enrollment application within 30 days of any changes of ownership, changes to the coach roster (including due to coach ineligibility or because the coach is no longer an employee, contractor, or volunteer of the MDPP supplier), and final adverse action history, and report all other changes, including but not limited to changes in the MDPP supplier's administrative location(s), to CMS within 90 days of the reportable event.

(6) The MDPP supplier must maintain a primary business telephone that operates either at administrative locations described in paragraph (d)(4) of this section or directly where services are furnished, if services are furnished in community settings. The associated telephone number must be listed with the either the legal or doing business as name of the supplier in public view, including on Web sites, flyers, and materials.

(7) The MDPP supplier must not knowingly sell to or allow another individual or entity to use its supplier billing number.

(8) Subject to paragraph (d)(8)(i) of this section, the MDPP supplier must not deny an MDPP beneficiary access to MDPP services during the MDPP services period described in § 410.79(c)(2) of this chapter, including on the basis of the beneficiary's weight, health status, or achievement of performance goals.

(i) Suppliers may deny an MDPP beneficiary access to MDPP services during the MDPP services period only under one of the following conditions:

(A) The MDPP beneficiary no longer meets the eligibility criteria for MDPP services under § 410.79(c)(1) of this chapter.

(B) The MDPP supplier lacks the self-determined capacity to furnish MDPP services to additional MDPP beneficiaries.

(C) The MDPP supplier determines that the MDPP beneficiary significantly disrupts the session for other MDPP beneficiaries or becomes abusive.

(ii) MDPP suppliers must maintain a record of the number of MDPP beneficiaries turned away for the reasons outlined in paragraphs (d)(8)(i)(B) and (C) of this section, to include the date each such beneficiary was turned away. For beneficiaries turned away for reasons described in paragraph (d)(8)(i)(C) of this section, the MDPP supplier must document details of the occurrence(s), including date(s) of the behavior, any remediation efforts taken by the MDPP supplier, and final action (for example, dismissal from an MDPP session or denial from future sessions) in the beneficiary's MDPP records.

(9) The MDPP supplier and other individuals or entities performing functions or services related to MDPP services on the MDPP supplier's behalf must not unduly coerce an MDPP beneficiary's decision to change or not to change to a different MDPP supplier, including through the use of pressure, intimidation, or bribery.

(10) Except as allowed under paragraph (d)(8) of this section, the MDPP supplier must offer an MDPP beneficiary no fewer than all of the following:

(i) Sixteen in-person core sessions no more frequently than weekly for the first 6 months of the MDPP services period, which begins on the date of attendance at the first such core session.

(ii) One in-person core maintenance session each month during months 7 through 12 (6 months total) of the MDPP services period.

(iii) One in-person ongoing maintenance session each month for months 13 through 36 of the MDPP services period, as long as the beneficiary maintains eligibility to receive such services in accordance with § 410.79(c)(1)(ii) and (iii) of this chapter.

(11) Before the initial core session is furnished, the MDPP supplier must disclose detailed information about the set of MDPP services to each MDPP beneficiary to whom it wishes to begin furnishing MDPP services. Such information must include all of the following:

(i) Eligibility requirements under § 410.79(c)(1) of this chapter, including the once-per-lifetime nature of MDPP services.

(ii) The MDPP supplier standards as outlined in this section.

(12) The MDPP supplier must answer MDPP beneficiaries' questions about MDPP services and respond to MDPP-related complaints within a reasonable timeframe. An MDPP supplier must

implement a complaint resolution protocol and maintain documentation of all beneficiary contact regarding such complaints, including the name and Medicare Beneficiary Identifier of the beneficiary, a summary of the complaint, related correspondences, notes of actions taken, and the names and/or NPIs of individuals who took such actions on behalf of the MDPP supplier. Failure to maintain a complaint resolution protocol or to retain information regarding MDPP related complaints in accordance with paragraph (g) of this section may be considered evidence that the MPPP supplier standards have not been met. This information must be kept at each administrative location and made available to CMS or its contractors upon request.

(13) The MDPP supplier must maintain a crosswalk file which indicates how beneficiary identifications for the purposes of CDC performance data requirements correspond to corresponding beneficiary health insurance claims numbers or Medicare Beneficiary Identifiers for each MDPP beneficiary receiving MDPP services from the MDPP supplier. The MDPP supplier must submit the crosswalk file to CMS or its contractor.

(14) The MDPP supplier must submit performance data for MDPP beneficiaries who attend ongoing maintenance sessions with data elements consistent with the CDC's DPRP standards for data elements required for the core services period.

(15) The MDPP supplier must allow CMS or its agents to conduct onsite inspections or recordkeeping reviews in order to ascertain the MDPP supplier's compliance with these standards, and must adhere to the documentation requirements as outlined in paragraph (g) of this section.

(e) *Coach eligibility*—(1) *Criteria.* To furnish MDPP services to a beneficiary, an MDPP coach must not:

(i) Currently have Medicare billing privileges revoked and be currently subject to the reenrollment bar.

(ii) Currently have its Medicaid billing privileges terminated for-cause or be excluded by a State Medicaid agency.

(iii) Currently be excluded from any other Federal health care program, as defined in 42 CFR 1001.2, in accordance with section 1128, 1128A, 1156, 1842, 1862, 1867 or 1892 of the Act.

(iv) Currently be debarred, suspended, or otherwise excluded from participating in any other Federal procurement or nonprocurement program or activity in accordance with the Federal Acquisition Streamlining Act implementing regulations and the Department of Health and Human Services nonprocurement common rule at 45 CFR part 76.

(v) Have, in the previous 10 years, one of the following State or Federal felony convictions:

(A) Crimes against persons, such as murder, rape, assault, and other similar crimes for which the individual was convicted, as defined under 42 CFR 1001.2, had a guilty plea or adjudicated pretrial diversion.

(B) Financial crimes, such as extortion, embezzlement, income tax evasion, insurance fraud and other similar crimes for which the individual was convicted, as defined under 42 CFR 1001.2, had a guilty plea or adjudicated pretrial diversion.

(C) Any felony that placed the Medicare or its beneficiaries at immediate risk, such as a malpractice suit that results in the individual being convicted, as defined under 42 CFR 1001.2, had a guilty plea or adjudicated pretrial diversion of criminal neglect or misconduct.

(D) Any felonies for which the individual was convicted, as defined under 42 CFR 1001.2, had a guilty plea or adjudicated pretrial diversion that would result in mandatory exclusion under section 1128(a) of the Act.

(2) *CMS determination of coach eligibility.* CMS will screen each individual identified on the roster of coaches included with the supplier's enrollment application described in paragraph (b)(4) of this section and updated in accordance with paragraph (d)(5) of this section to verify that the individual coach does not meet any of the conditions specified in paragraph (e)(1) of this section and that the coach can provide MDPP services on behalf of an MDPP supplier. For each individual coach successfully screened by CMS, his or her eligibility start date becomes effective and remains effective until an MDPP supplier or CMS takes action that results in an eligibility end date.

(f) *Effective date for billing privileges.* (1) For MDPP suppliers initially enrolling and for newly established administrative locations that result in a new enrollment record or Provider Transaction Access Number, the effective date for Medicare billing privileges for MDPP suppliers is—

(i) The later of—

(A) The date of filing of a Medicare enrollment application that was subsequently approved by a Medicare contractor;

(B) The date of filing of a corrective action plan that was subsequently approved by a Medicare contractor; or

(C) The date that the supplier first began furnishing services at a new administrative location that resulted in a new enrollment record or Provider Transaction Access Number

(ii) Under no circumstances should the effective date of billing privileges for any MDPP supplier be prior to April 1, 2018

(2) For any newly established administrative locations that do not result in a new enrollment record or Provider Transaction Access Number, the existing billing privilege effective date for their Provider Transaction Access Number will apply, but not earlier than April 1, 2018.

(g) *Documentation retention and provision requirements.* An MDPP supplier must maintain all documentation related to participation in the MDPP in accordance with all applicable Federal and State laws. The MDPP supplier must provide to CMS, a contractor acting on CMS' behalf, the Office of the Inspector General, and the Comptroller General or their designee(s) scheduled and unscheduled access to the MDPP supplier's records, including, but not limited to, all books, contracts, records, documents, and other evidence sufficient to enable the audit, evaluation, inspection, or investigation of the MDPP supplier's compliance with the MDPP expanded model's requirements, including the MDPP expanded model requirements for in-kind beneficiary incentive engagements in § 424.210 of this chapter in the event that the MDPP supplier chooses to offer such incentives to any MDPP beneficiary.

(1) The documentation for the first core session must be established contemporaneous with the furnishing of MDPP services and must include at least all of the following:

(i) Organizational information, including MDPP supplier name, CDC DPRP number, and NPI.

(ii) Basic beneficiary information for each MDPP beneficiary in attendance, including but not limited to beneficiary name, HICN, age.

(iii) Evidence that each such beneficiary satisfied the eligibility requirements under § 410.79(c) at the time of service.

(2) The documentation for each MDPP session attended must be established contemporaneous with the furnishing of MDPP services and must include at least all of the following:

(i) Documentation of the type of session, whether a core session, a core maintenance session, an ongoing maintenance session, an in-person make-up session, or a virtual make-up session.

(ii) Identification of which CDC-approved DPRP curriculum was associated with the session.

(iii) The NPI of the coach who furnished the session.

(iv) The date and place of service of the session.

(v) Each MDPP's beneficiary's weight and date weight taken, in a form and manner as specified by CMS.

(3) If an MDPP supplier chooses to offer in-kind beneficiary engagement incentives to MDPP beneficiaries as permitted under § 424.210, the records maintained by the MDPP supplier in accordance with this section must also include the information required by § 424.210(e).

(4) An MDPP supplier is required to maintain and handle any beneficiary Personally Identifiable Information (PII) and Protected Health Information (PHI) in compliance with HIPAA, other applicable state and federal privacy laws, and CMS standards.

(5) The MDPP supplier's records must include an attestation from the MDPP supplier that, as applicable, the MDPP beneficiary for which it is submitting a claim—

(i) Has attended their first, fourth or ninth core session, as applicable, if the claim submitted is for a performance payment under § 414.84(b)(1), (2), or (3) of this chapter.

(ii) Has attended at least three core maintenance sessions, achieved required minimum weight loss, or both, as applicable, if the claim submitted is for a performance payment under § 414.84(b)(4) of this chapter.

(iii) Has achieved the required minimum weight loss and attended at least three ongoing maintenance sessions within an ongoing maintenance session interval, if the claim submitted is for a performance payment under § 414.84(b)(5) of this chapter, if the claim submitted is for a performance payment under § 414.84(b)(6) of this chapter.

(iv) Has achieved required minimum weight loss as measured in-person during a core session or core maintenance session furnished by that supplier, if the claim submitted is for a performance payment under § 414.84(b)(6) of this chapter.

(v) Has achieved at least a 9-percent weight loss percentage as measured in-person during a core session, core maintenance session, or ongoing maintenance session furnished by that supplier, if the claim submitted is for a performance payment under § 414.84(b)(7) of this chapter.

(6) The MDPP supplier must maintain all records required under this section for a period of 10 years from the last day of the MDPP beneficiary's receipt of MDPP services provided by the MDPP supplier or from the date of completion of any audit, evaluation, inspection, or investigation, whichever is later, unless either of the following apply:

(i) CMS determines that there is a special need to retain a particular record or group of records for a longer period and notifies the MDPP supplier at least 30 calendar days before the normal disposition rate; or

(ii) There has been a dispute or allegation of fraud or similar fault against the MDPP supplier, in which case the records must be maintained for an additional 6 years from the date of any resulting final resolution of the dispute or allegation of fraud or similar fault, as defined at § 405.902 of this chapter.

(h) *Denial or revocation of MDPP supplier enrollment.* (1) An MDPP supplier is subject to enrollment denial or revocation of its MDPP supplier enrollment for one or more of the following reasons:

(i) *Failure to meet enrollment requirements.* The MDPP supplier does not satisfy the conditions specified in paragraph (b) of this section.

(A) An enrollment denial under this paragraph (h)(1)(i) is considered an enrollment denial under § 424.530(a)(1) of this chapter.

(B) A revocation under this paragraph (h)(1)(i) is considered a revocation under § 424.535(a)(1) of this chapter.

(C) An MDPP supplier that does not satisfy the requirements in paragraph (b)(1) of this section may become eligible to bill for MDPP services again if it successfully achieves MDPP preliminary recognition or full CDC DPRP recognition, and successfully enrolls again in Medicare as an MDPP supplier after any applicable reenrollment bar has expired.

(ii) *Failure to meet MDPP supplier standards.* The MDPP supplier fails to meet the standards specified in paragraph (d) of this section.

(A) An enrollment denial under this paragraph (h)(1)(ii) is considered an enrollment denial under § 424.530(a)(1) of this part.

(B) A revocation under this paragraph (h)(1)(ii) is considered a revocation under § 424.535(a)(1) of this part.

(iii) *Application of existing enrollment denial reasons.* One of the enrollment denial reasons specified in § 424.530(a) of this part applies.

(iv) *Application of existing revocation reasons.* One of the revocation reasons specified in § 424.535(a) of this chapter applies.

(v) *Use of an ineligible coach.* (A) The MDPP supplier knowingly allows an ineligible coach to furnish MDPP services to Medicare beneficiaries. Knowingly means that the MDPP supplier received an enrollment denial or revocation notice based on failing to meet the standard specified in § 424.205(d)(3), was provided notice by CMS or contractors working on its behalf of this coach's ineligibility including the reason(s) for ineligibility, submitted a corrective action plan (CAP) to remove the coach and become compliant therefore maintaining its enrollment, but continued to allow the coach to provide MDPP services in violation of the CAP.

(B) Revocation under this paragraph (h)(1)(v) is subject to the following requirements:

(*1*) The revocation becomes effective 30 days after CMS or the CMS contractor mails notice of its determination to the MDPP supplier.

(*2*) For the revocation authority under this paragraph, MDPP suppliers are barred from participating in the Medicare program from the date of the revocation, which begins 30 days after CMS or its contractor mails notice of the revocation, until the end of the reenrollment bar, which lasts a minimum of 1 year, but not greater than 3 years, depending on the severity of the basis for revocation.

(*3*) A revoked MDPP supplier must, within 60 calendar days after the effective date of revocation, submit all claims for items and services furnished before the date of the revocation letter.

(2) An MDPP supplier may appeal an enrollment denial or revocation decision in accordance with the procedures specified in part 498 of this chapter. References to suppliers in that section apply to MDPP suppliers.

§ 424.210 Beneficiary engagement incentives under the Medicare Diabetes Prevention Program expanded model.

(a) *Definitions.* In addition to the definitions specified at § 410.79(b) and § 424.205(a) of this chapter, the following definition applies to this section:

Engagement incentive period means the period of time during which an MDPP supplier may furnish in-kind beneficiary engagement incentives to a given MDPP beneficiary to whom the MDPP supplier is furnishing MDPP services. This period begins when an MDPP supplier furnishes any MDPP service to an MDPP eligible beneficiary and ends when one of the following occurs, whichever occurs first:

(i) The MDPP beneficiary's MDPP services period ends as described in § 410.79(c)(3) of this chapter.

(ii) The MDPP supplier knows the MDPP beneficiary will no longer be receiving MDPP services from the MDPP supplier.

(iii) The MDPP supplier has not had direct contact, either in-person, by telephone, or via other telecommunications technology, with the MDPP beneficiary for more than 90 consecutive calendar days during the MDPP services period.

(b) *General.* An MDPP supplier may choose to furnish an item or service as an in-kind beneficiary engagement incentive to an MDPP beneficiary only during the engagement incentive period, subject to the following conditions:

(1) The item or service must be furnished directly to an MDPP beneficiary by an MDPP supplier or by an agent of the MDPP supplier, such as a coach, under the MDPP supplier's direction and control.

(2) The item or service must be reasonably connected to the CDC-approved DPP curriculum furnished to the MDPP beneficiary during a core session, a core maintenance session, or ongoing maintenance session furnished by the MDPP supplier.

(3) The item or service must be a preventive care item or service or an item or service that advances a clinical goal, as specified in paragraph (d) of this section, for an MDPP beneficiary by engaging him or her in better managing his or her own health.

(4) The item or service must not be tied to the receipt of services outside of the MDPP services

(5) The item or service must not be tied to the receipt of services from a particular provider, supplier, or coach.

(6) The availability of the item or service must not be advertised or promoted as an in-kind beneficiary engagement incentive available to an MDPP beneficiary receiving MDPP services from the MDPP supplier except that an MDPP beneficiary may be made aware of the availability of the item or service at the time the MDPP beneficiary could reasonably benefit from it during the engagement incentive period.

(7) The cost of the item or service must not be shifted to another Federal health care program, as defined at section 1128B(f) of the Act.

(c) *Technology furnished to an MDPP beneficiary.* In-kind beneficiary engagement incentives involving technology furnished by an MDPP supplier to an MDPP beneficiary are subject to the following conditions:

(1) Items or services involving technology may not, in the aggregate, exceed $1,000 in retail value for any one MDPP beneficiary.

(2) Items or services involving technology must be the minimum necessary to advance a clinical goal, as listed in paragraph (d) of this section, for an MDPP beneficiary.

(3) Items involving technology exceeding $100 in retail value must—

(i) Remain the property of the MDPP supplier; and

(ii) Be retrieved from the MDPP beneficiary at the end of the engagement incentive period. The MDPP supplier must document all retrieval attempts, including the ultimate date of retrieval in accordance with paragraph (e)(3) of this section. Documented diligent, good faith attempts to retrieve items of technology will be deemed to meet the retrieval requirement.

(d) *Clinical goals of the MDPP expanded model.* The following are the clinical goals for MDPP beneficiaries, that may be advanced through in-kind beneficiary engagement incentives:

(1) Attendance at core sessions, core maintenance sessions, or ongoing maintenance sessions.

(2) Weight loss.

(3) Long-term dietary change.

(4) Adherence to long-term health behavior changes.

(e) *Documentation of beneficiary engagement incentives.* In addition to the documentation requirements at § 424.205(g), an MDPP supplier must maintain documentation of items and services furnished as in-kind beneficiary engagement incentives that exceed $25 in retail value.

(1) The documentation must be established contemporaneous with the furnishing of the in-kind items and services and must include at least the following:

(i) The date the item or service is furnished.

(ii) The identity of the MDPP beneficiary to whom the item or service is furnished.

(iii) The agent of the MDPP supplier who furnished the item or service, if applicable.

(iv) A description of the item or service.

(v) The retail value of the item or service.

(vi) Documentation establishing that the item or service was furnished to the MDPP beneficiary during the engagement incentive period.

(2) Documentation regarding items or services that are furnished to the MDPP beneficiary for use on an ongoing basis during the engagement incentive period, including items of technology exceeding $100 in retail value, must also include contemporaneous documentation establishing that the MDPP beneficiary is in the engagement incentive period throughout the time period that the MDPP beneficiary possesses or has access to the item or service furnished by the MDPP supplier.

(3) The documentation regarding items of technology exceeding $100 in retail value must also include contemporaneous documentation of any attempt to retrieve technology as required by paragraph (c)(3)(ii) of this section.

(4) The MDPP supplier must retain and provide access to the documentation required in this section in accordance with § 424.205(g).

■ 17. Section 424.502 is amended by revising the definition for ''Institutional provider'' to read as follows.

§ 424.502 Definitions.

* * * * *

Institutional provider means any provider or supplier that submits a paper Medicare enrollment application using the CMS–855A, CMS–855B (not including physician and nonphysician practitioner organizations), CMS–855S, any enrollment application designated for MDPP suppliers, or an associated Internet-based PECOS enrollment application.

* * * * *

■ 18. Section 424.516 is amended by revising paragraph (e) introductory text to read as follows.

§ 424.516 Additional provider and supplier requirements for enrolling and maintaining active enrollment status in the Medicare program.

* * * * *

(e) *Reporting requirements for all other providers and suppliers.* Reporting requirements for all other providers and suppliers not identified in paragraphs (a) through (d) of this section, with the exception of MDPP suppliers whose reporting requirements are established in § 424.205(d), must report to CMS the following information within the specified timeframes:

* * * * *

PART 425—MEDICARE SHARED SAVINGS PROGRAM

■ 19. The authority citation for part 425 continues to read as follows:

Authority: Secs. 1102, 1106, 1871, and 1899 of the Social Security Act (42 U.S.C. 1302, 1306 1395hh, and 1395jjjj).

■ 20. Section 425.20 is amended by revising the definitions of ''Primary care physician'' and ''Primary care services'' to read as follows:

§ 425.20 Definitions.

* * * * *

Primary care physician means:

(1) For performance years 2012 through 2015, a physician included in an attestation by the ACO as provided under § 425.404 for services furnished in an FQHC or RHC, or a physician who has a primary care specialty designation of internal medicine, general practice, family practice, or geriatric medicine;

(2) For performance years 2016 through 2018, a physician included in an attestation by the ACO as provided under § 425.404 for services furnished in an FQHC or RHC, or a physician who has a primary care specialty designation of internal medicine, general practice, family practice, geriatric medicine, or pediatric medicine; and

(3) For performance year 2019 and subsequent years, a physician who has a primary care specialty designation of internal medicine, general practice, family practice, geriatric medicine, or pediatric medicine.

Primary care services means the set of services identified by the HCPCS and revenue center codes designated under § 425.400(c).

* * * * *

■ 22. Section 425.112 is amended—

■ a. In paragraph (a)(3)(i) by removing the phrase ''Explain how it will require ACO participants'' and adding in its place the phrase ''Require ACO participants'';

■ b. In paragraph (a)(3)(ii) by removing the phrase ''Explain how it will employ its internal assessments'' and adding in its place the phrase ''Employ its internal assessments''; and

■ c. By revising paragraph (b)(4)(ii).

The revision reads as follows:

§ 425.112 Required processes and patient-centeredness criteria.

* * * * *

(b) * * *

(4) * * *

(ii) Have a written plan to:

(A) Implement an individualized care program that promotes improved outcomes for, at a minimum, the ACO's high-risk and multiple chronic condition patients.

(B) Identify additional target populations that would benefit from individualized care plans. Individualized care plans must take into account the community resources available to the individual.

(C) Encourage and promote use of enabling technologies for improving care coordination for beneficiaries. Enabling technologies may include one or more of the following:

(*1*) Electronic health records and other health IT tools.

(*2*) Telehealth services, including remote patient monitoring.

(*3*) Electronic exchange of health information.

(*4*) Other electronic tools to engage beneficiaries in their care.

(D) Partner with long-term and post-acute care providers, both inside and outside the ACO, to improve care coordination for its assigned beneficiaries.

■ 23. Section 425.204 is amended by—

■ a. Revising paragraph (c)(1) introductory text;

■ b. Removing paragraph (c)(5)(iii);

■ c. Redesignating paragraph (c)(5)(iv) as paragraph (c)(5)(iii); and

■ d. Revising paragraph (d).

The revisions read as follows:

§ 425.204 Content of the application.

* * * * *

(c) * * *

(1) As part of its application, an ACO must certify that the ACO satisfies the requirements set forth in this part. Upon request, the ACO must submit the following supporting materials to demonstrate that it satisfies the requirements set forth in this part:

* * * * *

(d) *Distribution of savings.* As part of its application to participate in the Shared Savings Program, an ACO must certify it has a mechanism and plan to receive and use payments for shared savings, including criteria for distributing shared savings among its ACO participants and ACO providers/suppliers.

* * * * *

■ 24. Section 425.306 is amended by revising paragraph (b)(2) to read as follows:

§ 425.306 Participant agreement and exclusivity of ACO participants.

* * * * *

(b) * * *

(2) Each ACO participant that submits claims for services used to determine the ACO's assigned population under subpart E of this part must be exclusive to one Shared Savings Program ACO. If, during a benchmark or performance year (including the 3-month claims runout for such benchmark or performance year), an ACO participant that participates in more than one ACO submits claims for services used in assignment under subpart E of this part, then:

(i) CMS will not consider any services billed through the TIN of the ACO participant when performing assignment under subpart E of this part for the benchmark or performance year.

(ii) The ACO may be subject to the pre-termination actions set forth in § 425.216, termination under § 425.218, or both.

■ 25. Section 425.400 is amended by adding paragraph (a)(1)(iii) and revising paragraph (c) to read as follows:

§ 425.400 General.

(a) * * *

(1) * * *

(iii) In determining final assignment for a benchmark or performance year, CMS will exclude any services furnished during the benchmark or performance year that are billed through the TIN of an ACO participant that is an ACO participant in more than one ACO.

* * * * *

(c) Primary care services for purposes of assigning beneficiaries are identified by selected HCPCS/CPT codes, or revenue center codes.

(1) Primary care service codes are as follows:

(i) For performance years 2012 through 2015:

(A) CPT codes:

(*1*) 99201 through 99215.

(*2*) 99304 through 99340.

(*3*) 99341 through 99350.

(B) HCPCS codes G0402 (the code for the Welcome to Medicare visit) and G0438 and G0439 (codes for the annual wellness visits).

(C) Revenue center codes 0521, 0522, 0524, and 0525 submitted by FQHCs (for services furnished prior to January 1, 2011), or by RHCs.

(ii) For performance year 2016 as follows:

(A) CPT codes:

(*1*) 99201 through 99215.

(*2*) 99304 through 99340.

(*3*) 99341 through 99350.

(*4*) 99495, 99496, and 99490.

(B) HCPCS codes:

(*1*) G0402 (the code for the Welcome to Medicare visit) and

(*2*) G0438 and G0439 (codes for the annual wellness visits).

(*3*) G0463 for services furnished in ETA hospitals.

(C) Revenue center codes 0521, 0522, 0524, and 0525 submitted by FQHCs (for services furnished prior to January 1, 2011), or by RHCs.

(iii) For performance year 2017 and 2018 as follows:

(A) CPT codes:

(*1*) 99201 through 99215.

(*2*) 99304 through 99318 (excluding claims including the POS 31 modifier).

(*3*) 99319 through 99340.

(*4*) 99341 through 99350.

(*5*) 99495, 99496, and 99490.

(B) HCPCS Codes:

(*1*) G0402 (the code for the Welcome to Medicare visit) and

(*2*) G0438 and G0439 (codes for the annual wellness visits).

(*3*) G0463 for services furnished in ETA hospitals.

(C) Revenue center codes 0521, 0522, 0524, and 0525 submitted by FQHCs (for services furnished prior to January 1, 2011), or by RHCs.

(iv) For performance year 2019 as follows:

(A) CPT codes:

(*1*) 99201 through 99215.

(*2*) 99304 through 99318 (excluding claims including the POS 31 modifier).

(*3*) 99319 through 99340.

(*4*) 99341 through 99350.

(*5*) 99487 and 99489.

(*6*) 99495, 99496, and 99490.

(B) HCPCS Codes:

(*1*) G0402 (the code for the Welcome to Medicare visit) and

(*2*) G0438 and G0439 (codes for the annual wellness visits).

(*3*) G0463 for services furnished in ETA hospitals.

(*4*) G0506 (code for chronic care management).

(*5*) G0502, G0503, G0504 and G0507 (codes for behavioral health integration).

■ 26. Section 425.404 is amended—

■ a. In the introductory text by removing the phrase ''with two special conditions:'' and adding in its place the phrase ''with special conditions:''; and

■ b. By revising paragraphs (a) and (b).

The revisions read as follows:

§ 425.404 Special assignment conditions for ACOs including FQHCs and RHCs.

* * * * *

(a) For performance years 2012 through 2018—

(1) Such ACOs are required to identify, through an attestation, physicians who directly provide primary care services in each FQHC or RHC that is an ACO participant and/or ACO provider/supplier in the ACO.

(2) Under the assignment methodology in § 425.402, CMS treats a service reported on an FQHC/RHC claim as a primary care service—

(i) If the claim includes a HCPCS or revenue center code that meets the definition of primary care services under § 425.20;

(ii) Performed by a primary care physician if the NPI of a physician identified in the attestation provided under paragraph (a)(1) of this section is reported on the claim for a primary care service (as described in paragraph (a)(2)(i) of this section) as the attending provider; and

(iii) Performed by a non-physician ACO professional if the NPI reported on the claim for a primary care service (as described in paragraph (a)(2)(i) of this section) as the attending provider is an ACO professional but is not identified in the attestation provided under paragraph (a)(1) of this section.

(b) For performance year 2019 and subsequent performance years, under the assignment methodology in § 425.402, CMS treats a service reported on an FQHC/RHC claim as a primary care service performed by a primary care physician.

§ 425.500 [Amended]

■ 27. Section 425.500 is amended—

■ a. In paragraph (e)(2) by removing the phrase ''of this section is less than 90 percent, absent unusual circumstances,'' and adding in its place the phrase ''of this section is less than 80 percent, absent unusual circumstances,''; and

■ b. In paragraph (e)(3) by removing the phrase ''determines there is a match rate of less than 90 percent, the ACO'' and adding in its place the phrase ''determines there is a match rate of less than 80 percent, the ACO''.

§ 425.502 [Amended]

■ 28. Section 425.502 is amended in paragraph (a)(5) by removing the phrase ''or causes patient harm.'' and adding in its place the phrase ''or causes patient harm, or when there is a determination under the Quality Payment Program that the measure has undergone a substantive change.''

■ 29. Section § 425.602 is amended by adding paragraphs (a)(1)(ii)(A) through (C) to read as follows:

§ 425.602 Establishing, adjusting, and updating the benchmark for an ACO's first agreement period.

(a) * * *

(1) * * *

(ii) * * *

(A) For agreement periods beginning before 2018, this calculation considers all individually beneficiary identifiable payments, including interim payments, made under a demonstration, pilot or time limited program.

(B) For agreement periods beginning in 2018 and subsequent years, this calculation considers individually beneficiary identifiable final payments made under a demonstration, pilot or time limited program.

(C) For the 2018 performance year and subsequent performance years in agreement periods beginning in 2015, 2016 and 2017, the benchmark is adjusted to reflect only individually beneficiary identifiable final payments made under a demonstration, pilot or time limited program.

* * * * *

■ 30. Section § 425.603 is amended by adding paragraphs (c)(1)(ii)(A) through (C) and (e)(2)(ii)(A) through (C) to read as follows:

§ 425.603 Resetting, adjusting, and updating the benchmark for a subsequent agreement period.

* * * * *

(c) * * *

(1) * * *

(ii) * * *

(A) For agreement periods beginning before 2018, considers all individually beneficiary identifiable payments, including interim payments, made under a demonstration, pilot or time limited program.

(B) For agreement periods beginning in 2018 and subsequent years, considers individually beneficiary identifiable final payments made under a demonstration, pilot or time limited program.

(C) For the 2018 and 2019 performance years in agreement periods beginning in 2017, the benchmark is adjusted to reflect only individually beneficiary identifiable final payments made under a demonstration, pilot or time limited program.

* * * * *

(e) * * *

(2) * * *

(ii) * * *

(A) For agreement periods beginning before 2018, considers all individually beneficiary identifiable payments, including interim payments, made under a demonstration, pilot or time limited program.

(B) For agreement periods beginning in 2018 and subsequent years, considers individually beneficiary identifiable final payments made under a demonstration, pilot or time limited program.

(C) For the 2018 and 2019 performance years in agreement periods beginning in 2017, risk adjusted county fee-for-service expenditures are adjusted to reflect only individually beneficiary identifiable final payments made under a demonstration, pilot or time limited program.

* * * * *

■ 31. Section § 425.604 is amended by adding paragraphs (a)(6)(ii)(A) and (B) to read as follows:

§ 425.604 Calculation of savings under the one-sided model.

(a) * * *

(6) * * *

(ii) * * *

(A) For performance years beginning before 2018, these calculations will take into consideration all individually beneficiary identifiable payments, including interim payments, made under a demonstration, pilot or time limited program.

(B) For performance year 2018 and subsequent performance years, these calculations will take into consideration individually beneficiary identifiable final payments made under a demonstration, pilot or time limited program.

* * * * *

■ 32. Section § 425.606 is amended by adding paragraphs (a)(6)(ii)(A) and (B) to read as follows:

§ 425.606 Calculation of shared savings and losses under Track 2.

(a) * * *

(6) * * *

(ii) * * *

(A) For performance years beginning before 2018, these calculations will take into consideration all individually beneficiary identifiable payments, including interim payments, made under a demonstration, pilot or time limited program.

(B) For performance year 2018 and subsequent performance years, these calculations will take into consideration individually beneficiary identifiable final payments made under a demonstration, pilot or time limited program.

* * * * *

■ 33. Section § 425.610 is amended by adding paragraphs (a)(6)(ii)(A) and (B) to read as follows:

§ 425.610 Calculation of shared savings and losses under Track 3.

(a) * * *

(6) * * *

(ii) * * *

(A) For performance years beginning before 2018, these calculations will take into consideration all individually beneficiary identifiable payments, including interim payments, made under a demonstration, pilot or time limited program.

(B) For performance year 2018 and subsequent performance years, these calculations will take into consideration individually beneficiary identifiable final payments made under a demonstration, pilot or time limited program.

* * * * *

§ 425.612 [Amended]

■ 34. Section 425.612 is amended by removing paragraphs (a)(1)(i)(A)(*4*) and (a)(1)(i)(C).

Dated: June 28, 2017.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: June 28, 2017.

Thomas E. Price,

Secretary, Department of Health and Human Services.

[FR Doc. 2017–14639 Filed 7–13–17; 4:15 pm]

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Part III

Environmental Protection Agency

40 CFR Part 80

Renewable Fuel Standard Program: Standards for 2018 and Biomass-Based Diesel Volume for 2019; Proposed Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 80

[EPA–HQ–OAR–2017–0091; FRL–9964–86–OAR]

RIN 2060–AT04

Renewable Fuel Standard Program: Standards for 2018 and Biomass-Based Diesel Volume for 2019

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: Under section 211 of the Clean Air Act, the Environmental Protection Agency (EPA) is required to set renewable fuel percentage standards every year. This action proposes the annual percentage standards for cellulosic biofuel, biomass-based diesel, advanced biofuel, and total renewable fuel that apply to gasoline and diesel transportation fuel produced or imported in the year 2018. Relying on statutory waiver authority that is available when projected cellulosic biofuel production volumes are less than the applicable volume specified in the statute, the EPA is proposing volume requirements for cellulosic biofuel, advanced biofuel, and total renewable fuel that are below the statutory applicable volumes, and lower than the 2017 requirements. In this action, we are also proposing the applicable volume of biomass-based diesel for 2019.

DATES: Comments must be received on or before August 31, 2017. EPA will announce the public hearing date and location for this proposal in a supplemental **Federal Register** document.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OAR–2017–0091, 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. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Julia MacAllister, Office of Transportation and Air Quality, Assessment and Standards Division, Environmental Protection Agency, 2000 Traverwood Drive, Ann Arbor, MI 48105; telephone number: 734–214–4131; email address: *macallister.julia@epa.gov.*

SUPPLEMENTARY INFORMATION: Entities potentially affected by this proposed rule are those involved with the production, distribution, and sale of transportation fuels, including gasoline and diesel fuel or renewable fuels such as ethanol, biodiesel, renewable diesel, and biogas. Potentially regulated categories include:

Category	NAICS [1] codes	SIC [2] codes	Examples of potentially regulated entities
Industry	324110	2911	Petroleum Refineries.
Industry	325193	2869	Ethyl alcohol manufacturing.
Industry	325199	2869	Other basic organic chemical manufacturing.
Industry	424690	5169	Chemical and allied products merchant wholesalers.
Industry	424710	5171	Petroleum bulk stations and terminals.
Industry	424720	5172	Petroleum and petroleum products merchant wholesalers.
Industry	221210	4925	Manufactured gas production and distribution.
Industry	454319	5989	Other fuel dealers.

[1] North American Industry Classification System (NAICS).
[2] Standard Industrial Classification (SIC) system code.

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be regulated by this proposed action. This table lists the types of entities that EPA is now aware could potentially be regulated by this proposed action. Other types of entities not listed in the table could also be regulated. To determine whether your entity would be regulated by this proposed action, you should carefully examine the applicability criteria in 40 CFR part 80. If you have any questions regarding the applicability of this proposed action to a particular entity, consult the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

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I. Executive Summary

The Renewable Fuel Standard (RFS) program began in 2006 pursuant to the requirements in Clean Air Act (CAA) section 211(o) that were added through the Energy Policy Act of 2005 (EPAct). The statutory requirements for the RFS program were subsequently modified through the Energy Independence and Security Act of 2007 (EISA), leading to the publication of major revisions to the regulatory requirements on March 26, 2010.[1] EISA's stated goals include moving the United States toward ''greater energy independence and security [and] to increase the production of clean renewable fuels.'' Today, nearly all of the approximately 143 billion gallons of gasoline used for transportation purposes contains 10 percent ethanol (E10), and on average diesel fuel contains approximately 4 percent biodiesel and/or renewable diesel.

The statute includes annual volume targets, and requires EPA to translate those volume targets (or alternative volume requirements established by EPA in accordance with statutory waiver authorities) into compliance obligations that obligated parties must meet every year. In this action, we are proposing the annual percentage standards for cellulosic biofuel, biomass-based diesel (BBD), advanced biofuel, and total renewable fuel that would apply to all gasoline and diesel produced or imported in 2018. We are also proposing the applicable volume of BBD for 2019.

Real-world challenges, such as the slower-than-expected development of the cellulosic biofuel industry, have slowed progress towards meeting Congressional goals for renewable fuels, even as progress has been made in some areas. Those challenges have made the volume targets established by Congress for 2018 beyond reach for all fuel categories other than BBD, for which the statute specifies a minimum requirement of 1.0 billion gallons. After careful review of the information before us, for 2018 we propose to use the cellulosic waiver authority provision provided by Congress to reduce the volume requirement for cellulosic biofuel to the projected volume available in 2018, and establish volume requirements for advanced biofuel and total renewable fuel that are lower than the statutory targets, but nevertheless will ensure these renewable fuels will continue to play a critical role as a complement to our petroleum-based fuels. We are not proposing to provide volume reductions through use of the general waiver authority.[2]

We note that while we are proposing to reduce the required volume of all of the fuel categories other than BBD due to an anticipated shortfall in the production of cellulosic biofuel, the proposed BBD volume exceeds the statutory minimum and the proposed volumes of total renewable fuel, advanced biofuel and cellulosic biofuel would achieve the implied statutory volumes for conventional biofuel[3] and non-cellulosic advanced biofuel.[4]

The proposed volume requirements for 2018 are shown in Table I–1 below. Relative to the levels finalized in 2017, the proposed 2018 volume requirements for advanced biofuel and total renewable fuel are lower by 40 million gallons. For the first time EPA is proposing in 2018 to reduce the advanced biofuel and total renewable fuel volumes by the same amount as we would reduce the required volume of cellulosic biofuel. These reductions effectively preserve the implied statutory volumes for conventional renewable fuel and non-cellulosic advanced biofuels, rather than requiring additional volumes of non-cellulosic advanced biofuels to backfill for some of the shortfall in cellulosic biofuel, as EPA has done in previous years. We are proposing no increase, relative to the finalized 2018 levels, in the volume requirement for biomass-based diesel for 2019.

TABLE I–1—PROPOSED VOLUME REQUIREMENTS [a]

	2018	2019
Cellulosic biofuel (million gallons)	238	n/a
Biomass-based diesel (billion gallons)	[b] 2.1	2.1
Advanced biofuel (billion gallons)	4.24	n/a
Renewable fuel (billion gallons)	19.24	n/a

[a] All values are ethanol-equivalent on an energy content basis, except for BBD which is biodiesel-equivalent.
[b] The 2018 BBD volume requirement was established in the 2017 final rule (81 FR 89746, December 12, 2016).

The Clean Air Act requires EPA to ''reset'' the statutory volume targets for future years when certain conditions are met. As discussed later in this Executive Summary, the Administrator has directed staff to begin technical analysis to inform a future reset rulemaking action.

A. Purpose of This Action

The national volume targets of renewable fuel that are intended to be achieved under the RFS program each year (absent an adjustment or waiver by EPA) are specified in CAA section

[1] 75 FR 14670, March 26, 2010.

[2] See 42 U.S.C. 7545(o)(7)(A)(i–ii). See also the discussion of the general waiver authority in Section II.A.2. below.

[3] Throughout this proposed rule conventional biofuel refers to biofuel that qualifies as renewable fuel, but does not qualify as an advanced biofuel. RINs generated for conventional biofuels have a D code of 6.

[4] Throughout this proposed rule non-cellulosic advanced biofuel refers to biofuel that qualifies as advanced biofuel, but does not qualify as cellulosic biofuel. RINs generated for non-cellulosic advanced biofuels have a D code of 4 or 5.

211(o)(2). The statutory volumes for 2018 are shown in Table I.A–1. The cellulosic biofuel and BBD categories are nested within the advanced biofuel category, which is itself nested within the total renewable fuel category. This means, for example, that each gallon of cellulosic biofuel or BBD that is used to satisfy the individual volume requirements for those fuel types can also be used to satisfy the requirements for advanced biofuel and total renewable fuel.

TABLE I.A–1—APPLICABLE 2018 VOLUMES SPECIFIED IN THE CLEAN AIR ACT

[Billion gallons] [a]

Cellulosic biofuel	7.0
Biomass-based diesel	≥1.0
Advanced biofuel	11.0
Renewable fuel	26.0

[a] All values are ethanol-equivalent on an energy content basis, except values for BBD which are given in actual gallons.

Under the RFS program, EPA is required to determine and publish annual percentage standards for each compliance year. The percentage standards are calculated to ensure use in transportation fuel of the national ''applicable volumes'' of the four types of biofuel (cellulosic biofuel, BBD, advanced biofuel, and total renewable fuel) that are set forth in the statute or established by EPA in accordance with the Act's requirements. The percentage standards are used by obligated parties (generally, producers and importers of gasoline and diesel fuel) to calculate their individual compliance obligations. Each of the four percentage standards is applied to the volume of non-renewable gasoline and diesel that each obligated party produces or imports during the specified calendar year to determine their individual volume obligations with respect to the four renewable fuel types. The individual volume obligations determine the number of RINs of each renewable fuel type that each obligated party must acquire and retire to demonstrate compliance.

EPA is proposing the annual applicable volume requirements for cellulosic biofuel, advanced biofuel, and total renewable fuel for 2018, and for BBD for 2019.[5] Table I.A–2 lists the statutory provisions and associated criteria relevant to determining the national applicable volumes used to set the percentage standards in this proposed rule.

TABLE I.A–2—STATUTORY PROVISIONS FOR DETERMINATION OF APPLICABLE VOLUMES

Applicable volumes	Clean air act reference	Criteria provided in statute for determination of applicable volume
Cellulosic biofuel	211(o)(7)(D)(i)	Required volume must be lesser of volume specified in CAA 211(o)(2)(B)(i)(III) or EPA's projected volume.
	211(o)(7)(A)	EPA in consultation with other federal agencies may waive the statutory volume in whole or in part if implementation would severely harm the economy or environment of a State, region, or the United States, or if there is an inadequate domestic supply.
Biomass-based diesel [6]	211(o)(2)(B)(ii) and (v)	Required volume for years after 2012 must be at least 1.0 billion gallons, and must be based on a review of implementation of the program, coordination with other federal agencies, and an analysis of specified factors.
	211(o)(7)(A)	EPA in consultation with other federal agencies may waive the statutory volume in whole or in part if implementation would severely harm the economy or environment of a State, region, or the United States, or if there is an inadequate domestic supply.
Advanced biofuel	211(o)(7)(D)(i)	If applicable volume of cellulosic biofuel is reduced below the statutory volume to the projected volume, EPA may reduce the advanced biofuel and total renewable fuel volumes in CAA 211(o)(2)(B)(i)(I) and (II) by the same or lesser volume. No criteria specified.
	211(o)(7)(A)	EPA in consultation with other federal agencies may waive the statutory volume in whole or in part if implementation would severely harm the economy or environment of a State, region, or the United States, or if there is an inadequate domestic supply.
Total renewable fuel	211(o)(7)(D)(i)	If applicable volume of cellulosic biofuel is reduced below the statutory volume to the projected volume, EPA may reduce the advanced biofuel and total renewable fuel volumes in CAA 211(o)(2)(B)(i)(I) and (II) by the same or lesser volume. No criteria specified.
	211(o)(7)(A)	EPA in consultation with other federal agencies may waive the statutory volume in whole or in part if implementation would severely harm the economy or environment of a State, region, or the United States, or if there is an inadequate domestic supply.

As shown in Table I.A–2, the statutory authorities allowing EPA to modify or set the applicable volumes differ for the four categories of renewable fuel. Under the statute, EPA must annually determine the projected volume of cellulosic biofuel production for the following year. If the projected volume of cellulosic biofuel production is less than the applicable volume specified in section 211(o)(2)(B)(i)(III) of the statute, EPA must lower the applicable volume used to set the annual cellulosic biofuel percentage standard to the projected production volume. In Section III of this proposed rule, we present our analysis of cellulosic biofuel production and the

[5] The 2018 BBD volume requirement was established in the 2017 final rule.

[6] CAA section 211(o)(7)(E) also authorizes EPA in consultation with other federal agencies to issue a temporary waiver of applicable volumes of BBD where there is a significant feedstock disruption or other market circumstance that would make the price of BBD fuel increase significantly.

proposed applicable volume for 2018. This analysis is based primarily on information reported to EPA through our Electronic Moderated Transaction System (EMTS) and an evaluation of producers' production plans and progress to date following discussions with cellulosic biofuel producers.

With regard to BBD, CAA section 211(o)(2)(B) specifies the applicable volumes of BBD to be used in the RFS program only through year 2012. For subsequent years the statute sets a minimum volume of 1 billion gallons, and directs EPA, in coordination with the U.S. Departments of Agriculture (USDA) and Energy (DOE), to determine the required volume after review of implementation of the renewable fuels program and consideration of a number of factors. The BBD volume requirement must be established 14 months before the year in which it will apply. In the 2017 final rule we established the BBD volume for 2018. In Section VI of this preamble we discuss our assessment of statutory and other relevant factors and our proposed volume requirement for BBD for 2019, which has been developed in coordination with USDA and DOE. We are proposing an applicable volume of 2.1 billion gallons of BBD for use in deriving the BBD percentage standard in 2019. This volume is equal to the applicable volume of BBD established in a prior rulemaking for 2018, and would provide continued support to an industry that is a significant contributor to the pool of advanced biofuel while at the same time setting the volume requirement in a manner anticipated to provide continued incentive for the development of other types of advanced biofuel.

Regarding advanced biofuel and total renewable fuel, Congress provided several mechanisms through which the statutory targets could be reduced if necessary. If we reduce the applicable volume of cellulosic biofuel below the volume specified in CAA section 211(o)(2)(B)(i)(III), we also have the authority to reduce the applicable volumes of advanced biofuel and total renewable fuel by the same or a lesser amount. We refer to this as the ''cellulosic waiver authority.'' We may also reduce the applicable volumes of any of the four renewable fuel types using the ''general waiver authority'' provided in CAA section 211(o)(7)(A) if EPA, in consultation with USDA and DOE, finds that implementation of the statutory volumes would severely harm the economy or environment of a State, region, or the United States, or if there is inadequate domestic supply. Sections II, IV, and V of this proposed rule describe our use of the cellulosic waiver authority alone to derive proposed volumes of advanced biofuel and total renewable fuel that are below the statutory target volumes, and our assessment that the resulting volumes can be met. We believe that reductions in the statutory targets for 2018 are necessary. However, in light of our review of available information, we are proposing to make those reductions under the cellulosic waiver authority alone and are not proposing any additional increment of reduction under the general waiver authority. Thus, the reductions proposed can be attributed to the significant shortfall in cellulosic biofuel production, as compared to the statutory targets. EPA, however, solicits comment on whether it would be appropriate to exercise the general waiver authority in the final rule, and will evaluate comments and updated data to consider whether such an approach is warranted.

B. Summary of Major Provisions in This Action

This section briefly summarizes the major provisions of this proposed rule. We are proposing applicable volume requirements and associated percentage standards for cellulosic biofuel, advanced biofuel, and total renewable fuel for 2018; for BBD we are proposing the percentage standard for 2018 and the applicable volume requirement for 2019.

1. Approach to Setting Volume Requirements

The approach we have taken in this proposed rule to project cellulosic biofuel is modified from that presented in the 2017 final rule, as described in further detail below. The approach we have taken in this proposed rule of using the cellulosic waiver authority to reduce advanced biofuel and total renewable fuel is similar to that presented in the 2017 final rule, however, we are proposing to reduce the advanced biofuel and total renewable fuel volume requirements by the same amount as the cellulosic biofuel volume requirement. In previous years we have used the cellulosic waiver authority to reduce the advanced biofuel and total renewable fuel volume requirements by a lesser amount than the cellulosic biofuel volume requirement to allow reasonably attainable volumes of advanced biofuels to partially backfill for missing cellulosic biofuel volumes. In this rule we are proposing to reduce all three volume requirements by the same amount after considering the greenhouse gas (GHG), energy security benefits, and anticipated costs of advanced biofuels beyond the level proposed in this rule.

Section II provides a general description of our approach to setting volume requirements in today's rule, including a review of the statutory waiver authorities and our consideration of carryover RINs. Section III provides our assessment of the 2018 cellulosic biofuel volume based on a projection of production that reflects a neutral aim at accuracy. Sections IV and V describe our assessments of advanced biofuel and total renewable fuel, respectively. Finally, Section VI provides our determination regarding the 2019 BBD volume requirement, and reflects an analysis of a set of factors stipulated in CAA section 211(o)(2)(B)(ii).

2. Cellulosic Biofuel

In the past several years the cellulosic biofuel industry has continued to make progress towards increased commercial scale production. Cellulosic biofuel production reached record levels in 2016, driven largely by compressed natural gas (CNG) and liquefied natural gas (LNG) derived from biogas. Cellulosic ethanol, while produced in much smaller quantities than CNG/LNG derived from biogas, was produced consistently on a commercial scale in 2015. Cellulosic ethanol production levels increased from existing facilities in 2016, and significant work continues to be done to enable the production of cellulosic ethanol at new facilities, as well as to increase production volumes at existing facilities in 2017 and beyond. In this rule we are proposing a cellulosic biofuel volume requirement of 238 million ethanol-equivalent gallons for 2018 based on Renewable Identification Number (RIN) generation data available to EPA through EMTS, the information we have received regarding individual facilities' capacities, production start dates and biofuel production plans, a review of cellulosic biofuel production relative to EPA's projections in previous annual rules, input from other government agencies, and EPA's own engineering judgment. We expect to update all of this information for the final rule, and to take into account the Energy Information Administration's (EIA) projection of cellulosic biofuel availability, which should be available in October 2017.

As part of estimating the volume of liquid cellulosic biofuel that will be made available in the U.S. in 2018, we considered all potential production sources by company and facility. This included facilities still in the commissioning or start-up phases, as

well as facilities already producing some volume of cellulosic biofuel.[7] From this universe of potential liquid cellulosic biofuel sources, we identified the subset that is expected to produce commercial volumes of qualifying liquid cellulosic biofuel for use as transportation fuel, heating oil, or jet fuel by the end of 2018. To arrive at projected volumes, we collected relevant information on each facility. We then developed projected production ranges based on factors such as the status of the technology being used, progress towards construction and production goals, facility registration status, production volumes achieved, and other significant factors that could potentially impact fuel production or the ability of the produced fuel to qualify for cellulosic biofuel RINs. We also used this information to group these companies based on production history and to select a value within the aggregated projected production ranges that we believe best represents the most likely production volume from each group of companies in 2018.

For 2018, EPA is proposing to use an industry wide, rather than a facility-by-facility approach to project the production of CNG/LNG derived from biogas. We believe this approach is appropriate due to the mature state of this technology and the large number of facilities that are registered to produce cellulosic biofuel RINs for these fuels. Further discussion on our projection of cellulosic biofuel production in 2018, including the factors considered and the way these factors were used to determine our proposed cellulosic biofuel projection, can be found in Section III.

3. Advanced Biofuel

The conditions that compelled us to reduce the 2017 volume requirement for advanced biofuel below the statutory target remain relevant in 2018. As for 2017, we investigated the ability of volumes of non-cellulosic advanced biofuels to backfill unavailable volumes of cellulosic biofuel in 2018, through domestic production or import. We took into account the various constraints on the ability of the market to make advanced biofuels available, the ability of the standards we set to bring about market changes in the time available, the potential impacts associated with diverting biofuels and/or biofuel feedstocks from current use to the production of advanced biofuel used in the United States, and the potential impact of the expiration of the biodiesel tax credit. Based on these considerations, along with consideration of the estimated cost of the non-cellulosic advanced biofuels most likely to be used to backfill for the shortfall in cellulosic biofuel, we are proposing to make a determination that it would not be appropriate to set an advanced biofuel standard that would require the market to backfill a portion of the shortfall in cellulosic biofuel.

We are proposing to exercise our cellulosic waiver authority to reduce the statutory applicable volume of advanced biofuel to a proposed volume requirement of 4.24 billion gallons for 2018. This proposed applicable volume for 2018 is 40 million gallons lower than the applicable volume for advanced biofuel for 2017.

4. Total Renewable Fuel

Following our proposed determination of the appropriate volume reduction for advanced biofuel for 2018 using the cellulosic waiver authority, we calculated what the total renewable fuel volume would be if we provide the same level of reduction using the cellulosic waiver authority. The resulting volume would be 19.24 billion gallons. We then evaluated this total renewable fuel volume to determine if it is reasonably attainable given assessments of individual fuel types, including biodiesel, renewable diesel, ethanol (in the form of E10 or higher ethanol blends such as E15 or E85), and other renewable fuels.[8] Our proposed assessment indicates that a total renewable fuel volume of 19.24 billion gallons is reasonably attainable in 2018. We do not propose, therefore, to use the general waiver authority to further reduce the total renewable fuel volume requirement due to a finding of inadequate domestic supply.

We note that this proposal includes an assessment of E0 (ethanol-free gasoline) use that marks a change in how we have addressed this issue in past standard-setting rulemaking actions. In previous years, stakeholders have provided comment to EPA concerning the amount of E0 that is used in the United States each year for transportation fuel, and how such information should be used in development of the annual volume requirements. EPA has reassessed this issue, and we have found that use of E0 in 2016 was higher than we had assumed in setting the 2016 standards. Our proposal for 2018 includes consideration of this fact (see Section V.B.1).

5. Biomass-Based Diesel

In EISA, Congress specified increasing applicable volumes of BBD through 2012. Beyond 2012 Congress stipulated that EPA, in coordination with DOE and USDA, was to establish the BBD volume taking into consideration implementation of the program to date and various specified factors, providing that the required volume for BBD could not be less than 1.0 billion gallons. For 2013, EPA established an applicable volume of 1.28 billion gallons. For 2014 and 2015 we established the BBD volume requirement to reflect the actual volume for each of these years of 1.63 and 1.73 billion gallons.[9] For 2016 and 2017, we set the BBD volume requirements at 1.9 and 2.0 billion gallons respectively. Finally, for 2018 the BBD volume requirement was set a 2.1 billion gallons.

Given current and recent market conditions, the advanced biofuel volume requirement is driving the production and use of biodiesel and renewable diesel volumes over and above volumes required through the separate BBD standard, and we expect this to continue. For 2019, EPA continues to believe that it would still be appropriate to provide a floor above the statutory minimum of 1 billion gallons to provide a guaranteed level of support for the continued production and use of BBD. However, we also believe that the volume of biomass-based diesel supplied in previous years demonstrates that the advanced biofuel standard is capable of incentivizing additional supply of these fuels above the volume required by the biomass-based diesel standard.

Thus, based on a review of the implementation of the program to date and all the factors required under the statute, and in coordination with USDA and DOE, we are proposing to maintain the applicable volume of BBD for 2019 at the same level finalized for 2018, 2.1

[7] Facilities primarily focused on research and development (R&D) were not the focus of our assessment, as production from these facilities represents very small volumes of cellulosic biofuel, and these facilities typically have not generated RINs for the fuel they have produced.

[8] As described further in Section V.B, EPA's total renewable fuel volume assessment is intended to identify whether domestic supply concerns are present that would require a more exacting analysis of the maximum reasonably achievable volumes, as EPA has previously done when using the general waiver authority based on a finding of inadequate domestic supply. Since EPA's proposed assessment indicates that the volumes associated with this proposed rule are reasonably attainable, we do not believe that supply concerns exist that would necessitate the more exacting analysis needed to identify the maximum reasonably achievable volumes.

[9] The 2015 BBD standard was based on actual data for the first 9 months of 2015 and on projections for the latter part of the year for which data on actual use was not available at the time.

billion gallons. Maintaining the volume at this level will provide a guaranteed level of support to BBD producers, who will also be incentivized under the advanced and total standards to manufacture higher volumes of fuel. This approach leaves opportunity within the advanced biofuel mandate for investment in and growth in production of other, potentially less costly, types of advanced biofuel with comparable or potentially superior environmental or other attributes.

6. Annual Percentage Standards

The renewable fuel standards are expressed as a volume percentage and are used by each producer and importer of fossil-based gasoline or diesel to determine their renewable fuel volume obligations. The percentage standards are set so that if each obligated party meets the standards, and if EIA projections of gasoline and diesel use for the coming year prove to be accurate, then the amount of renewable fuel, cellulosic biofuel, BBD, and advanced biofuel actually used will meet the applicable volumes used to derive the percentage standards.

Four separate percentage standards are required under the RFS program, corresponding to the four separate renewable fuel categories shown in Table I.A–1. The specific formulas we use in calculating the renewable fuel percentage standards are contained in the regulations at 40 CFR 80.1405. The percentage standards represent the ratio of renewable fuel volume to projected non-renewable gasoline and diesel volume. The volume of transportation gasoline and diesel used to calculate the proposed percentage standards was derived from reports published by the EIA, and we intend to update this information for the final rule. The proposed percentage standards for 2018 are shown in Table I.B.6–1. Detailed calculations can be found in Section VII, including the projected gasoline and diesel volumes used.

TABLE I.B.6–1—PROPOSED 2018 PERCENTAGE STANDARDS

Cellulosic biofuel	0.131
Biomass-based diesel	1.74
Advanced biofuel	2.34
Renewable fuel	10.62

C. Statutory Requirement To Reset Volumes

The Clean Air Act requires EPA to ''reset'' the statutory volume targets for future years through 2022 if annual volume requirements are waived (reduced) beyond one of two specified thresholds:

(1) At least 20 percent of the statutory volume target for 2 consecutive years; or

(2) At least 50 percent of the statutory volume target for a single year.[10]

If either of these thresholds is reached, EPA is required to promulgate a rule within one year of the triggering waiver action that modifies the applicable volume targets for future years for the affected standard. However, the statute also indicates that 2016 is the first year to which any reset volume would apply.

In light of these requirements, the Administrator has directed EPA staff to initiate the required technical analysis to inform a reset rule.

When resetting the statutory targets, the EPA must comply with the processes, criteria, and standards set forth in CAA section 211(o)(2)(B)(ii). In addition to reviewing the implementation of the program during previous years and coordinating with the Secretary of Energy and the Secretary of Agriculture, the EPA must also analyze a number of factors:

- The impact of the production and use of renewable fuels on the environment, including on air quality, climate change, conversion of wetlands, ecosystems, wildlife habitat, water quality, and water supply;
- The impact of renewable fuels on the energy security of the United States;
- The expected annual rate of future commercial production of renewable fuels, including advanced biofuels in each category (cellulosic biofuel and BBD);
- The impact of renewable fuels on the infrastructure of the United States, including deliverability of materials, goods, and products other than renewable fuel, and the sufficiency of infrastructure to deliver and use renewable fuel;
- The impact of the use of renewable fuels on the cost to consumers of transportation fuel and on the cost to transport goods; and
- The impact of the use of renewable fuels on other factors, including job creation, the price and supply of agricultural commodities, rural economic development, and food prices.

EPA is not undertaking the analysis of these factors in this rulemaking. We are not soliciting comments on the reset rulemaking process at this time, but we are including mention of it in this Executive Summary in recognition of the importance of, and widespread interest in, a potential ''reset rule.'' Any comments received related to a possible future reset rule will be deemed beyond the scope of this rulemaking.

D. RIN Market Operation

Some stakeholders have expressed concerns the current provisions related to RIN trading render the RFS program vulnerable to market manipulation. EPA takes such issues seriously. The RIN system was originally designed with an open trading market in order to maximize its liquidity and ensure a robust marketplace for RINs. However, EPA is interested in further assessing whether and how the current trading structure provides an opportunity for market manipulation. To that effect, EPA seeks comment and input on potential changes to the RIN trading system that might help address these concerns. EPA is not soliciting comment on any aspect of the current RFS regulatory program other than those specifically related to RIN trading, as mentioned above, and the proposed annual standards for 2018 and biomass-based diesel applicable volume for 2019. In particular, EPA is not re-opening for public comment in this rulemaking the current definition of ''obligated party.''[11]

Separate from evaluating the RIN trading options in the RFS program, the EPA is working with appropriate market regulators to analyze targeted concerns of some stakeholders. For example, the EPA has executed a memorandum of understanding with the Commodity Futures Trading Commission (CFTC) and welcomes CFTC involvement in evaluating RIN market concerns.

In the meantime, EPA has continued to explore additional ways to increase program transparency in order to support the program and share data with all stakeholders. EPA already publishes RFS program data on our Web site, including data related to RIN generation, sales and holdings, and annual compliance. We are interested in providing more information, to the extent consistent with our obligations to protect confidential business information. EPA seeks comment on specific data elements and posting frequency that stakeholders believe would be useful to help with market transparency and liquidity.

E. Biofuel Imports

In establishing the RFS program, Congress sought to bolster energy security and independence by boosting the amount of renewable fuels used in

[10] CAA section 211(o)(7)(F).

[11] Separately, EPA has received a number of petitions seeking reconsideration of the definition of ''obligated party,'' and solicited public comment on its proposed resolution of those petitions. See 81 FR 83776 (November 22, 2016).

the domestic transportation fuel pool. Indeed, EISA's stated goals include moving the United States toward ''greater energy independence and security [and] to increase the production of clean renewable fuels.'' [12] This is not simply a general goal, but is embedded in statutory provisions, as well: for example, one of the factors EPA is directed to consider in the context of establishing the biomass-based diesel standard for 2019 under CAA section 211(o)(2)(B)(ii) is the impact of renewable fuels on the energy security of the United States.

In recent years increasing volumes of renewable fuels have been imported and used by obligated parties to comply with their RFS obligations. For example, data from EPA's EMTS system show that in 2016, 46 million gallons of ethanol and 731 million gallons of advanced biodiesel and renewable diesel were imported into the United States.[13] Due to their origin outside the United States, imported renewable fuels may not have the same impact on energy independence as those produced domestically. Industry stakeholders have observed the trend of increasing imports, too. The United States Department of Commerce, in response to a petition filed by U.S. biodiesel interests, has instituted countervailing duty and antidumping duty investigations regarding alleged subsidized and dumped imports of biodiesel.[14]

EPA is interested in stakeholder views on this topic and on what steps EPA might take to ensure energy independence and security. Furthermore, and in light of these considerations, EPA requests comment on whether or not to reduce the biomass-based diesel required volume below the level specified in this proposed rule for 2019. Finally, we request comment on whether and to what degree these considerations could support the use of the general waiver authority, inherent authority or other basis consistent with general construction of authority in the statute to reduce the required volume of advanced biofuel (with a corresponding reduction to the total renewable fuel requirement) below the level proposed for 2018.

II. Authority and Need for Waiver of Statutory Applicable Volumes

The statute provides the EPA with the authority to reduce volume requirements below the applicable volume targets specified in the statute under specific circumstances. This section discusses those authorities and our use of the cellulosic waiver authority alone to set 2018 volume requirements for cellulosic biofuel, advanced biofuel, and total renewable fuel that are below the statutory volume targets.

Within this rulemaking action under CAA section 211(o)(3)(i), EPA is using its authority under CAA section 211(o)(7) to take an administrative action to reduce the required volumes of cellulosic biofuel, advanced biofuel, and total renewable fuel below the statutory volume targets.

A. Statutory Authorities for Reducing Volume Targets

In CAA section 211(o)(2), Congress specified increasing annual volume targets for total renewable fuel, advanced biofuel, and cellulosic biofuel for each year through 2022, and for BBD through 2012, and authorized EPA to set volume requirements for subsequent years in coordination with USDA and DOE, and after consideration of specified factors. However, Congress also recognized that under certain circumstances it would be appropriate for EPA to set volume requirements at a lower level than reflected in the statutory volume targets, and thus provided waiver provisions in CAA section 211(o)(7).

1. Cellulosic Waiver Authority

Section 211(o)(7)(D)(i) of the CAA provides that if EPA determines that the projected volume of cellulosic biofuel production for a given year is less than the applicable volume specified in the statute, that EPA must reduce the applicable volume of cellulosic biofuel required to the projected production volume for that calendar year. In making this projection, EPA must take a ''neutral aim at accuracy.'' *API* v. *EPA,* 706 F.3d 474 (D.C. Cir. 2013). Pursuant to this provision, EPA has set the cellulosic biofuel requirement lower than the statutory volumes for each year since 2010. As described in Section III.D, the projected volume of cellulosic biofuel production for 2018 is less than the 7.0 billion gallon volume target in the statute. Therefore, for 2018, we are proposing to set the cellulosic biofuel volume requirement at a level lower than the statutory applicable volume, in accordance with this provision.

CAA section 211(o)(7)(D)(i) also provides EPA with the authority to reduce the applicable volume of total renewable fuel and advanced biofuel in years where it reduces the applicable volume of cellulosic biofuel. The reduction must be less than or equal to the reduction in cellulosic biofuel. For 2018, we are also proposing to reduce applicable volumes of advanced biofuel and total renewable fuel under this authority.

The cellulosic waiver authority is discussed in detail in the preamble to the 2017 final rule. See also, *API* v. *EPA,* 706 F.3d 474 (D.C. Cir. 2013) (requiring that EPA's cellulosic biofuel projections reflect a neutral aim at accuracy) and *Monroe Energy* v. *EPA,* 750 F.3d 909 (D.C. Cir. 2014) (affirming EPA's broad discretion under the cellulosic waiver authority to reduce volumes of advanced biofuel and total renewable fuel).

EPA is proposing an equal reduction from the statutory volume targets for advanced biofuels and total renewable fuel, as was our approach in using the cellulosic waiver authority for the 2014–2017 standards. EPA's reasoning for an equal reduction is explained in the 2017 final rule.[15] We are proposing, as described in Section IV, that the applicable volume for advanced biofuels specified in the statute for 2018 cannot be achieved and we are proposing to exercise our cellulosic waiver authority to lower the applicable volume of advanced biofuel to a level that is both reasonably attainable and appropriate, and to provide an equal reduction in the applicable volume of total renewable fuel. In addition, we have determined that there is likely to be adequate supply to satisfy the total renewable fuel volume derived through applying an equal volume reduction as for advanced biofuel. Therefore, we are proposing that no further reductions of the total renewable fuel volume requirement are necessary to address supply concerns. The resulting volume requirements provide for an implied volume requirement for conventional biofuel

[12] Energy Independence and Security Act of 2007.

[13] 66 and 95 million gallons of ethanol were imported in 2014 and 2015 respectively. Of the 731 million gallons of advanced biodiesel and renewable diesel imported into the United States in 2016, 561 million gallons (which generated 842 million RINs) were advanced biodiesel and 170 million gallons (which generated 289 million RINs) were advanced renewable diesel. 259 and 382 million gallons of advanced biodiesel and renewable diesel were imported in 2014 and 2015 respectively. An additional 113 million gallons of conventional biodiesel (generating 170 million RINs) and 43 million gallons of conventional renewable diesel (generating 73 million RINs) were also imported in 2016. 52 and 180 million gallons of conventional biodiesel and renewable diesel were imported in 2014 and 2015 respectively. Imported biofuel represented a significant percentage of the RINs available for compliance with the total renewable fuel volume requirement (8%), and especially the advanced biofuel (29%) and BBD (29%) volume requirements in 2016.

[14] See 82 FR 22155 (May 12, 2017).

[15] 81 FR 89752–89753, December 12, 2016.

equal to that envisioned by Congress for 2018.

2. General Waiver Authority

Section 211(o)(7)(A) of the CAA provides that EPA, in consultation with the Secretary of Agriculture and the Secretary of Energy, may waive the applicable volumes specified in the Act in whole or in part based on a petition by one or more States, by any person subject to the requirements of the Act, or by the EPA Administrator on his own motion. Such a waiver must be based on a determination by the Administrator, after public notice and opportunity for comment that (1) implementation of the requirement would severely harm the economy or the environment of a State, a region or the United States, or (2) there is an inadequate domestic supply.

Based on a preliminary evaluation of the availability of renewable fuel in the market, regarding which we seek public comment, EPA is not proposing to use the general waiver authority to further reduce volumes for 2018. However, EPA solicits comments on whether it is appropriate to exercise the general waiver authority and will evaluate comments and updated data in considering whether such an approach is warranted.

B. Treatment of Carryover RINs

Consistent with our approach in the 2013, 2014–16, and 2017 final rules, we have also considered the availability and role of carryover RINs in evaluating whether we should exercise our discretion to use the cellulosic waiver authority in setting the cellulosic, advanced, and total volume requirements for 2018. Neither the statute nor EPA regulations specify how or whether EPA should consider the availability of carryover RINs in exercising its cellulosic waiver authority.[16] As noted in the context of the rules establishing the 2014–16 and 2017 RFS standards, we believe that a bank of carryover RINs is extremely important in providing obligated parties compliance flexibility in the face of substantial uncertainties in the transportation fuel marketplace, and in providing a liquid and well-functioning RIN market upon which success of the entire program depends.[17] Carryover RINs provide flexibility in the face of a variety of circumstances that could limit the availability of RINs, including weather-related damage to renewable fuel feedstocks and other circumstances potentially affecting the production and distribution of renewable fuel.[18] On the other hand, carryover RINs can be used for compliance purposes, and in the context of the 2013 RFS rulemaking we noted that an abundance of carryover RINs available in that year, together with possible increases in renewable fuel production and import, justified maintaining the advanced and total renewable fuel volume requirements for that year at the levels specified in the statute.[19]

An adequate RIN bank serves to make the RIN market liquid. Just as the economy as a whole functions best when individuals and businesses prudently plan for unforeseen events by maintaining inventories and reserve money accounts, we believe that the RFS program functions best when sufficient carryover RINs are held in reserve for potential use by the RIN holders themselves, or for possible sale to others that may not have established their own carryover RIN reserves. Were there to be no RINs in reserve, then even minor disruptions causing shortfalls in renewable fuel production or distribution, or higher than expected transportation fuel demand (requiring greater volumes of renewable fuel to comply with the percentage standards that apply to all volumes of transportation fuel, including the unexpected volumes) could lead to the need for a new waiver of the standards, undermining the market certainty so critical to the RFS program. However, a significant drawdown of the carryover RIN bank leading to a scarcity of RINs may stop the market from functioning in an efficient manner, even where the market overall could satisfy the standards. For all of these reasons, the collective carryover RIN bank provides a needed programmatic buffer that both facilitates individual compliance and provides for smooth overall functioning of the program.[20]

At the time of the 2017 final rule, we estimated that there would be at most 1.54 billion carryover RINs available for compliance with the 2017 standards and decided that carryover RINs should not be counted on to avoid or minimize the need to reduce the 2017 statutory volume targets. We also stated that we may or may not take a similar approach in future years, and that we would evaluate the issue on a case-by-case basis considering the facts present in future years. Since that time, obligated parties have submitted their compliance demonstrations for the 2015 and 2016 compliance years and we now estimate that there are now at most 2.06 billion carryover RINs available,[21] an increase of 520 million RINs from the previous estimate of 1.54 billion carryover RINs in the 2017 final rule.[22] The volume of carryover RINs currently available is approximately 11 percent of the proposed 2018 total renewable fuel volume standard, which is less than the 20 percent limit permitted by the regulations to be carried over for use in complying with the 2018 standards.[23] However, there remains considerable uncertainty surrounding this number since compliance demonstrations still need to be made for the 2017 RFS standards, and it is unclear at this time whether some portion of the currently available carryover RINs will be used for compliance prior to 2018. In addition, we note that there have been enforcement actions in past years that have resulted in the retirement of RINs to true up past compliance demonstrations. These enforcement actions have involved the generation and use of invalid RINs and the failure to retire RINs for exported renewable fuel. Future enforcement actions could have similar results, and require that obligated parties and/or renewable fuel exporters settle past enforcement-related

[16] CAA section 211(o)(5) requires that EPA establish a credit program as part of its RFS regulations, and that the credits be valid to show compliance for 12 months as of the date of generation. EPA implemented this requirement though the use of RINs, which can be used to demonstrate compliance for the year in which they are generated or the subsequent compliance year. Obligated parties can obtain more RINs than they need in a given compliance year, allowing them to ''carry over'' these excess RINs for use in the subsequent compliance year, although use of these carryover RINs is limited to 20% of the obligated party's renewable volume obligation. For the bank of carryover RINs to be preserved from one year to the next, individual carryover RINs are used for compliance before they expire and are essentially replaced with newer vintage RINs that are then held for use in the next year. For example, if the volume of the collective carryover RIN bank is to remain unchanged from 2016 to 2017, then all of the vintage 2016 carryover RINs must be used for compliance in 2017, or they will expire. However, the same volume of 2017 RINs can then be ''banked'' for use in the next year.

[17] See 80 FR 77482–87 (December 14, 2015) and 81 FR 89754–55 (December 12, 2016).

[18] See id., and 72 FR 23900 (May 1, 2007).

[19] See 79 FR 49794 (August 15, 2013).

[20] Here we use the term ''buffer'' as shorthand reference to all of the benefits that are provided by a sufficient bank of carryover RINs.

[21] The calculations performed to estimate the number of carryover RINs currently available can be found in the memorandum, ''Carryover RIN Bank Calculations for 2018 NPRM,'' available in the docket.

[22] This increase in the carryover RIN bank compared to that projected in the 2017 final rule is not due to an underestimate by EPA in the amount of gasoline, diesel fuel, or ethanol that was consumed in 2016, but rather is driven almost entirely by a combination of over-compliance by biodiesel producers facing an expiring biodiesel tax credit at the end of 2016 and approximately 390 million RINs that small refineries granted a hardship exemption for 2016 were not required to retire.

[23] See § 80.1427(a)(5).

obligations in addition to the annual standards, thereby potentially creating demand for RINs greater than can be accommodated through actual renewable fuel blending in 2018. Collectively, the result of satisfying RFS obligations in 2017 and settling enforcement-related accounts could be an effective reduction in the size of the collective bank of carryover RINs. Thus, we believe there is considerable uncertainty that a RIN bank as large as 11 percent of the proposed 2018 total renewable fuel standard will be available in 2018.

Therefore, for the reasons noted above, and consistent with the approach we took in the 2014–2016 and 2017 final rules, we are proposing that, under current circumstances, an intentional drawdown of the carryover RIN bank should not be assumed in establishing the 2018 volume requirements. The current bank of carryover RINs will provide an important and necessary programmatic buffer that will both facilitate individual compliance and provide for smooth overall functioning of the program. Therefore, we are not proposing to set the renewable fuel volume requirements at levels that would envision a drawdown in the bank of carryover RINs.

III. Cellulosic Biofuel Volume for 2018

In the past several years the cellulosic biofuel industry has continued to make progress towards increased commercial-scale production. Cellulosic biofuel production reached record levels in 2016, driven largely by CNG and LNG derived from biogas.[24] While multiple large cellulosic ethanol facilities struggled to achieve consistent commercial scale production, several facilities consistently produced cellulosic ethanol from corn kernel fiber at a smaller scale during 2016 and the first few months of 2017. This section describes our assessment of the volume of cellulosic biofuel that we project will be produced or imported into the United States in 2018, and some of the uncertainties associated with those volumes.

In order to project the volume of cellulosic biofuel production in 2018 we considered data reported to EPA through EMTS along with information we collected through meetings with representatives of facilities that have produced or have the potential to produce qualifying volumes of cellulosic biofuel for consumption as transportation fuel, heating oil, or jet fuel in the U.S. in 2018. Upon receipt of EIA's projection of cellulosic biofuel production for 2018, EPA will consider these estimates, together with updated information regarding the potential for contributions from individual facilities and groups of facilities, in determining the projected volume of cellulosic biofuel production in 2018 for the final rule.

In this proposed rule we use the same general methodology as in the 2017 final rule to project the range of potential production volumes of liquid cellulosic biofuel, however we have adjusted the percentile values used to select a point estimate within a projected production range for each group of companies based on recent information, and with the objective of improving the accuracy of the projections. We use a new methodology to project the production of cellulosic biofuel RINs for CNG/LNG derived from biogas that reflects the mature status of this industry and the large number of facilities registered to generate cellulosic biofuel RINs from these fuels. These methodologies are described in more detail in Section III.C below.

New cellulosic biofuel production facilities projected to be brought online in the United States over the next few years could increase the production capacity of the cellulosic industry. Operational experience gained at the first few commercial scale cellulosic biofuel production facilities could also lead to increased production of cellulosic biofuel from existing production facilities. Section B, below, discusses the companies the EPA reviewed in the process of projecting qualifying cellulosic biofuel production in the United States in 2018. Information on these companies forms the basis for our projection of 238 million ethanol-equivalent gallons of cellulosic biofuel produced for use as transportation fuel, heating oil, or jet fuel in the United States in 2018.

A. Statutory Requirements

The volumes of renewable fuel to be produced and used as transportation fuel under the RFS program each year (absent an adjustment or waiver by EPA) are specified in CAA section 211(o)(2). The volume of cellulosic biofuel specified in the statute for 2018 is 7 billion gallons. The statute provides that if EPA determines, based on EIA's estimate, that the projected volume of cellulosic biofuel production in a given year is less than the statutory volume, then EPA shall reduce the applicable volume of cellulosic biofuel to the projected volume available during that calendar year.[25]

In addition, if EPA reduces the required volume of cellulosic biofuel below the level specified in the statute, the Act also indicates that we may reduce the applicable volumes of advanced biofuels and total renewable fuel by the same or a lesser volume, and we are required to make cellulosic waiver credits available.[26] Our consideration of the 2018 volume requirements for advanced biofuel and total renewable fuel is presented in Sections IV and V of this rule.

B. Cellulosic Biofuel Industry Assessment

In order to project cellulosic biofuel production for 2018, we have tracked the progress of several dozen potential cellulosic biofuel production facilities. As we have done in previous years, we have focused on facilities with the potential to produce commercial-scale volumes of cellulosic biofuel rather than small R&D or pilot-scale facilities. Larger commercial-scale facilities are much more likely to generate RINs for the fuel they produce and the volumes they produce will have a far greater impact on the cellulosic biofuel standard for 2018. The volume of cellulosic biofuel produced from R&D and pilot-scale facilities is quite small in relation to that expected from the commercial-scale facilities. R&D and demonstration-scale facilities have also generally not generated RINs for the fuel they have produced in the past. Their focus is on developing and demonstrating the technology, not producing commercial volumes. RIN generation from R&D and pilot-scale facilities in previous years has not contributed significantly to the overall number of cellulosic RINs generated.[27]

From this list of commercial-scale facilities we used information from EMTS, publically available information (including press releases and news reports), and information provided by representatives of potential cellulosic

[24] The majority of the cellulosic RINs generated for CNG/LNG are sourced from biogas from landfills, however the biogas may come from a variety of sources including municipal wastewater treatment facility digesters, agricultural digesters, separated MSW digesters, and the cellulosic components of biomass processed in other waste digesters.

[25] The United States Court of Appeals for the District of Columbia Circuit evaluated this requirement in *API* v. *EPA* 706 F.3d 474, 479–480 (D.C. Cir. 2013), in the context of a challenge to the 2012 cellulosic biofuel standard. The Court stated that in projecting potentially available volumes of cellulosic biofuel EPA must apply an ''outcome-neutral methodology'' aimed at providing a prediction of ''what will actually happen.''

[26] See § 80.1456.

[27] While a few small R&D and pilot scale facilities have registered as cellulosic RIN generators, total production from each of these facilities from 2010 through March 2017 has been less than 100,000 RINs.

biofuel producers, to make a determination of which facilities are most likely to produce cellulosic biofuel and generate cellulosic biofuel RINs in 2018. Each of these companies was investigated further in order to determine the current status of its facilities and its likely cellulosic biofuel production and RIN generation volumes for 2018. Both in our discussions with representatives of individual companies and as part of our internal evaluation process we gathered and analyzed information including, but not limited to, the funding status of these facilities, current status of the production technologies, anticipated construction and production ramp-up periods, facility registration status, and annual fuel production and RIN generation targets.

The methodology used by EPA to project cellulosic biofuel production in 2015–2017 has resulted in a total cellulosic biofuel production projection that was lower than the actual number of cellulosic RINs made available in 2015,[28] and higher than the actual number of RINs generated in 2016.[29] This methodology is most recently described in the 2017 final rule.[30] The fact that the projections in both years proved somewhat inaccurate, under-estimating the actual number of RINs made available one year and over-estimating the next, reflects the inherent difficulty with projecting cellulosic biofuel production.

EPA's projections of liquid cellulosic biofuel, however, were higher than the actual volume of liquid cellulosic biofuel produced in both 2015 and 2016. We believe that new data warrants a change to the methodology for projecting liquid cellulosic biofuel in an effort to make the projections more accurate. We are therefore proposing to adjust the percentile values used to project liquid cellulosic biofuel production based on actual liquid cellulosic biofuel production in 2016. We believe that the use of this methodology, with the adjusted approach to developing the percentile values used to project production volumes for liquid cellulosic biofuels, results in a projection that reflects a neutral aim at accuracy since it accounts for expected growth in the near future, and does so in a way that directly reflects the accuracy of EPA's projections in the most recent year (2016) for which complete data is available.

In previous years we used the same methodology for CNG/LNG derived from biogas as for liquid cellulosic biofuel, but with different percentile values reflecting the more established nature of the CNG/LNG industry relative to liquid cellulosic biofuel production. For 2018, EPA is proposing to use an industry wide approach, rather than an approach that projects volumes for individual companies or facilities, to project the production of CNG/LNG derived from biogas. This updated approach reflects the fact that this industry is far more mature than the liquid cellulosic biofuel industry, and that there are a large number of facilities registered to generate cellulosic biofuel RINs from biogas, rendering a facility-by-facility analysis difficult and of questionable need for purposes of accuracy. As described in Section V.C.2 below, EPA is instead proposing to use the rate of growth in the renewable CNG/LNG industry observed between the first five months of 2016 and the first five months of 2017,[31] together with actual data on total RINs generated for CNG/LNG in 2016, to estimate the production of CNG/LNG derived from biogas in 2018.

For the final rule we intend to review all available data with respect to cellulosic biofuel production in 2017 for the months for which data will be available. We will consider that information, together with comments received and updated information on the status of potential production facilities, to make any appropriate adjustments to the methodology and/or projected production volume in the final rule. The remainder of this Section discusses the companies and facilities EPA expects to be in a position to produce commercial-scale volumes of cellulosic biofuel by the end of 2018 and describes in more detail the methodology EPA is proposing to use to project cellulosic biofuel production in 2018 (including a review of cellulosic biofuel production and the accuracy of the projection methodology in previous years). This information forms the basis for the proposed applicable volume for cellulosic biofuel for 2018.

1. Potential Domestic Producers

There are a number of companies and facilities[32] located in the United States that have either already begun producing cellulosic biofuel for use as transportation fuel, heating oil, or jet fuel at a commercial scale, or are anticipated to be in a position to do so at some time during 2018. The financial incentive provided by cellulosic biofuel RINs,[33] combined with the facts that to date nearly all cellulosic biofuel produced in the United States has been used domestically[34] and all the domestic facilities we have contacted in deriving our projections intend to produce fuel on a commercial scale for domestic consumption using approved pathways, gives us a high degree of confidence that cellulosic biofuel RINs will be generated for any fuel produced by commercial scale facilities. In order to generate RINs, each of these facilities must be registered under the RFS program and comply with all the regulatory requirements. This includes using an approved RIN-generating pathway and verifying that their feedstocks meet the definition of renewable biomass. Most of the companies and facilities considered in our assessment of potential cellulosic biofuel producers in 2018 have already successfully completed facility registration, and many have successfully generated RINs.[35] A brief description of each of the companies (or group of companies for cellulosic CNG/LNG producers) that EPA believes may produce commercial-scale volumes of RIN generating cellulosic biofuel by the end of 2018 can be found in a memorandum to the docket for this

[28] EPA only projected cellulosic biofuel production for the final three months of 2015, since data on the availability of cellulosic biofuel RINs (D3+D7) for the first nine months of the year were available at the time the analyses were completed for the final rule.

[29] EPA projected that 123 million and 230 million cellulosic RINs would be generated in 2015 and 2016, respectively. The number of available cellulosic RINs in these years (RINs generated minus RINs retired for non-compliance reasons) was 140 and 190 million RINs. See ''Assessment of the Accuracy of Cellulosic Biofuel Production Projections in 2015 and 2016 (June 2016 Update)'', memorandum from Dallas Burkholder to EPA Air Docket EPA–HQ–OAR–2017–0091 for more detail.

[30] For a full description of this approach, see 81 FR 89746, 89755 (December 12, 2016).

[31] At the time of this proposal, EPA has RIN generation data for the first five months of 2017 (January–May).

[32] The volume projection from CNG/LNG producers does not represent production from a single company or facility, but rather a group of facilities utilizing the same production technology.

[33] According to data from Argus, the price for 2017 cellulosic biofuel RINs averaged $2.67 in 2017 (through March 2017). Alternatively, obligated parties can obtain a RIN value equivalent to a cellulosic biofuel RIN by purchasing an advanced (or biomass-based diesel) RIN and a cellulosic waiver credit. The price for 2017 advanced biofuel RINs averaged $0.94 in 2017 (through March 2017) while the price for a 2017 cellulosic waiver credit is $2.00.

[34] The only known exception was a small volume of fuel produced at a demonstration scale facility exported to be used for promotional purposes.

[35] All of the facilities listed in Table III.B.3–1 are registered to produced cellulosic (D3 or D7) RINs with the exception of several of the producers of CNG/LNG derived from biogas, many of the facilities projected to produce cellulosic ethanol using Edeniq's technology, and Ensyn's Port-Cartier, Quebec facility.

proposed rule.[36] General information on each of these companies or group of companies considered in our projection of the potentially available volume of cellulosic biofuel in 2018 is summarized in Table III.B.3–1 below.

2. Potential Foreign Sources of Cellulosic Biofuel

In addition to the potential sources of cellulosic biofuel located in the United States, there are several foreign cellulosic biofuel companies that may produce cellulosic biofuel in 2018. These include facilities owned and operated by Beta Renewables, Enerkem, Ensyn, GranBio, and Raizen. All of these facilities use fuel production pathways that have been approved by EPA for cellulosic RIN generation provided eligible sources of renewable feedstock are used and other regulatory requirements are satisfied. These companies would therefore be eligible to register these facilities under the RFS program and generate RINs for any qualifying fuel imported into the United States. While these facilities may be able to generate RINs for any volumes of cellulosic biofuel they import into the United States, demand for the cellulosic biofuels they produce is expected to be high in their own local markets.

EPA is charged with projecting the volume of cellulosic biofuel that will be produced or imported into the United States. For the purposes of this proposed rule we have considered all of the registered foreign facilities under the RFS program to be potential sources of cellulosic biofuel in 2018. We believe that due to the strong demand for cellulosic biofuel in local markets, the significant technical challenges associated with the operation of cellulosic biofuel facilities, and the time necessary for potential foreign cellulosic biofuel producers to register under the RFS program and arrange for the importation of cellulosic biofuel to the United States, cellulosic biofuel imports from foreign facilities not currently registered to generate cellulosic biofuel RINs are generally highly unlikely in 2018. For purposes of our 2018 cellulosic biofuel projection we have, with only one exception (described below) excluded from our proposal potential volumes from foreign cellulosic biofuel production facilities that are not currently registered under the RFS program. Two foreign facilities (Ensyn's Renfrew facility and the CNG/LNG facility Complexe Enviro Progressive Ltee) that have registered as cellulosic biofuel producers have already generated cellulosic biofuel RINs for fuel exported to the United States; projected volumes from each of these facilities are included in our projection of available volumes for 2018. Three additional foreign facilities (Gran Bio's Bioflex Agroindustrial S/A, Saint-Thomas Biomethane Plant, and Raizen's Costa Pinto) have registered as cellulosic biofuel producers, but have not yet generated any cellulosic RINs. EPA attempted to contact representatives from these facilities to inquire about their intentions to export cellulosic biofuel to the United States in 2018. In two cases (Gran Bio's Bioflex Agroindustrial S/A and Saint-Thomas Biomethane Plant), company representatives indicated they intended to export cellulosic biofuel to the United States, and EPA believes that there is sufficient reason to believe imports of cellulosic biofuel from these companies are likely. Finally, EPA has included projected volume from one foreign facility (Ensyn's Port-Cartier, Quebec facility) that is not currently registered to generate cellulosic biofuel RINs under the RFS program. We believe that it is appropriate to include volume from this facility in light of the facility's proximity to the United States, the proven technology used by the facility, the volumes of cellulosic biofuel exported to the United States by the company in previous years, and the company's stated intention to market all of the fuel produced at this facility to qualifying markets in the United States. All of the facilities included in EPA's cellulosic biofuel projection for 2018 are listed in Table III.B.3–1 below.

3. Summary of Volume Projections for Individual Companies

General information on each of the cellulosic biofuel producers (or group of producers in the case of producers of CNG/LNG derived from biogas and facilities using Edeniq's technology) that factored into our projection of cellulosic biofuel production for 2018 is shown in Table III.B.3–1. This table includes both facilities that have already generated cellulosic RINs, as well as those that have not yet generated cellulosic RINs, but are projected to do so by the end of 2018. As discussed above, we have focused on commercial-scale cellulosic biofuel production facilities. Each of these facilities (or group of facilities) is discussed further in a memorandum to the docket.[37] In addition to the facilities (or groups of facilities) discussed in Table III.B.3–1 below, EPA is aware of two additional technologies that may be used to produce qualifying cellulosic biofuel in 2018. Multiple companies, in addition to Edeniq and Quad County Corn Processors, are working to commercialize technology to convert corn kernel fiber to cellulosic ethanol at existing corn ethanol facilities. At this point, however, none of these companies have successfully registered a facility to generate cellulosic RINs using their technology.[38] Several other companies are seeking to register to generate cellulosic biofuel RINs for anaerobic digesters that produce CNG/LNG from a variety of waste feedstocks.[39] If the outstanding technical issues related to these processes are resolved prior to the final rule, EPA anticipates including production projections from these technologies in our projection of cellulosic biofuel production for 2018.

TABLE III.B.3–1—PROJECTED PRODUCERS OF CELLULOSIC BIOFUEL BY 2018

Company name	Location	Feedstock	Fuel	Facility capacity (million gallons per year)[40]	Construction start date	First production[41]
CNG/LNG Producers[42]	Various (US and Canada)	Biogas	CNG/LNG	Various	N/A	August 2014.
DuPont	Nevada, IA	Corn Stover	Ethanol	30	November 2012	1Q 2017.

[36] "Cellulosic Biofuel Producer Company Descriptions (May 2017)", memorandum from Dallas Burkholder to EPA Air Docket EPA–HQ–OAR–2017–0091.

[37] "Cellulosic Biofuel Producer Company Descriptions (May 2017)", memorandum from Dallas Burkholder to EPA Air Docket EPA–HQ–OAR–2017–0091.

[38] A significant issue that must be resolved to register a facility to produce cellulosic biofuel from corn kernel fiber at an existing ethanol production facility is the quantification of the volume of ethanol produced from cellulosic feedstocks rather than non-cellulosic feedstocks such as starch. Until these companies develop a methodology for quantifying cellulosic biofuel production that is approved by EPA we do not believe it is appropriate to include an estimate of cellulosic biofuel production from these facilities in our projection of cellulosic biofuel production in 2018.

[39] These facilities must be able to quantify the volume of CNG/LNG produced from cellulosic feedstocks and the volume of CNG/LNG produced from non-cellulosic feedstocks. To date none of the quantification methodologies proposed by the companies interested in registering as cellulosic biofuel producers has been approved by EPA. While these companies may be able to register to generate advanced biofuel (D5) RINs, they cannot generate cellulosic (D3) RINs until this issue is resolved.

TABLE III.B.3–1—PROJECTED PRODUCERS OF CELLULOSIC BIOFUEL BY 2018—Continued

Company name	Location	Feedstock	Fuel	Facility capacity (million gallons per year) [40]	Construction start date	First production [41]
Edeniq	Various	Corn Kernel Fiber	Ethanol	Various	Various	October 2016.
Ensyn	Renfrew, ON, Canada	Wood Waste	Heating Oil	3	N/A	2014.
Ensyn	Port-Cartier, QC, Canada	Wood Waste	Heating Oil	10.5	June 2016	April 2018.
GranBio	São Miguel dos Campos, Brazil.	Sugarcane bagasse	Ethanol	21	Mid 2012	September 2014.
Poet	Emmetsburg, IA	Corn Stover	Ethanol	24	March 2012	4Q 2015.
QCCP	Galva, IA	Corn Kernel Fiber	Ethanol	4	Late 2013	October 2014.

C. Cellulosic Biofuel Volume for 2018

1. Liquid Cellulosic Biofuel

For our 2018 liquid cellulosic biofuel projection, we use a modified version the same general methodology we used in establishing the cellulosic biofuel volume standards for 2015 (the final three months for which data were not available), 2016, and 2017. This methodology is briefly described here, and is described in detail in the 2017 annual rule.[43] We are proposing to use the same methodology to come up with the range of potential volumes for the different categories of facilities. However, we are proposing to adjust the percentile values used to project liquid cellulosic biofuel production from within the range of projected production values, based on an analysis of actual liquid cellulosic biofuel production in 2016. We believe an adjustment to our methodology is warranted, as EPA's estimates for liquid cellulosic biofuel exceeded actual production of liquid cellulosic biofuel in both 2015 and 2016,[44] and that this adjusted methodology will continue to improve the accuracy of the production projection that will further EPA's objective to project volumes with a ''neutral aim at accuracy.''

The projected ranges for liquid cellulosic biofuel production in 2016, along with the percentile values used to project a production volume within the calculated ranges and the actual number of cellulosic RINs generated in 2016 that are available for compliance, are shown in Table III.C.1–1 below.

TABLE III.C.1–1—PROJECTED AND ACTUAL LIQUID CELLULOSIC BIOFUEL PRODUCTION IN 2016

[Million gallons]

	Low end of the range	High end of the range	Percentile	Projected production	Actual production [45]
New Facilities	0	76	25th	19	1.06
Consistent Producers [46]	2	5	50th	4	3.28

Since the actual production in 2016 was lower than projected production for both new facilities and consistent producers, it seems appropriate to adjust the percentiles downward for the purposes of making projections for 2018. To this end, EPA calculated the percentile values that would have resulted in accurate production projections in 2016 based on the actual number of cellulosic biofuel RINs generated for liquid cellulosic biofuels and available for compliance in 2016. These calculated percentile values are the 1st percentile for new facilities (replacing the 25th percentile used for 2016 and 2017) and the 43rd percentile for consistent producers (replacing the 50th percentile used for 2016 and 2017). In this rule EPA is proposing to use these updated percentile values to project the production of liquid cellulosic biofuel in 2018. We believe it is appropriate to use 2016 production data to calculate these percentile values as EPA first adopted the methodology for calculating expected production ranges used in this rule in the 2014–2016 final rule. While EPA also has projected production ranges for the final three months of 2015 as well as all of 2017, we do not have sufficient data to compare our projected volumes to actual production volumes over a full year for either of these years. For purposes of this proposal, therefore, we have selected 2016 data as the most representative source of data currently available for purposes of projecting what may occur in 2018. We anticipate that we will review these percentile values as additional data from 2017 become available, and update them as appropriate for the final rule. We request comment on methods that EPA could use to take into account available 2017 data for the final rule,

[40] The Facility Capacity is generally equal to the nameplate capacity provided to EPA by company representatives or found in publicly available information. If the facility has completed registration and the total permitted capacity is lower than the nameplate capacity then this lower volume is used as the facility capacity. For companies generating RINs for CNG/LNG derived from biogas the Facility Capacity is equal to the lower of the annualized rate of production of CNG/LNG from the facility at the time of facility registration or the sum of the volume of contracts in place for the sale of CNG/LNG for use as transportation fuel (reported as the actual peak capacity for these producers).

[41] Where a quarter is listed for the first production date EPA has assumed production begins in the middle month of the quarter (*i.e.,* August for the 3rd quarter) for the purposes of projecting volumes.

[42] For more information on these facilities see ''June 2017 Assessment of Cellulosic Biofuel Production from Biogas (2018)'', memorandum from Dallas Burkholder to EPA Air Docket EPA–HQ–OAR–2017–0091.

[43] See 81 FR 89755 (December 12, 2016) for additional detail.

[44] EPA notes that once standards are set based on these projections, cellulosic biofuel RINs can be generated for either type of cellulosic biofuel. Cellulosic biofuel RINs generated for liquid biofuels and CNG/LNG derived from biogas can be used to satisfy an obligated party's cellulosic biofuel obligation. There are no separate standards for liquid and gaseous cellulosic biofuels.

[45] Actual production is calculated by subtracting RINs retired for any reason other than compliance with the RFS standards from the total number of cellulosic RINs generated.

[46] In the 2014–2016 Annual Rule EPA categorized Ensyn and Quad County Corn Processors as consistent cellulosic biofuel producers for 2016. All other companies were categorized as new facilities. This is in contrast to 2018, for which EPA has categorized additional facilities as consistent cellulosic biofuel producers. See below.

notwithstanding the expected lack of data for the last few months of 2017.

EPA also considered whether it would be appropriate to modify other individual components of the past methodology for liquid cellulosic biofuel based on a narrow consideration of each factor, but we do not believe there is currently sufficient information to support these changes. Making the single proposed adjustment to the percentile values used in the methodology should, we believe, provide an appropriate adjustment to the methodology that reflects recent past experience. We acknowledge, however, that using the calculated percentile values from previous years to project liquid cellulosic biofuel production in future years does not eliminate the possibility that actual production will differ from our projections. This is especially true for the liquid cellulosic biofuel industry, which is currently in the early stages of commercialization. We will continue to evaluate the success of this methodology, including a consideration of the data on cellulosic biofuel production in 2017 available at the time of the final rule, and will consider adjusting the methodology if it appears warranted. If the methodology appears to be projecting volumes that are significantly higher or lower than actual production volumes for months in 2017 for which data is available (after taking into account the seasonality of RIN generation and the expected ramp-up of production volumes in the latter half of 2017) we may consider adjustments to the methodology used in the final rule, such as further adjusting the percentile values used to project liquid cellulosic biofuel production within the projected range for a group of companies, or creating new groupings of companies with similar types and levels of risk associated with cellulosic biofuel production. We request comment on our methodology and adjustments that could be made to increase the accuracy of the projection.

Consistent with our approach for 2016 and 2017, to project liquid cellulosic biofuel production in 2018 we separated the list of potential producers of cellulosic biofuel into two groups according to whether or not the facilities have achieved consistent commercial-scale production and cellulosic biofuel RIN generation (See Table III.C.1–2 through Table III.C–.1–3). We next defined a range of likely production volumes for each group of potential cellulosic biofuel producers. The low end of the range for each group of producers reflects actual RIN generation data over the last 12 months for which data are available at the time our technical assessment was completed (April 2016–March 2017). For potential producers that have not yet generated any cellulosic RINs, the low end of the range is zero. For the high end of the range of production volumes for companies expected to produce liquid cellulosic biofuel we considered a variety of factors, including the expected start-up date and ramp-up period,[47] facility capacity, and fuel off-take agreements. The projected ranges for each of the companies considered in our 2018 cellulosic biofuel projection are shown in Tables III.C.1–2 and III.C.1–3 below.[48]

TABLE III.C.1–2—2018 PRODUCTION RANGES FOR LIQUID CELLULOSIC BIOFUEL PRODUCERS WITHOUT CONSISTENT COMMERCIAL SCALE PRODUCTION

[Million gallons]

	Low end of the range	High end of the range
DuPont	0	15
Edeniq (New Producers)	0	80
GranBio	0	5
Ensyn (Port-Cartier)	0	5
Aggregate Range	0	105

TABLE III.C.1–3—2018 PRODUCTION RANGES FOR LIQUID CELLULOSIC BIOFUEL PRODUCERS WITH CONSISTENT COMMERCIAL SCALE PRODUCTION

[Million gallons]

	Low end of the range	High end of the range
Edeniq (Active Facilities)	[a] X	5
Ensyn	[a] X	3
Poet	[a] X	20
Quad County Corn Processors	[a] X	3
Aggregate Range	3.9	31

[a] The low end of the range for each individual company is based on actual production volumes and is therefore withheld to protect information claimed to be confidential business information.

After defining likely production ranges for each group of companies we used the percentile values described earlier in this section to project a production volume within the production ranges. We used the 1st and 43rd percentiles, respectively, for liquid cellulosic biofuel producers without and with a history of consistent cellulosic biofuel production and RIN generation. The resulting projections for liquid cellulosic biofuel in 2018 are shown in Table III.C.1–4 below.

TABLE III.C.1–4—PROJECTED VOLUME OF LIQUID CELLULOSIC BIOFUEL IN 2018

[Million gallons]

	Low end of the range [a]	High end of the range [a]	Percentile	Projected volume [a]
Liquid Cellulosic Biofuel Producers; Producers without Consistent Commercial Scale Production	0	105	1st	1
Liquid Cellulosic Biofuel Producers; Producers with Consistent Commercial Scale Production	3.9	31	43rd	16

[47] As in our 2015–2017 projections, EPA calculated a high end of the range for each facility (or group of facilities) based on the expected start-up date and a six-month straight line ramp-up period. The high end of the range for each facility (or group of facilities) is equal to the value calculated by EPA using this methodology, or the number of RINs the producer expects to generate in 2018, whichever is lower.

[48] More information on the data and methods EPA used to calculate each of the ranges in these tables can be found in ''May 2017 Cellulosic Biofuel Individual Company Projections for 2018 (CBI)'', memorandum from Dallas Burkholder to EPA Air Docket EPA–HQ–OAR–2017–0091.

TABLE III.C.1–4—PROJECTED VOLUME OF LIQUID CELLULOSIC BIOFUEL IN 2018—Continued

[Million gallons]

	Low end of the range [a]	High end of the range [a]	Percentile	Projected volume [a]
Total	N/A	N/A	N/A	17

[a] Volumes rounded to the nearest million gallons.

We believe our range of projected production volumes for each company (or group of companies for those using the Edeniq technology) reasonably represents the range of potential production volumes for each company, and that projecting overall production in 2018 in the manner described above results in a neutral estimate (neither biased to produce a projection that is either too high or too low) of likely liquid cellulosic biofuel production in 2018 (17 million gallons).

2. CNG/LNG Derived From Biogas

For 2018, EPA is proposing to use a new methodology to project production of CNG/LNG derived from biogas used as transportation fuel. We believe a new methodology is warranted for purposes of this rule for two primary reasons: The over-projection of CNG/LNG derived from biogas in 2016 and, the relative maturity of the CNG/LNG industry relative to the liquid cellulosic biofuel industry. EPA's projection of the production of CNG/LNG derived from biogas in 2016 was 207 million ethanol-equivalent gallons. Actual production of cellulosic biofuel RINs for CNG/LNG derived from biogas that were available for compliance in 2016 was 185 million gallons, suggesting that the approach we took to projecting CNG/LNG derived from biogas in 2016 resulted in an overestimate by 22 million ethanol-equivalent gallons. More importantly, we believe that the technology and market for CNG/LNG derived from biogas used as transportation fuel is sufficiently mature that a facility-by-facility assessment of potential production is unnecessary, and is not the most appropriate method for projecting the production of these fuels in 2018 across the entire industry.

EPA is proposing to use an industry-wide approach, rather than a projecting production from each specific facility or company, to project the 2018 production of CNG/LNG derived from biogas. EPA has calculated the observed year-over-year growth in the number of RINs generated for CNG/LNG derived from biogas based on data from the first five months of both 2016 and 2017.[49] These production volumes are shown in Table III.C.2–1 below.

TABLE III.C.2–1—GENERATION OF CELLULOSIC BIOFUEL RINS FOR CNG/LNG DERIVED FROM BIOGAS

[Million gallons]

RIN generation (January 2016–May 2016)	RIN generation (January 2017–May 2017)	Year-over-year increase (Jan.–May 2016 to Jan.–May 2017)
62.91	68.75	9.3%

Under the assumption that this growth rate based on five months of data is representative of the annual growth rate, EPA then applied this 9.3% growth rate to the total number of 2016 cellulosic RINs generated for CNG/LNG that were available for compliance (185.14 million) to project the production of cellulosic RINs from these fuels in 2017, and then repeated the calculation to arrive at a projection for 2018. This methodology results in a projection of 221.2 million gallons of CNG/LNG derived from biogas in 2018.[50] We believe that projecting the production of CNG/LNG derived from biogas in this manner appropriately takes into consideration the actual recent rate of growth of this industry, and that this growth rate accounts for both the potential for future growth and the challenges associated with increasing RIN generation from these fuels in future years. While this methodology may not be appropriate to use once the projected volume of CNG/LNG derived from biogas approaches the total volume of CNG/LNG that is used as transportation fuel, our projection for 2018 is well below the total volume of CNG/LNG that is currently used as transportation fuel.[51] For the final rule we intend to review the year-over-year increase with additional data and modify the year-over-year increase from 2016 to 2017 and the resulting projection of CNG/LNG derived from biogas in 2018 as appropriate. We request comment on the use of an industry-wide, rather than a facility-by-facility projection of the production of CNG/LNG derived from biogas, as well as possible adjustments to the methodology used in this proposed rule or alternative methodologies that could be used for this purpose.

3. Total Cellulosic Biofuel in 2018

After projecting production of cellulosic biofuel from liquid cellulosic biofuel production facilities and producers of CNG/LNG derived from biogas, EPA combined these projections to project total cellulosic biofuel production for 2018. These projections are shown in Table III.C.3–1. Using the methodologies described in this section,

[49] At the time of this proposal, EPA has RIN generation data for the first five months of 2017 (January–May).

[50] To calculate this value, EPA multiplied the total number of 2016 RINs generated for CNG/LNG derived from biogas and available for compliance by 1.093 (representing a 9.3% year-over-year increase), and then multiplied the product by 1.093 a second time (to project the annual production volume in 2018, rather than 2017). The number 2016 of RINs generated for CNG/LNG derived from biogas and available for compliance (185.14) is based on EMTS data.

[51] EPA projects that 580 million ethanol-equivalent gallons of CNG/LNG will be used as transportation fuel in 2018 based on EIA's April 2017 Short Term Energy Outlook (STEO). To calculate this estimate, EPA used the Natural Gas Vehicle Use from the STEO Custom Table Builder (0.12 billion cubic feet/day in 2018). This projection includes all CNG/LNG used as transportation fuel from both renewable and non-renewable sources. EIA does not project the amount of CNG/LNG from biogas used as transportation fuel. To convert billion cubic feet/day to ethanol-equivalent gallons EPA used conversion factors of 1020 BTU per cubic foot of natural gas and 77,000 BTU of natural gas per ethanol-equivalent gallon.

we project that 238 million ethanol-equivalent gallons of cellulosic biofuel will be produced in 2018. We believe that projecting overall production in 2018 in the manner described above results in a neutral estimate (neither biased to produce a projection that is too high nor too low) of likely cellulosic biofuel production in 2018.

TABLE III.C.3–1—PROJECTED VOLUME OF CELLULOSIC BIOFUEL IN 2018

[Million gallons]

	Projected volume [a]
Liquid Cellulosic Biofuel Producers; Producers without Consistent Commercial Scale Production	1
Liquid Cellulosic Biofuel Producers; Producers with Consistent Commercial Scale Production	16
CNG/LNG Derived from Biogas	221
Total	238

[a] Volumes rounded to the nearest million gallons.

A brief overview of individual companies we believe will produce cellulosic biofuel and make it commercially available in 2018 can be found in a memorandum to the docket.[52] In the case of cellulosic biofuel produced from CNG/LNG and facilities using Edeniq's technology we have discussed the production potential from these facilities as a group rather than individually.[53] We request comment on the methodology used to project cellulosic biofuel production in 2018 [54] potential adjustments to the methodology that may result in more accurate projections, the companies listed as potential cellulosic biofuel producers and the volume of cellulosic biofuel projected to be produced in 2018 (including potential volumes from additional produces of cellulosic biofuel from corn kernel fiber and anaerobic waste digesters as discussed in Section III.B.3).

IV. Advanced Biofuel Volume for 2018

The national volume targets for advanced biofuel to be used under the RFS program each year through 2022 are specified in CAA section 211(o)(2)(B)(i)(II). Congress set annual renewable fuel volume targets that envisioned growth at a pace that far exceeded historical growth and, for years after 2011, prioritized that growth as occurring principally in advanced biofuels (contrary to previous growth patterns where most growth was in conventional renewable fuel, principally corn-ethanol). Congressional intent is evident in the fact that the portion of the total renewable fuel volume target in the statutory volume tables that is not required to be advanced biofuel is 15 billion gallons for all years after 2014, while the advanced volumes, driven by growth in cellulosic volumes, continue to grow through 2022 to a total of 21 billion gallons.

We have evaluated the capabilities of the market and are proposing to find that the 11.0 billion gallons specified in the statute for advanced biofuel cannot be reached in 2018. This is primarily due to the expected continued shortfall in cellulosic biofuel; production of this fuel type has consistently fallen short of the statutory targets by 95 percent or more, and as described in Section III, it will fall far short of the statutory target of 7.0 billion gallons again in 2018. In addition, although for the 2016 and 2017 standards we determined that the projected reasonably attainable supply of non-cellulosic advanced biofuel and other considerations justified establishing standards that include a partial backfill of the shortfall in cellulosic biofuel, for reasons described in this section we are not proposing such partial backfilling for 2018.

In previous years when exercising the cellulosic waiver authority to determine the required volume of advanced biofuel, we have taken into account the availability of advanced biofuels, their energy security and GHG benefits, and the apparent intent of Congress as reflected in the statutory volumes tables to substantially increase the use of advanced biofuels over time, as well as factors such as increased costs associated with the use of advanced biofuels and the environmental and food competition concerns raised by some commenters. In considering these factors, in those years, we have concluded that it was appropriate to set the advanced biofuel standard in a manner that would allow the partial backfilling of missing cellulosic volumes with non-cellulosic advanced biofuels. For purposes of this NPRM we are focusing primarily on the availability of advanced biofuels, their GHG and energy security benefits, and the costs associated with increased advanced biofuel mandates to propose no such backfilling with non-cellulosic advanced biofuel volumes in 2018. In other words, we propose to reduce the statutory volume target for advanced biofuel by the same amount as our proposed reduction in cellulosic biofuel. This action takes into account the fact that the substantial growth in advanced biofuel volumes after 2015 that was anticipated by Congress, and reflected in the statutory tables, was to be driven primarily by increases in cellulosic biofuel as opposed to non-cellulosic advanced biofuels. In addition, we recognize that the proposed approach involves placing a greater reliance on cost considerations than we have in past rulemakings. We believe this proposed new approach to balancing relevant considerations and exercising our discretion under the cellulosic waiver authority is permissible under the statute, and consistent with the principles articulated in *FCC* v. *Fox TV Stations,* 556 U.S. 502, 514–15 (2009), regarding circumstances when an agency may appropriately depart from prior policy. We will, as in past years, consider comments on these factors, their appropriate balancing, and any other factors identified by commenters that are relevant to the exercise of our cellulosic waiver authority in finalizing this rule, and will consider making appropriate adjustments for the final rule.

We note that the predominant non-cellulosic advanced biofuels available in the near term are advanced biodiesel and renewable diesel. We expect a decreasing rate of growth in the availability of feedstocks used to

[52] "Cellulosic Biofuel Producer Company Descriptions (May 2017)", memorandum from Dallas Burkholder to EPA Air Docket EPA–HQ–OAR–2017–0091.

[53] For individual company information see "May 2017 Cellulosic Biofuel Individual Company Projections for 2018 (CBI)", memorandum from Dallas Burkholder to EPA Air Docket EPA–HQ–OAR–2017–0091.

[54] For a more complete description of the methodology used to calculate the likely production ranges for the liquid cellulosic biofuel producers see 81 FR 89758, December 12, 2016.

produce these fuel types. To the extent that higher advanced biofuel requirements cannot be satisfied through growth in the production of advanced biofuel feedstocks, they would instead be satisfied through a re-direction of advanced feedstocks from competing uses, leading to lower overall GHG emission benefits. There would also likely be market disruptions and increased burden associated with shifting feedstocks among the wide range of companies that are relying on them today and which have optimized their processes to accommodate them. Furthermore, the fact that the tax credit for biodiesel has not been renewed, and if renewed could be in the form of a producer's tax credit rather than a blender's tax credit, has resulted in added uncertainty regarding the potential for volumes to be made available to the United States at levels above the proposed volume.

We believe that the factors and considerations noted above are all appropriately considered in our exercise of the broad discretion provided under the cellulosic waiver authority, and that a comprehensive consideration of these factors supports our proposed approach.[55] Some of the considerations discussed in this proposal are clearly related to the availability of non-cellulosic biofuels (*e.g.,* historic data on supply, expiration of the biodiesel blenders' tax credit, and anticipated decreasing growth in production of advanced feedstocks), while others clearly focus on the potential benefits and costs of requiring use of available volumes (*e.g.,* relative cost of advanced biofuels to the petroleum fuels they displace, GHG reduction benefits and energy security benefits). One important consideration does not fall neatly in these two categories—the likelihood that higher advanced biofuel standards would be satisfied by diversion of advanced feedstocks from other uses or diversion of foreign advanced biofuel from foreign markets, and the diminished benefits associated with such diversions. We believe, in the exercise of our discretion under the cellulosic waiver authority, and as discussed in more detail below, that it would not be appropriate to set the advanced biofuel volume requirement at a level that would lead to such diversions. Accordingly, we have factored this consideration into our assessment of available supplies. In other words, we first identify below volumes that we believe would be reasonably attainable in 2018 without these diversions, and then discuss whether or not other considerations, such as cost and GHG benefits, indicate that it would be appropriate to set the advanced biofuel volume requirement so as to require use of such reasonably attainable volumes to partially backfill for missing cellulosic volumes.

If finalized, the net impact of today's proposal would be that the volume requirement for advanced biofuel for 2018 would be 40 million gallons less than the applicable volume used to derive the 2017 percentage standard.

A. Volumetric Limitation on Use of the Cellulosic Waiver Authority

As described in Section II.A, when making reductions in advanced biofuel and total renewable fuel under the cellulosic waiver authority, the statute limits those reductions to no more than the reduction in cellulosic biofuel. As described in Section III.D, we are proposing a 2018 applicable volume for cellulosic biofuel of 238 million gallons, representing a reduction of 6,762 million gallons from the statutory target of 7,000 million gallons. As a result, 6,762 million gallons is the maximum volume reduction for advanced biofuel and total renewable fuel that is permissible using the cellulosic waiver authority.[56] If we were to use the cellulosic waiver authority to this maximum extent, the resulting 2018 volumes would be 4.24 and 19.24 billion gallons for advanced biofuel and total renewable fuel, respectively, following standard rounding methods applied to the applicable volumes expressed in billion gallons with two decimal places, as done in previous annual standard-setting rulemakings.

TABLE IV.A–1—LOWEST PERMISSIBLE VOLUME REQUIREMENTS USING ONLY THE CELLULOSIC WAIVER AUTHORITY

[Million gallons]

	Advanced biofuel	Total renewable fuel
Statutory target	11,000	26,000
Maximum reduction permitted under the cellulosic waiver authority	6,762	6,762
Lowest 2018 volume requirement permitted using only the cellulosic waiver authority	4,238	19,238

We are authorized under the cellulosic waiver authority to reduce the advanced biofuel and total renewable fuel volumes ''by the same or a lesser'' amount as the reduction in the cellulosic biofuel volume. Thus, we are not required to use the authority to its maximum extent. Indeed, in exercising the cellulosic waiver authority in setting standards for 2014–2017, we did not use the full extent of the authority. As discussed in Section II.A, EPA has broad discretion in using the cellulosic waiver authority in instances where its use is authorized under the statute, since Congress did not specify factors that EPA must consider in determining whether to use the authority or what appropriate volume reductions (within the range permitted by statute) should be. Thus, EPA could potentially set the 2018 advanced biofuel standard at a level that is designed to partially backfill for the shortfall in cellulosic biofuel. However, based on our consideration of the factors described in more detail below, we are proposing to use the full extent of the cellulosic waiver authority. The proposed advanced biofuel applicable volume is, therefore, 4.24 billion gallons.[57]

B. Reasonably Attainable Volumes of Advanced Biofuel

After use of the cellulosic waiver authority to reduce volumes of cellulosic biofuel, the statute does not specify conditions or any criteria or factors that EPA should consider in determining whether, and to what extent, to use the authority to reduce advanced biofuel and total renewable

[56] If we determined it necessary to provide further reductions to address inadequate domestic supply or severe economic or environmental harm, such further reductions would only be possible using the general waiver authority.

[57] We specify the volume requirements as billion gallons with two decimal places to be consistent with the volume targets as given in the statute. The only exception is for cellulosic biofuel which we specify in million gallons due to the substantial reduction from the statutory target. However, calculations are typically shown in million gallons for all four standards for clarity.

fuel. Thus, under the cellulosic waiver authority, Congress provided EPA with broad discretion to lower advanced biofuel and total renewable fuel applicable volumes in instances where it lowers the cellulosic biofuel requirement, as we are proposing to do in today's rule. In exercising this broad discretion, we need not require use of the maximum achievable volumes as would be the case if we were using the general waiver authority based on a finding of inadequate domestic supply, as we did for total renewable fuels in the 2014–2016 RFS standards rule.

As noted above, a higher advanced biofuel volume requirement has a greater potential to increase the incentive for switching advanced biofuel feedstocks from existing uses to biofuel production. Such market reactions could cause disruptions and/or price increases in the non-biofuel markets that currently use these feedstocks. Increasing the required volumes of advanced biofuels without giving the market adequate time to adjust by increasing supplies could also result in diversion of advanced biofuels from foreign countries to the U.S. without increasing total global supply. Increasing the supply of advanced biofuels in this way (by shifting the end use of advanced feedstocks to biofuel production and satisfying the current markets for these advanced feedstocks with non-qualifying or petroleum based feedstocks or simply shifting advanced biodiesel or renewable diesel from foreign to domestic use) would likely not produce the additional GHG benefits that might otherwise be expected. We are proposing that we not set the advanced volume requirement at a level that would require such diversions. Our individual assessments of reasonably attainable volumes reflect this approach. That is, while we refer to them as ''reasonably attainable'' volumes for convenience, they represent those volumes that are not likely to lead to feedstock diversions. Greater volumes could likely be made available if feedstock diversions were not of concern.

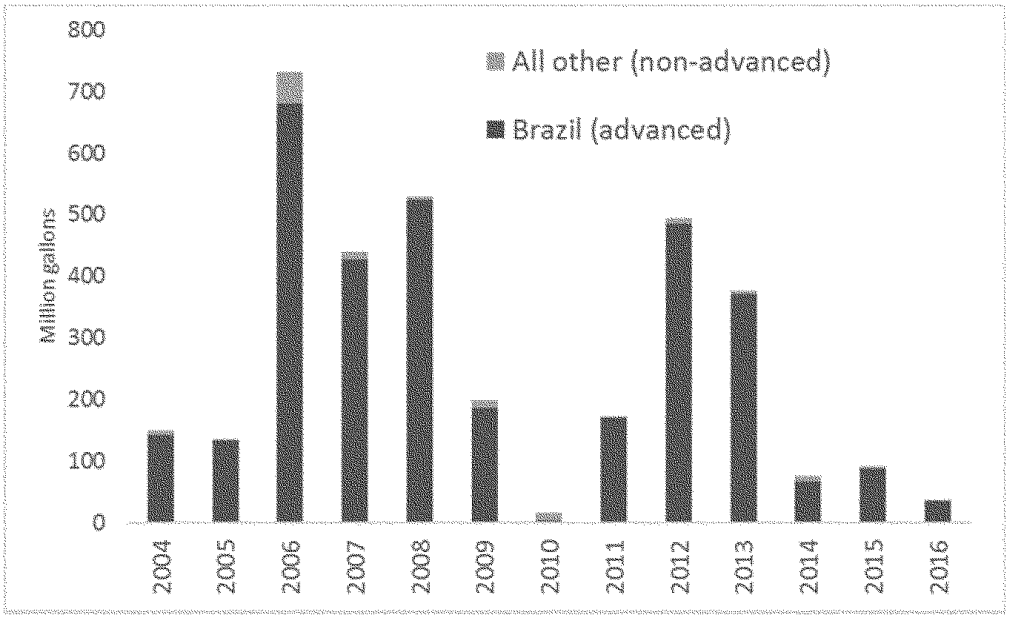
1. Imported Sugarcane Ethanol

The predominant available source of advanced biofuel other than cellulosic biofuel and BBD is imported sugarcane ethanol. For both the 2016 and 2017 standards, we used a volume of 200 million gallons of imported sugarcane ethanol for purposes of determining the reasonably attainable volume of advanced biofuel. In using this volume of sugarcane ethanol, we attempted to balance indications of lower potential imports from recent data with indications that higher volumes were possible based on older data. We also pointed to the high variability in ethanol import volumes in the past (including of Brazilian sugarcane ethanol, the predominant form of imported ethanol, and the only significant source of imported advanced ethanol), increasing gasoline consumption in Brazil, and variability in Brazilian production of sugar as reasons that it would be inappropriate to assume that sugarcane ethanol imports would reach the much higher levels suggested by some stakeholders.

The data currently available on 2016 ethanol imports suggests that we overestimated the volume of sugarcane ethanol imports for that year. Despite the fact that the applicable standards for 2016 were set prior to the beginning of 2016, and despite suggestions from UNICA [58] that 2016 imports could reach as high as 2 billion gallons, total ethanol imports only reached 34 million gallons. The low observed 2016 volume indicates that an increase in the advanced biofuel standard does not necessarily result in an increase in imports of sugarcane ethanol, and also implies that even California's Low Carbon Fuel Standard (LCFS), which applies in addition to the RFS program, has not resulted in the large volumes of advanced ethanol imports that some stakeholders believed would occur.

[58] UNICA is the Brazilian Sugarcane Industry Association.

Figure IV.B.1-1
Historical Ethanol Imports[a]



Source: "US Imports of Fuel Ethanol from EIA," docket EPA-HQ-OAR-2017-0091.
[a] Imports from Brazil include those that are transmitted through the Caribbean Basin Initiative (CBI) and Central America Free Trade Agreement (CAFTA), and are produced from sugarcane. Imports from other countries are typically not produced from sugarcane and do not qualify as advanced biofuel.

While the low import levels of sugarcane ethanol in 2014 and 2015 could, at least in part, be attributed to the fact that the applicable RFS standards had not been set prior to the beginning of the compliance period, this was not true for 2016. The experience in 2016 suggests that 200 million gallons may be too high for the purposes of projecting reasonably attainable volumes of advanced biofuel for 2018. At the same time, higher import volumes than those which occurred in 2016 are clearly possible, and could potentially be achieved under the influence of a higher RFS standard. Taking all of these considerations into account, we propose to use 100 million gallons of imported sugarcane ethanol for the purposes of projecting reasonably attainable volumes of advanced biofuel for 2018. This level takes into account the lower than expected import volumes that occurred in 2016, but also the fact that higher volumes have occurred in past years.

We recognize that there are factors that could result in lower import volumes of sugarcane ethanol in 2018 than 100 million gallons. These include weather and harvests in Brazil, world ethanol demand and prices, and constraints associated with the E10 blendwall in the U.S. Also, global sugar consumption has continued to increase steadily, while production has decreased. If the trend continues, Brazilian production of sugar could increase, with a concurrent reduction in production of ethanol.[59] On the other hand, the world average price of sugar is projected to remain relatively flat between 2016 and 2018, suggesting little change in sugar production and implying that ethanol production in Brazil might likewise remain unchanged.[60] In light of these and other considerations discussed above, we request comment on whether it would be appropriate to use a volume of imported sugarcane ethanol different than 100 million gallons in the final determination of the advanced biofuel volume requirement for 2018.

2. Biodiesel and Renewable Diesel

With regard to biodiesel and renewable diesel, there are many different factors that could potentially influence the *total* reasonably attainable volume of these fuels (including both advanced and non-advanced forms) used as transportation fuel or heating oil in the United States.[61] These factors could include the availability of qualifying biodiesel and renewable diesel feedstocks, the production capacity of biodiesel and renewable diesel facilities (both in the United States and internationally), the market's ability to distribute biodiesel, and diesel engine manufacturers' recommendations for biodiesel use in the engines they produce. The degree to which these and other factors may affect the total supply of biodiesel and renewable diesel in 2018, is discussed in Section V.B.2.

However, the primary considerations in our determination of the reasonably attainable volumes of *advanced* biodiesel and renewable diesel for 2018 are a review of the supply of advanced biodiesel and renewable diesel in previous years, the uncertain impact of the expiration of the biodiesel tax credit

[59] ''Sugar—World Markets and Trade,'' USDA, November 2016.

[60] ''Commodity Markets Outlook,'' World Bank Group, January 2017.

[61] For a further discussion of the factors that influence the availability of biodiesel and renewable diesel see Section V.B.2 of the preamble and a further discussion of these factors from the 2017 final rule (81 FR 89781—89789, December 12, 2016).

on biodiesel production and importation, the projected growth in production of advanced biodiesel and renewable diesel feedstocks in 2018, and consideration of the extent to which our decision in setting advanced biofuel requirements could influence the market.[62] A review of the volumes of advanced biodiesel and renewable diesel made available in previous years is especially useful in projecting the potential for growth in such fuels, since for these fuels there are a number of complex and inter-related factors (including the expiration of the biodiesel tax credit) that are likely to affect the total supply. We also believe the likely growth in production of feedstocks used to produce these fuels is an important factor to consider. This is because the maximum energy security and GHG reduction value associated with the growth in the use of advanced biofuels is obtained when that growth is associated with an increase in advanced feedstock production, rather than a switching of existing advanced feedstocks from other uses. Such feedstock switching could result in unintended negative consequences, such as market disruption in the renewable oils market, which could offset some of the anticipated benefits of the production and use of advanced biofuels.

The volume of advanced biodiesel and renewable diesel projected to be available based on a consideration of these factors is less than the total volume of biodiesel and renewable diesel we believe could be produced (based solely on an assessment of the available production capacity) or consumed (based on an assessment of the ability of the market to distribute and use biodiesel and renewable diesel). Production capacity and the ability for the market to distribute and use biodiesel and renewable diesel are therefore not constraining factors in our assessment of the reasonably attainable volume of advanced biodiesel and renewable diesel in 2018.

Before considering the projected growth in the production of qualifying feedstocks that could be used to produce advanced biodiesel and renewable diesel, it is helpful to review the supply of biodiesel and renewable diesel to the United States in recent years. While historic data and trends alone are insufficient to project the volumes of biodiesel and renewable diesel that could be provided in future years, historic data can serve as a useful frame of reference in considering future volumes. Past experience suggests that a high percentage of the biodiesel and renewable diesel used in the United States (from both domestic production and imports) qualifies as advanced biofuel.[63] In previous years, biodiesel and renewable diesel produced in the United States has been almost exclusively advanced biofuel.[64] Imports of advanced biodiesel have increased in recent years, however, as seen in Table IV.B.2–1. Volumes of imported advanced biodiesel and renewable diesel have varied significantly from year to year, as they are impacted both by domestic and foreign policies, as well as economic factors.

TABLE IV.B.2–1—ADVANCED (D4 AND D5) BIODIESEL AND RENEWABLE DIESEL FROM 2011 TO 2016

[Million gallons] [a]

	2011	2012	2013	2014 [b]	2015 [b]	2016
Domestic Biodiesel (Annual Change)	967 (N/A)	1,014 (+47)	1,376 (+362)	1,303 (−73)	1,253 (−50)	1,633 (+380)
Domestic Renewable Diesel (Annual Change)	58 (N/A)	11 (−47)	92 (+81)	155 (+63)	175 (+20)	221 (+46)
Imported Biodiesel (Annual Change)	44 (N/A)	40 (−4)	156 (+116)	130 (−26)	261 (+131)	561 (+300)
Imported Renewable Diesel (Annual Change)	0 (N/A)	28 (+28)	145 (+117)	129 (−16)	121 (−8)	170 (+49)
Exported Biodiesel and Renewable Diesel (Annual Change)	48 (N/A)	102 (+54)	125 (+23)	134 (+9)	133 (−1)	129 (−4)
Total (Annual Change)	1,021 (N/A)	991 (−30)	1,644 (+653)	1,583 (−61)	1,677 (+94)	2,456 (+779)

[a] All data for 2011–2016 from EMTS. EPA reviewed all advanced biodiesel and renewable diesel RINs retired for reasons other than demonstrating compliance with the RFS standards and subtracted these RINs from the RIN generation totals for each category in the table above to calculate the supply in each year.

[b] RFS required volumes for these years were not established until December 2015.

TABLE IV.B.2–2—CONVENTIONAL (D6) BIODIESEL AND RENEWABLE DIESEL FROM 2011 TO 2016

[Million gallons] [a]

	2011	2012	2013	2014 [b]	2015 [b]	2016
Domestic Biodiesel (Annual Change)	0 (N/A)	0 (+0)	6 (+6)	1 (−5)	0 (+0)	0 (+0)
Domestic Renewable Diesel (Annual Change)	0 (N/A)	0 (+0)	0 (+0)	0 (+0)	0 (+0)	0 (+0)
Imported Biodiesel (Annual Change)	0 (N/A)	0 (+0)	31 (+31)	52 (+21)	74 (+22)	113 (+39)
Imported Renewable Diesel (Annual Change)	0 (N/A)	0 (+0)	53 (+53)	0 (−53)	106 (+106)	43 (−63)

[62] Throughout this section we refer to advanced biodiesel and renewable diesel as well as advanced biodiesel and renewable diesel feedstocks. In this context, advanced biodiesel and renewable diesel refer to any biodiesel or renewable diesel for which RINs can be generated that satisfy an obligated party's advanced biofuel obligation (*i.e.,* D4 or D5 RINs). An advanced biodiesel or renewable feedstock refers to any of the biodiesel, renewable diesel, jet fuel, and heating oil feedstocks listed in Table 1 to § 80.1426 that can be used to produce fuel that qualifies for D4 or D5 RINs. These feedstocks include soy bean oil; oil from annual cover crops; oil from algae grown photosynthetically; biogenic waste oils/fats/greases; non-food grade corn oil; camelina sativa oil; and canola/rapeseed oil (See pathways F, G, and H of Table 1 to § 80.1426).

[63] From 2011 through 2016 over 95% of all biodiesel and renewable diesel supplied to the United States (including domestically-produced and imported biodiesel and renewable diesel) qualified as advanced biodiesel and renewable diesel (9,372 million gallons of the 9,850 million gallons) according to EMTS data.

[64] From 2011 through 2016 over 99.9% of all the domestically produced biodiesel and renewable diesel supplied to the United States qualified as advanced biodiesel and renewable diesel (8,258 million gallons of the 8,265 million gallons) according to EMTS data.

TABLE IV.B.2–2—CONVENTIONAL (D6) BIODIESEL AND RENEWABLE DIESEL FROM 2011 TO 2016—Continued

[Million gallons] [a]

	2011	2012	2013	2014 [b]	2015 [b]	2016
Exported Biodiesel and Renewable Diesel (Annual Change)	0 (N/A)	0 (+0)	0 (+0)	0 (+0)	0 (+0)	1 (+1)
Total (Annual Change)	0 (N/A)	0 (+0)	90 (+90)	53 (−37)	180 (+127)	155 (−25)

[a] All data for 2011–2016 from EMTS. EPA reviewed all conventional biodiesel and renewable diesel RINs retired for reasons other than demonstrating compliance with the RFS standards and subtracted these RINs from the RIN generation totals for each category in the table above to calculate the supply in each year.

[b] RFS required volumes for these years were not established until December 2015.

Since 2011 the year-over-year changes in the volume of advanced biodiesel and renewable diesel in the United States have varied greatly, from a low of negative 61 million gallons from 2011 to 2012 to a high of 779 million gallons from 2015 to 2016. These changes were likely influenced by a number of factors such as the cost of biodiesel feedstocks and petroleum diesel, the status of the biodiesel blenders tax credit, growth in marketing of biodiesel at high volume truck stops and centrally fueled fleet locations, demand for biodiesel and renewable diesel in other countries, biofuel policies in both the United States and foreign countries, and the volumes of renewable fuels (particularly advanced biofuels) required by the RFS. This historical information does not indicate that the maximum previously observed increase of 779 million gallons of advanced biodiesel and renewable diesel would be reasonable to expect from 2017 to 2018, nor does it indicate that the low growth rates observed in other years represent the limit of potential growth in 2018. Rather, these data illustrate both the magnitude of the increases in advanced biodiesel and renewable diesel in previous years and the significant variability in these increases.

The historic data indicates that the biodiesel tax policy in the United States can have a significant impact on the supply of biodiesel and renewable diesel in any given year. While the biodiesel blenders tax credit has applied in each year from 2010–2016, it has only been in effect during the calendar year in 2011, 2013 and 2016, while other years it has been applied retroactively. The biodiesel blenders tax credit expired at the end of 2009 and was re-instated to apply retroactively in 2010 and extend through the end of 2011 in December 2010. Similarly, after expiring at the end of 2011, 2013, and 2014 the tax credit was re-instated in January 2013 (for 2012 and 2013), December 2014 (for 2014), and December 2015 (for 2015 and 2016). Each of the years in which the biodiesel blenders tax credit was in effect during the calendar year (2013 and 2016) resulted in significant increases in the supply of advanced biodiesel and renewable diesel over the previous year (653 million gallons and 779 million gallons respectively). However, following this large increase in 2013, the supply of advanced biodiesel and renewable diesel in 2014 and 2015 was minimal, only 33 million gallons from 2013 to 2015. This pattern is likely the result of both accelerated production and/or importation of biodiesel and renewable diesel in the final few months of 2013 to take advantage of the expiring tax credit as well as relatively lower volumes of biodiesel and renewable diesel production and import in 2014 and 2015 than would have occurred if the tax credit had been in place.[65]

We believe it is reasonable to anticipate a similar production pattern in 2016 through 2018 as observed in 2013 through 2015; that increases in the volumes of advanced biodiesel and renewable diesel will be modest in 2017–2018, following a significant increase in 2016. Available RIN generation data further supports this pattern. Very high volumes of advanced biodiesel and renewable diesel were supplied in the last quarter of 2016, likely driven by a desire to capture the expiring tax credit, while significantly smaller volumes of these fuels were supplied in the first quarter of 2017.[66] We request comment on the likely impact of the expiration of the blenders tax credit on supplies of biodiesel and renewable diesel in 2018.

In addition to a review of the historical supply of advanced biodiesel and renewable diesel and consideration of the possible impact of the expiration of the biodiesel tax credit (discussed above) EPA has also focused on the expected increase in the availability of advanced biodiesel and renewable diesel feedstocks in 2018 in projecting the reasonably attainable volume of biodiesel and renewable diesel in the context of the 2018 advanced biofuel standard. We acknowledge that the availability of advanced biodiesel and renewable diesel in 2018 is not strictly tied to the increase in the availability of the feedstocks used to produce these fuels, and that it may be possible to realize higher volumes of advanced biodiesel and renewable diesel in 2018 through a diversion of advanced feedstocks from other uses, or a diversion of advanced biodiesel and renewable diesel from existing markets in other countries. We perceive the net benefits associated with such increased advanced biofuel and renewable fuel supply to be significantly less than the net benefits associated with the production of additional advanced biodiesel and renewable diesel with the use of newly-available advanced feedstocks. This is both because of the potential disruption and associated cost impacts to other industries resulting from feedstock switching, as well as reduced GHG reduction benefit related to use of feedstocks for biofuel production that would have been used for other purposes, and must now be backfilled with other feedstocks with potentially lesser environmental benefits. By focusing our assessment of the reasonably attainable volume of biodiesel and renewable diesel on the expected growth in the production of advanced feedstocks (rather than the total supply of these feedstocks in 2018, which would include feedstocks currently being used for non-biofuel purposes), we are attempting to minimize the incentives for the RFS program to increase the supply of advanced biodiesel and renewable diesel through feedstock switching.

Advanced biodiesel and renewable diesel feedstocks include both waste oils, fats and greases and oils from planted crops. While we believe a small

[65] We also acknowledge that the fact that EPA did not finalize the required volumes of renewable fuel under the RFS program for 2014 and 2015 until December 2015 likely had an impact on the volume of advanced biodiesel and renewable diesel supplied in these years.

[66] According to data on EPA's public Web site, RINs were generated for 823 million gallons of biomass-based diesel in the last quarter of 2016 while RINs were generated for 444 million gallons of biomass-based diesel in the first quarter of 2017. The vast majority of advanced biodiesel and renewable diesel qualifies as biomass-based diesel.

increase in supply of waste oils, fats, and greases may be possible in 2018, we believe this increase is limited as much of these oils, fats, and greases are already being recovered and used in biodiesel and renewable diesel production or for other purposes. Many of the planted crops that supply vegetable oil for advanced biodiesel and renewable diesel production are primarily grown as livestock feed with the oil as a co-product or by-product, rather than specifically as biodiesel and renewable diesel feedstocks.[67] This is true for soy beans and corn, which are the two largest sources of feedstock from planted crops used for biodiesel production in the United States.[68] This means that the planted acres of these crops are likely to be made based on the projected demand for livestock feed, rather than for vegetable oil to produce biofuels or for other markets, as the vegetable oils produced are not the primary source of revenue for these crops.

Increasing the demand for advanced biodiesel and renewable diesel beyond the projected increase in the feedstocks used to produce these fuels would likely require diverting volumes of advanced biodiesel and renewable diesel (or the feedstocks used to produce these fuels) from existing markets to be used to produce biofuels supplied to the United States. Increasing the short-term supply of advanced biodiesel and renewable diesel to the United States in this manner (simply shifting the end use of advanced feedstocks to biodiesel and renewable diesel production and meeting non-biofuel demand for these feedstocks with conventional renewable and/or petroleum based feedstocks) may not advance the full GHG or energy security goals of the RFS program. In a worst case scenario, higher standards could cause supply disruptions to a number of markets as biodiesel and renewable diesel producers seek additional supplies of advanced feedstocks and the parties that previously used these feedstocks, both within and outside of the fuels marketplace, seek out alternative feedstocks. This could result in significant cost increases, for both biodiesel and renewable diesel as well as other products produced from renewable oils.

We believe the most reliable source for projecting the expected increase in vegetable oils in the United States is USDA's World Agricultural Supply and Demand Estimates (WASDE). At this time the most current version of the WASDE report only projects domestic vegetable oil production through 2017. Based on domestic vegetable oil production from 2011–2016 as reported by WASDE, the average annual increase in vegetable oil production in the United States was 0.288 million metric tons per year.[69] Assuming a similar increase in domestic vegetable oil production from 2017 to 2018, this quantity of vegetable oils could be used to produce approximately 65 million gallons of advanced biodiesel or renewable diesel.[70]

In addition to virgin vegetable oils, we also expect increasing volumes of distillers corn oil to be available for use in 2018. The WASDE report does not project distillers corn oil production, so EPA must use an alternative source to project the growth in the production of this feedstock. EPA is proposing to use the results of the World Agricultural Economic and Environmental Services (WAEES) model to project the growth in the production of distillers corn oil.[71] In assessing the likely increase in the availability of distillers corn oil from 2017 to 2018, the authors of the WAEES model considered the impacts of an increasing adoption rate of distillers corn oil extraction technologies at domestic ethanol production facilities, as well as increased corn oil extraction rates enabled by advances in this technology. The projected increase in the production of distillers corn oil, if devoted entirely to biofuel production, could be used to produce approximately 42 million gallons of biodiesel or renewable diesel in 2018.[72] We believe that this is a reasonable projection. While the vast majority of the increase in advanced biodiesel and renewable diesel feedstocks produced in the United States from 2016 to 2017 is expected to come from virgin vegetable oils and distillers corn oil, increases in the supply of other sources of advanced biodiesel and renewable diesel feedstocks, such as biogenic waste oils, fats, and greases, may also occur. These increases, however, are expected to be modest, as many of these feedstocks that can be recovered economically are already being used for the production of biodiesel or renewable diesel, or in other markets. In total, we expect that increases in feedstocks produced in the United States are sufficient to produce approximately 100 million more gallons of advanced biodiesel and renewable diesel in 2018 relative to 2017.

We have also considered the expected increase in the imports of advanced biodiesel and renewable diesel produced in other countries. In previous years, significant volumes of foreign produced advanced biodiesel and renewable diesel have been supplied to markets in the United States (see Table IV.B.2–1 above). These significant imports were likely the result of a strong U.S. demand for advanced biodiesel and renewable diesel, supported by both the RFS standards, the LCFS in California, and the biodiesel blenders tax credit. At this time the impacts of the expiration of the biodiesel blenders tax credit on the volumes of foreign-produced biodiesel and renewable diesel imported into the United States, is highly uncertain. In light of this uncertainty, we do not believe it is reasonable at this point to project increasing volumes of imported advanced biodiesel and renewable diesel in 2018, and for the purposes of projecting the reasonably attainable volume of advanced biodiesel and renewable diesel in 2018 we have assumed that imported volumes of biodiesel and renewable diesel will not increase from the volumes imported in 2017.[73] This approach also seeks to minimize the incentives to increase the

[67] For example, corn oil is a co-product of corn grown primarily for feed or ethanol production, while soy and canola oil are primarily grown as livestock feed.

[68] According to EIA data 6,096 million pounds of soy bean oil and 1,306 million pounds of corn oil were used to produce biodiesel in the United States in 2016. Other significant sources of feedstock were yellow grease (1,389 million pounds), canola oil (1,130 million pounds), white grease (578 million pounds), tallow (332 million pounds), and poultry fat (220 million pounds). Numbers from EIA's February 2017 Monthly Biodiesel Production Report. Available at *https://www.eia.gov/biofuels/biodiesel/production/archive/2016/2016_12/biodiesel.pdf*.

[69] According to the April 2017 WASDE report, US vegetable oil production in the 2015/2016 agricultural marketing year is estimated to be 11.20 million metric tons. According to the January 2013 WASDE report, US vegetable oil production in the 2010/2011 agricultural marketing year was 9.76 million metric tons.

[70] To calculate this volume we have used a conversion of 7.7 pounds of feedstock per gallon of biodiesel. This is based on the expected conversion of soy oil (*http://extension.missouri.edu/p/G1990*), which is the largest source of feedstock used to produce advanced biodiesel and renewable diesel. We believe that it is also a reasonable conversion factor to use for all virgin vegetable oils.

[71] For the purposes of this proposed rule, EPA relied on WAEES modeling results submitted as comments on the 2017 final rule (Kruse, J., ''Implications of Higher Biodiesel Volume Obligations for Global Agriculture and Biofuels'', 2016, World Agricultural Economic and Environmental Services (WAEES), EPA–HQ–OAR–2016–0004–2904 (Attachment 13)).

[72] Kruse, J., ''Implications of Higher Biodiesel Volume Obligations for Global Agriculture and Biofuels'', 2016, World Agricultural Economic and Environmental Services (WAEES), EPA–HQ–OAR–2016–0004–2904 (Attachment 13).

[73] We further note that there have been recent efforts to reinstate the biodiesel tax credit as a producers tax credit, rather than a blenders tax credit. If the biodiesel tax credit were reinstated as a producers tax credit it would not apply to foreign biodiesel producers, further impacting the likely supply of imported advanced biodiesel and renewable diesel.

supply of advanced biodiesel and renewable diesel by diverting fuels that would otherwise be used in foreign countries to the United States. We believe the historic volumes of imported advanced biodiesel and renewable diesel support this projection, with a slight decrease in the total volume of imported biodiesel and renewable diesel in 2014 after the expiration of the biodiesel blenders tax credit, followed by a slight increase in 2015 after the tax credit was reinstated in December 2015 (see Table IV.B.2–1).

After a careful consideration of the historic supply of advanced biodiesel and renewable diesel to the United States in previous years, the likely impact of the expiration of the biodiesel tax credit, and an assessment of the availability of feedstocks used to produced advanced biodiesel and renewable diesel in 2018, EPA has determined, for the purposes of our proposal, that approximately 2.5 billion gallons of advanced biodiesel and renewable diesel is reasonably attainable for use in our determination of the advanced biofuel standard for 2018. This volume is 100 million gallons higher than the volume of advanced biodiesel and renewable diesel determined to be reasonably attainable and appropriate for the purposes of deriving the advanced biofuel standard in 2017.

The 100 million gallon increase in advanced biodiesel and renewable diesel that we project will be reasonably attainable for 2018 represents a smaller annual increase in advanced biodiesel and renewable diesel than we assumed in deriving the 2017 advanced biofuel standard (approximately 300 million gallons). We believe that this is reasonable because the circumstances we are facing in this action are different from those we were facing in the 2017 final rule. The primary differences are a smaller projected increase in advanced feedstock production in the United States and the expiration of the biodiesel tax credit. While the biodiesel blenders tax credit was still in effect at the end of 2016 when EPA completed the 2017 final rule, this tax credit has since expired. It is uncertain whether the tax credit will be renewed for 2017 and 2018 as it has in the past.

3. Other Advanced Biofuel

In addition to cellulosic biofuel, imported sugarcane ethanol, and advanced biodiesel and renewable diesel, there are other advanced biofuels that can be counted in the determination of reasonably attainable volumes of advanced biofuel for 2018. These other advanced biofuels include biogas, naphtha, heating oil, butanol, jet fuel, and domestically-produced advanced ethanol. However, the supply of these fuels has been relatively low in the last several years.

TABLE IV.B.3–1—HISTORICAL SUPPLY OF OTHER ADVANCED BIOFUELS

[Million ethanol-equivalent gallons]

	CNG	Heating oil	Naphtha	Renewable diesel [a]	Domestic ethanol	Total
2013	26	0	3	64	23	116
2014	20	0	18	15	26	79
2015	0	1	24	8	25	58
2016	0	2	26	8	27	63

[a] Some renewable diesel generates D5 rather than D4 RINs as a result of being produced through co-processing with petroleum or being produced from the non-cellulosic portions of separated food waste or annual cover crops.

The downward trend over time in biogas as advanced biofuel with a D code of 5 is due to the re-categorization in 2014 of landfill biogas from advanced (D code 5) to cellulosic (D code 3).[74] Apart from biogas, total supply of advanced biofuel other than imported sugarcane ethanol has been relatively constant during 2014–2016. Based on this historical record, we propose to find that 60 million gallons would be reasonably attainable in 2018.[75]

We recognize that the potential exists for additional volumes of advanced biofuel from sources such as jet fuel, liquefied petroleum gas (LPG), and liquefied natural gas (as distinct from compressed natural gas), as well as non-cellulosic biogas such as from digesters. However, since they have been produced in only de minimis amounts in the past, we do not have a basis for projecting substantial volumes from these sources in 2018. For the final rule, we may modify our projection of 60 million gallons for other advanced biofuel as information becomes available.

4. Total Advanced Biofuel

The total volume of advanced biofuel that we believe is reasonably attainable in 2018 is the combination of cellulosic biofuel and the sources described above: Imported sugarcane ethanol, biodiesel and renewable diesel which qualifies as BBD, and other advanced biofuels such as advanced biogas that does not qualify as cellulosic biofuel, heating oil, naphtha, domestic advanced ethanol, and advanced renewable diesel that does not qualify as BBD. Our assessment of the reasonably attainable volumes of these sources, discussed in the preceding sections, is summarized below. We note that the reasonably attainable volumes of each of these advanced biofuels cannot themselves be viewed as volume requirements. These volumes are merely one part of the analysis used to determine the volume requirement for advanced biofuel. As discussed in more detail in Section V.C below, there are many ways that the market could respond to the percentage standards we establish, including use of higher or lower volumes of these fuel types than discussed in this section. In addition, as discussed below, we do not believe it would be appropriate to require use of all volumes we have determined to be reasonably attainable.

TABLE IV.B.4–1—POTENTIAL VOLUMES OF ADVANCED BIOFUEL IN 2018

[Million ethanol-equivalent gallons except as noted]

Cellulosic biofuel	238
Advanced biodiesel and renewable diesel (ethanol-equivalent volume/physical volume)	3,875/2,500
Imported sugarcane ethanol	100
Other advanced	60
Total advanced biofuel	4,273

[74] 79 FR 42128, July 18, 2014.

[75] For the purposes of determining the availability of total renewable fuel, we propose to use a volume of 40 million gallons of non-ethanol other advanced biofuel and 20 million gallons of advanced domestic ethanol (see discussion in Section V.B.2).

C. Proposed Advanced Biofuel Volume Requirement for 2018

Based on the information presented above, we believe that 4.27 billion gallons of advanced biofuel would be reasonably attainable in 2018. This volume is 30 million gallons higher than the 4.24 billion gallons that would result from reducing the applicable volume of advanced biofuel by the same amount as the proposed reduction to the statutory applicable volume of cellulosic biofuel (see Section III for a discussion of the proposed cellulosic biofuel standard for 2018). Requiring use of the additional 30 million gallons to partially backfill for missing cellulosic volumes would be expected to result in GHG reduction and energy security benefits. In exercising the cellulosic waiver authority in past years, we sought to capture such benefits by requiring a partial backfilling of missing cellulosic volumes with volumes of non-cellulosic biofuel we determined to be reasonably attainable and appropriate. We did so, notwithstanding consideration of the increase in costs associated with our actions.[76] However, this year we are proposing to balance these considerations in a different manner in setting the 2018 standards, placing a greater emphasis on cost considerations.[77]

In Section V.D we present illustrative cost projections for sugarcane ethanol and soybean biodiesel in 2018, the two advanced biofuels that have been most widely supplied in previous years and that would be most likely to provide the marginal volume of advanced biofuel in 2018. Our projected costs for sugarcane ethanol range from $0.58–$1.53 per ethanol-equivalent gallon of gasoline displaced ($0.87–$2.29 for every gallon of gasoline displaced) and the costs for soybean biodiesel range from $0.83–$1.13 per ethanol-equivalent gallon of diesel displaced ($1.36–$1.85 for every gallon of diesel replaced).[78] These costs are high on a per gallon basis compared to the petroleum fuels they displace. In light of these comparative costs, we believe it is reasonable to forgo the marginal benefit that might be achieved by establishing the advanced biofuel standard to require an additional 30 million gallons. See Section V.D for a further discussion of the projected cost of this proposed rule.

Based on consideration of the volumes that may be reasonably attainable in 2018, along with a balancing of the costs and benefits associated with the option of setting the advanced biofuel standard at a level that would require use of all volumes that we have estimated could be reasonably attainable, we are proposing an advanced biofuel volume requirement of 4.24 billion gallons for 2018. This proposed reasonably attainable and appropriate volume requirement for advanced biofuel for 2018 would represent a decrease of 40 million gallons from the 2017 advanced biofuel volume requirement of 4.28 billion gallons. As discussed in Section I.E, we request comment on use of the general waiver authority to further reduce the required volume of advanced biofuel (with a corresponding reduction to the total renewable fuel requirement) in an effort to increase the energy independence impacts of the RFS program.

We propose to use the cellulosic waiver authority to provide an equivalent reduction in the applicable volume of total renewable fuel as the reduction we are proposing for advanced biofuel. That step is described in more detail in Section V.A, together with our proposed assessment that no further increment of reduction is required for total renewable fuel in 2018.

V. Total Renewable Fuel Volume for 2018

The national volume targets of total renewable fuel to be used under the RFS program each year through 2022 are specified in CAA section 211(o)(2)(B)(i)(I). For 2018 the statute stipulates a volume target of 26 billion gallons. Since we are proposing to reduce the statutory volume target for cellulosic biofuel to reflect the projected production volume of that fuel type in 2018, we are authorized under CAA section 211(o)(7)(D)(i) to reduce the advanced biofuel and total renewable fuel targets by the same or a lesser amount. We also have the authority to reduce any volume target pursuant to the general waiver authority in CAA section 211(o)(7)(A) under specific conditions as described in Section II.A.2, including based on a finding of ''inadequate domestic supply.'' Our proposed assessment indicates that there will be adequate supply of total renewable fuel in 2018 to meet a total renewable fuel volume requirement of 19.24 billion gallons that would result from the use of the cellulosic waiver authority alone. The use of the general waiver authority for 2018 to further reduce the total renewable fuel standard on the basis of supply considerations would therefore not be necessary. As a result, the implied volume for conventional renewable fuel (calculated by subtracting the advanced volume from the total volume) would be 15.0 billion gallons, consistent with the statutory targets provided in the statute for 2018.

A. Volumetric Limitation on Use of the Cellulosic Waiver Authority

In Section IV.B we explained our proposed use of the cellulosic waiver authority to reduce the 11 billion gallon 2018 statutory volume target for advanced biofuel to 4.24 billion gallons for purposes of setting the 2018 advanced biofuel volume standard. This represents a reduction of 6.76 billion gallons.

As discussed in Section II.A.1, we believe that the cellulosic waiver provision is best interpreted to require equal reductions in advanced biofuel and total renewable fuel. We have consistently articulated this interpretation.[79] We also believe this interpretation is consistent with statutory language and best effectuates the objectives of the statue. If EPA were to reduce the total renewable fuel volume requirement by a lesser amount than the advanced biofuel volume requirement, we would effectively increase the opportunity for conventional biofuels to participate in the RFS program beyond the implied statutory cap of 15 billion gallons.[80]

[76] See, *e.g.,* Response to Comments Document for the 2014–16 Rule, pages 628–631, available at *https://www.epa.gov/sites/production/files/2015-12/documents/420r15024.pdf.*

[77] EPA notes that while the factors considered under the cellulosic waiver authority to reduce volumes could apply to volumes beyond the reduction in cellulosic biofuel, EPA is limited in the exercise of its cellulosic waiver authority to reductions up to the amount of the reduction in cellulosic biofuel. Any further reductions would require a determination under the general waiver authority that the volumes would result in severe economic or environmental harm, or that there is an inadequate domestic supply.

[78] These ethanol-equivalent gallon costs are calculated by dividing the total projected cost for soybean biodiesel ($33–$45 million) and sugarcane ethanol ($23–$61 million) by the proposed decrease in the required volume advanced biofuel for 2018 (40 million ethanol-equivalent gallons). All costs comparisons are on an energy-equivalent, rather than a volumetric, basis.

[79] For instance, see discussion in the final rules setting the 2013, 2014–2016, and 2017 standards: 78 FR 49809–49810, August 15, 2013; 80 FR 77434, December 14, 2015; 81 FR 89752–89753, December 12, 2016.

[80] Since the advanced biofuel volume requirement is nested within the total renewable fuel volume requirement, the statutory implied volume for conventional renewable fuel in the statutory tables can be discerned by subtracting the applicable volume of advanced biofuel from that of total renewable fuel. Performing this calculation with respect to the tables in CAA section 211(o)(2)(B) indicates a Congressional expectation that in the time period 2015–2022, advanced biofuel volumes would grow from 5.5 to 21 billion gallons, while the implied volume for conventional

Applying an equal reduction of 6.76 billion gallons to both the statutory target for advanced biofuel and the statutory target for total renewable fuel results in a total renewable fuel volume of 19.24 billion gallons as shown in Table IV.A–1. If we were to determine that there is a basis to exercise the general waiver authority, described in Section II.A.2, we could provide further reductions. However, as described below in Section V.B, we believe that there will be adequate supply to meet a total renewable fuel volume requirement of 19.24 billion gallons in 2018. This means that we believe that 15.0 billion gallons of conventional renewable fuel is reasonably attainable, and that further reductions in the total renewable fuel applicable volume using the general waiver authority are not necessary to address supply issues. We note that EPA has received numerous comments in previous annual standard rulemakings asserting that there are negative environmental impacts that may be associated with the RFS program.[81] A significant portion of these concerns center on feedstock production, particularly feedstocks used to produce conventional biofuels. Although we are authorized to reduce the statutory volume targets on the basis of a finding of ''severe environmental harm,'' we are not proposing any reductions on this basis. Similarly, although EPA is authorized to reduce volumes on the basis of a finding of ''severe economic harm,'' we are not proposing any reductions on that basis.

B. Assessing Attainable Volumes

As noted above, the proposed volume requirement for total renewable fuel was derived by applying the same volume reduction to the statutory volume target for total renewable fuel as we are proposing for advanced biofuel, using the cellulosic waiver authority. This section describes our proposed determination that there will be adequate renewable fuel to meet an applicable volume requirement of 19.24 billion gallons in 2018. We have evaluated available sources of renewable fuel to determine if in the aggregate it appears that a total renewable fuel volume of 19.24 billion gallons is reasonably attainable. Since we believe that this volume is indeed reasonably attainable, as discussed below, we propose that it is unnecessary to consider further reductions through use of the general waiver authority on the basis of an inadequate domestic supply. Therefore, in this assessment, we have not attempted to identify the maximum reasonably achievable volume of total renewable fuel based on the sum of estimates of each type of renewable fuel, such as total ethanol, biodiesel and renewable diesel, biogas, and other non-ethanol renewable fuels, as we would do if we were proposing to use the general waiver authority based on a finding of inadequate domestic supply. However, as noted previously, we are soliciting comment on whether it would be appropriate to exercise the general waiver authority.

As for previous annual standard-setting rulemakings, we note that it is a very challenging task to estimate the available volumes in light of the myriad complexities of the fuels market and how individual aspects of the industry might change in the future, and also because we cannot precisely predict how the market will respond to the standards we set. This is the type of assessment that is not given to precise measurement and necessarily involves considerable exercise of judgment.

Our investigation into whether the total renewable fuel volume shown in Table V.A–1 is reasonably attainable in 2018 was driven primarily by a consideration of the reasonable availability of ethanol, biodiesel, and renewable diesel. We also considered smaller contributions from non-ethanol cellulosic and other types of renewable fuels (*i.e.,* naphtha, heating oil, butanol, and jet fuel). After estimating what we consider to be the reasonably attainable supply of ethanol in 2018, and taking into account the estimates of non-ethanol cellulosic biofuel supply discussed in Section III.D above and estimates of the supply of other non-ethanol renewable fuels discussed in Section IV.B.3, we considered whether the reasonably attainable supply of total biodiesel and renewable diesel would be adequate to satisfy a requirement of 19.24 billion gallons.[82] The following sections provide our preliminary assessment of ethanol and biodiesel/renewable diesel volumes.

The proposed volume requirements are based on the data available to EPA at the time of this proposal. However, we recognize that there is uncertainty related to some of this data with respect to the volume of renewable fuels that can be supplied in the United States in 2018 and the economic and environmental impacts associated with requiring renewable fuel use. We request comment on the data presented in this proposed rule, and invite commenters to submit additional data relevant to these issues. Additional data could also indicate that it would be appropriate to finalize volume requirements lower than indicated in this proposed rule, through use of either the general waiver authority in CAA section 211(o)(7)(A) or as a result of a lower projection of cellulosic biofuel production, combined with corresponding increased waivers of advanced and total renewable fuel using the cellulosic waiver authority in CAA section 211(o)(7)(D).

We note that in prior annual RFS rulemaking actions, some stakeholders have commented to EPA that the Agency should exercise its discretion to use the general waiver authority to reduce volumes to avoid severe harm to the economy or environment of a state, region, or the United States. For example, some commenters suggested that standards that would result in ethanol use beyond the blendwall would cause severe economic harm, justifying use of the general waiver authority. Additionally, as discussed in Section I.E, we also request comment on use of the general waiver authority to reduce the required volume of renewable fuel in an effort to increase the energy independence impacts of the RFS program. EPA invites comment and data on these issues, including data and analysis that would support different use of the waiver authorities than we are proposing in today's action, such as use of the general waiver authority to achieve greater reductions than proposed.

1. Ethanol

Ethanol is the most widely produced and consumed biofuel, both domestically and globally. Since the beginning of the RFS program, the total volume of renewable fuel produced and consumed in the United States has grown substantially each year, primarily due to the increased production and use of corn ethanol. However, the rate of growth in the supply of ethanol to the U.S. market has decreased in recent years as the gasoline market has become saturated with gasoline that contains 10 volume percent ethanol (E10), favorable blending economics have diminished, and efforts to expand the use of higher ethanol blends such as E15 and E85

renewable fuel would remain constant at 15 billion gallons.

[81] For instance, see public comments provided in response to the proposed 2017 standards in docket EPA–HQ–OAR–2016–0004.

[82] As noted earlier, ''reasonably attainable'' volumes may be less than the ''maximum achievable'' volumes we would seek to identify when using the general waiver authority based on a finding of inadequate domestic supply. It follows that if there are sufficient reasonably attainable volumes of renewable fuel to satisfy a total renewable fuel requirement of 19.24 billion gallons, then there is no basis for a finding that there is an inadequate domestic supply to satisfy a 19.24 billion gallon requirement.

have not been sufficient to maintain past growth rates in total ethanol supply. Although we believe that use of higher ethanol blends is growing and can continue to grow, the low number of retail stations selling these higher-level ethanol blends, along with poor price advantages compared to E10, and a limited number of flexible fuel vehicles (FFVs), among other considerations, represent challenges to the rate of growth of ethanol as a transportation fuel in the United States.

In the 2014–2016 final rule, we discussed in detail the factors that constrain growth in ethanol supply and the opportunities that exist for pushing the market to overcome those constraints.[83] That discussion generally remains relevant for 2018 just as it was relevant for 2017, though we believe that the supply of ethanol can be somewhat higher in 2018 than in 2017.

Ethanol supply is not currently limited by production and import capacity, which is in excess of 15 billion gallons.[84] Instead, the amount of ethanol supplied is constrained by the following:

- Overall gasoline use and the volume of ethanol that can be blended into gasoline as E10 (typically referred to as the E10 blendwall).
- The number of retail stations that offer higher ethanol blends such as E15 and E85.
- The number of vehicles that can both legally and practically consume E15 and/or E85.
- Relative pricing of E15 and E85 versus E10 and the ability of RINs to affect this relative pricing.
- The supply of gasoline without ethanol (E0).

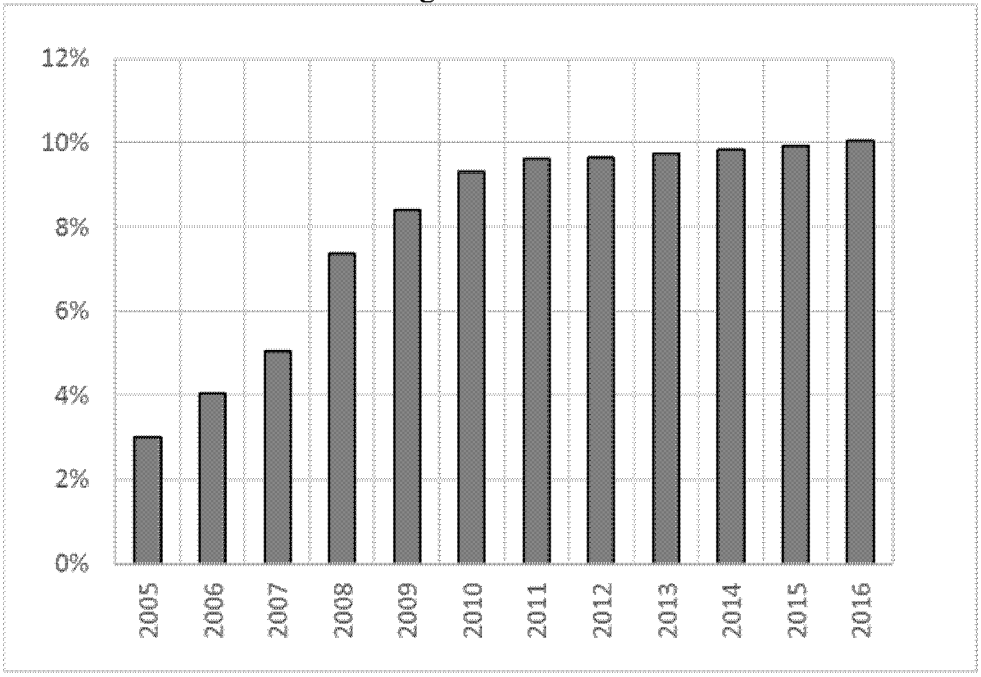
The applicable standards that we set under the RFS program provide incentives for the market to overcome many of these ethanol-related constraints.

While in the short term the RFS program is unlikely to have a direct effect on overall gasoline demand or the number of vehicles designed to use higher ethanol blends, it can provide incentives for changes in some other market factors, such as the number of retail stations that offer higher ethanol blends and the relative pricing of those higher ethanol blends in comparison to E10.

a. Ethanol Concentration in the Gasoline Pool

As stated in the 2014–2016 final rule and in the 2017 final rule, we continue to believe that there are real constraints on the ability of the market to exceed an average nationwide ethanol content of 10 percent. However, these constraints do not have the same significance at all ethanol concentrations above 10 percent. Instead, for the state of infrastructure that can be available in 2018, the constraints represent a continuum of mild resistance to growth at the first increments above 10 percent ethanol and evolve to significant obstacles at higher levels of ethanol. In short, the E10 blendwall is not the barrier that some stakeholders believe it to be, but neither are increases in poolwide ethanol concentrations above 10 percent unlimited in the 2018 timeframe. These views are demonstrated by the fact that the poolwide ethanol concentration of all gasoline increased dramatically until about 2010, after which growth has been much slower and has remained very close to 10.0 percent. In 2016, the average ethanol concentration reached 10.05 percent.[85]

Figure V.B.1-1
Historical Poolwide Average Ethanol Concentration of Gasoline



Source: EIA's Short-Term Energy Outlook

[83] 80 FR 77456–77465, December 14, 2015.

[84] ''RFA 2016 Annual Industry Outlook,'' docket EPA–HQ–OAR–2016–0004.

[85] According to the March, 2017 version of EIA's Short-Term Energy Outlook, total ethanol consumption in 2016 was 14,406 mill gal, while total gasoline consumption was 143,367 mill gal.

We continue to believe that the constraints associated with the E10 blendwall do not represent a firm barrier that cannot be crossed. Rather, the E10 blendwall marks the transition from relatively straightforward and easily achievable increases in ethanol consumption as E10 to those increases in ethanol consumption as E15 and E85 that are more challenging to achieve.

However, we also recognize that the market is not unlimited in its ability to respond to the standards we set. This is true both for expanded use of ethanol and for non-ethanol renewable fuels. The fuels marketplace in the United States is large, diverse, and complex, made up of many different players with different, and often competing, interests. Substantial growth in the renewable fuel volumes beyond current levels will require action by many different parts of the fuel market, and a constraint in any one part of the market can act to limit the growth in renewable fuel supply. Whether notable constraints are in the technology development and commercialization stages, as has been the case with cellulosic biofuels, the development of distribution infrastructure as is the case with ethanol, or in the accessibility of feedstocks as with biodiesel, the end result is that these constraints limit the annual growth rate in the availability of renewable fuel as transportation fuel, heating oil, or jet fuel. These constraints were discussed in detail in the 2014–2016 final rule and summarized in the 2017 final rule, and while the market continues to grow, we believe that the same constraints will operate to limit growth in the availability of renewable fuel in 2018 as well, both for ethanol and non-ethanol renewable fuels.[86] Other factors outside the purview of the RFS program also impact the availability of renewable fuel, including the price of crude oil and global supply and demand of both renewable fuels and their feedstocks. These factors add uncertainty to the task of estimating the attainability of renewable fuel requirements in the future.

The total volume of ethanol that can be supplied is a function of total volume of gasoline that is used, as well as the potential for sales of different ethanol fuel blends (*i.e.,* E0, E15, and E85). According to the April, 2017 version of EIA's Short-Term Energy Outlook (STEO), the Department of Energy projects that total use of gasoline energy in 2018 will be 17.198 Quadrillion Btu.[87] This is somewhat lower than the total projected gasoline energy use that we used in setting the 2017 standards. As a result, the projected volume of ethanol that can be sold as E10 in 2018 is also somewhat lower.

TABLE V.B.1.iii–1—PROJECTED GASOLINE ENERGY USE AND E10 BLENDWALL

	2017	2018
STEO edition	October, 2016	April, 2017.
Quad Btu	17.288	17.198.
Equivalent volume of E10 if there were no E0, E15, or E85	14,362	14,287.

The volumes of E15 and E85 used in the near term will continue to be primarily a function of the number of retail service stations that offer it since the number of vehicles that are legally permitted to use E15 (2001 model year and later) and E85 (flexible fuel vehicles, or FFVs) currently exceeds the retail dispensing capacity by a substantial margin. We acknowledge that a larger percentage of FFVs in the fleet could increase the volume of E85 consumed, but in the short term we believe that it is the relatively very small number of retail stations offering E85 that is operating as the primary constraint on the volumes of E85 sold, and to a lesser extent the relative price of higher ethanol blends and E10.

Growth in the number of retail stations offering E15 and/or E85 has been relatively slow, but accelerated in 2016 as a result of USDA's Biofuels Infrastructure Partnership (BIP) program and the ethanol industry's Prime the Pump program. While these grant programs have increased E15 and E85 offerings at retail, we expect the programs to be fully phased in by the end of 2017 and thus have no influence on further growth in the number of retail stations offering E15 and E85 in 2018. In the 2017 final rule, we noted that while the BIP program was intended to be fully phased in by the end of 2016, it was not expected to meet this deadline. The BIP program permits states to extend implementation by up to two additional years. Currently, we have no reason to believe that the BIP program will not be fully implemented by the end of 2017; indeed, this was our assumption in projecting attainable volumes in the context of the 2017 final rule. Similarly, the Prime the Pump program was expected to complete all projects by the end of 2017.

b. Assessment of E0 in the Gasoline Pool

For the 2016 and 2017 standards, we based the total renewable fuel volume requirement in part on the expectation that the RFS program would result in all but a tiny portion—estimated at 200 million gallons—of gasoline to contain at least 10 percent ethanol. We based this determination on the fact that higher volume requirements would provide an incentive for the market to transition from E0 to E10 and other higher level ethanol blends through the RIN mechanism, but that recreational marine engines represented a market segment that we believed would be particularly difficult to completely transition from E0 since they are used in a water environment where there is a greater potential for water contamination of the fuel.

While we continue to believe that the market is capable of reaching a point wherein all but about 200 million gallons contains some amount of ethanol, we note that this did not occur in 2016 despite the fact that the 2016 standards were based in part on the expectation that it would occur. As described in a memorandum to the docket, we now estimate that the volume of E0 used in 2016 was about 500 million gallons.[88] While this is considerably less than the historical volumes of E0 cited by some stakeholders in response to the proposed 2016 standards, it does suggest that the market chose to respond to the 2016 standards by increasing the use of non-ethanol renewable fuels such as biodiesel rather than by reducing E0 use down to 200 million gallons. We do

[86] See 80 FR 77450 (December 14, 2015) and 81 FR 89774 (December 12, 2016).

[87] Derived from Table 4a of the STEO, converting consumed gasoline and ethanol projected volumes into energy using conversion factors supplied by EIA. Excludes gasoline consumption in Alaska. For further details, see ''Calculation of proposed % standards for 2018'' in docket EPA–HQ–OAR–2017–0091.

[88] ''Estimate of E0 use in 2016,'' memorandum from David Korotney to docket EPA–HQ–OAR–2017–0091.

not yet have adequate information about the use of E0 in 2017, but we believe it is reasonable to adjust our approach to estimating the volume of ethanol that is reasonably attainable in 2018 to account for the likely market response to the applicable standards in terms of E0 volumes.

c. Ethanol Supply Volume for Assessment of Total Renewable Fuel

Given that the BIP and Prime the Pump grant programs are expected to be fully phased in by the end of 2017, we expect less growth in E15 and E85 supply in 2018 than in 2017. Moreover, any growth in ethanol use due to higher volumes of E15 and E85 may be offset by a higher volume of E0 as discussed above in terms of total ethanol supply. For example, a 40 million gallon increase in the volume of E85 supplied in 2018 could be offset by a 250 million gallon increase in the volume of E0 supplied.[89] Therefore, for the purposes of determining whether 19.24 billion gallons of renewable fuel is reasonably attainable in 2018, we believe that it would be appropriate to assume that the poolwide ethanol concentration would be the same in 2018 as the level used in the determination of the final 2017 standards. This level was 10.13 percent.[90] Based on the projected 2018 gasoline energy use shown in Table V.B.1.iii–1, this ethanol concentration would correspond to 14,479 million gallons of ethanol in 2018.[91]

The market will ultimately determine the extent to which compliance with the annual standards is achieved through the use of greater volumes of ethanol versus other, non-ethanol renewable fuels. We nevertheless believe that while the market could supply a volume of ethanol greater than 14,479 million gallons, this volume represents a reasonably attainable level of ethanol supply in 2018 that takes into account the constraints to fuel supply that we have noted. For the final rule, we intend to use an updated version of the STEO as well as a more detailed assessment of the volumes of E15 and E85 that may be reasonably attainable in 2018.

As described in the 2017 final rule, we do not believe that setting the applicable standards at levels exceeding those we believe to be reasonably attainable would result in dramatic increases in the number of additional retail stations offering E15 or E85 in 2018 beyond those that may be upgraded through independent efforts.[92] We do not believe, for instance, that the core concerns retailers have with liability over equipment compatibility and misfueling for E15 would change if the RFS volume requirements were increased significantly. Similarly, while higher RFS volume requirements could make it incrementally more attractive for retailers to upgrade infrastructure to offer E15, the concerns they have expressed in the past about high capital costs and opportunities for return on their investment would remain. With regard to E85, we continue to believe that the full value of the RIN is not passed through to retail fuel prices, diluting the influence that the RFS program would otherwise have on E85 sales.[93] Moreover, in light of these constraints on RIN pass-through and the unpredictability of crude oil prices, many retailers are concerned about the return on investment for the substantial capital costs required for retail stations to offer E85. Notably, as pointed out in the 2017 final rule, some retail station owners who had offered E85 have stopped doing so as a result of poor sales, despite the annual increases in the RFS standards in previous years.[94]

2. Biodiesel and Renewable Diesel

While the market constraints on ethanol supply are relatively well understood, it is more difficult to identify and assess the market components that may limit potential growth in the use of all qualifying forms of biodiesel and renewable diesel in 2018. Therefore, as discussed in the introduction to Section V.B, after estimating the supply of ethanol in 2018, and taking into account the estimates of non-ethanol cellulosic biofuel supply discussed in Section III.D and estimates of other non-ethanol renewable fuel supply discussed in Section IV.B.3, we considered whether the supply of total biodiesel and renewable diesel would be adequate to satisfy the remainder of the volume needed to achieve a requirement of 19.24 billion gallons.

In Section V.A we described how use of the cellulosic waiver authority to provide a volume reduction for total renewable fuel that equals that provided for advanced biofuels yields a volume of 19.24 billion gallons. In addition to the ethanol volume discussed in Section V.B.1.iv above, cellulosic biogas can also contribute to this total volume of renewable fuel, as described more fully in Section III.C. While other renewable fuels such as naphtha, heating oil, butanol, and jet fuel can be expected to continue growing in 2018, collectively, we expect them to contribute considerably less than ethanol and biodiesel/renewable diesel to the total volume of renewable fuel supplied in 2018. These fuels were discussed in Section IV.B.3. Based on these estimates, about 2.9 billion gallons of biodiesel and renewable diesel, including both advanced and conventional biodiesel and renewable diesel, would be needed in order to meet a total renewable fuel volume requirement of 19.24 billion gallons (see Table V.B.2–1 below).

TABLE V.B.2–1—DETERMINATION OF VOLUME OF BIODIESEL AND RENEWABLE DIESEL NEEDED IN 2018 TO ACHIEVE 19.24 BILLION GALLONS OF TOTAL RENEWABLE FUEL

[Million ethanol-equivalent gallons except as noted]

Total renewable fuel volume	19,238
Ethanol	14,479
Non-ethanol cellulosic biofuel	223
Other non-ethanol renewable fuels [a]	40
Biodiesel and renewable diesel needed (ethanol-equivalent volume/physical volume)	4,496/2,901

[a] Includes naphtha, heating oil, butanol, and jet fuel. See further discussion in Section IV.B.3.

A starting point in developing a projection of the attainable supply of biodiesel and renewable diesel in 2018 is a review of the volumes of these fuels supplied for RFS compliance in previous years. In examining the data, both the absolute volumes of the supply of biodiesel and renewable diesel in previous years, as well as the rates of growth between years are relevant considerations. The volumes of biodiesel and renewable diesel (including D4, D5, and D6 biodiesel and renewable diesel) supplied each year from 2011 through 2016 are shown below, along with the volume of these fuels projected for 2017 in the 2017 final rule.

[89] Alternatively, a 250 million gallon increase in the volume of E0 supplied could be offset by a 500 million gallon increase in the volume of E15 supplied or an increase of 17 million gallons of biodiesel supplied.

[90] 14,561 million gallons of ethanol in 143,683 million gallons of gasoline. See Table V.B.1.iv–1, 81 FR 89780.

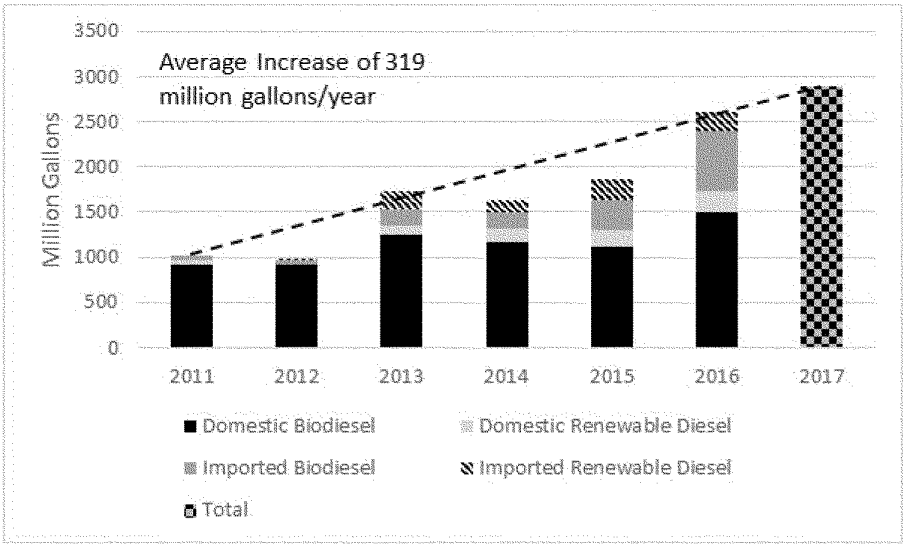
[91] We note that the purpose of our analysis here is to establish an amount of ethanol that is reasonably attainable to be supplied as transportation fuel. To the extent stakeholders believe higher amounts can be supplied, that would simply confirm our decision not to exercise the general waiver authority on the ground of inadequate domestic supply.

[92] For instance, see 81 FR 89779, December 12, 2016.

[93] See more detailed discussion in Section 2.3.8 of the Response to Comments document for the 2017 final rule (EPA–HQ–OAR–2016–0004).

[94] See 81 FR 89778, December 12, 2016.

Figure V.B.2-1
Biodiesel and Renewable Supply by Year (2011-2017)[a]



[a] Values represent current estimates of the net supply of biodiesel and renewable diesel (including conventional, advanced, and BBD biodiesel and renewable diesel) from EMTS, accounting for the production, import, and export of biodiesel and renewable diesel. 2017 supply is based on the projections for 2017 in the 2017 final rule

After examining the historical data (shown in the figure above) we believe it is very likely that there will be a sufficient supply of biodiesel and renewable diesel (volumes at least as high as 2.9 billion gallons) in 2018 to meet the total renewable fuel volume requirement after exercising the cellulosic waiver authority. Indeed, there would be sufficient supply of biodiesel and renewable diesel to meet the 2018 total renewable fuel volume requirement after using the cellulosic waiver authority even if there was no increase in the supply of these fuels from 2017 to 2018. Alternatively, even if the supply of biodiesel and renewable diesel in 2017 falls short of the projected supply from the 2017 final rule, an increase in supply from 2016 to 2018 equal to the average annual supply increase observed from 2011–2016 would be sufficient to meet the total renewable fuel requirement for 2018 after using the cellulosic waiver authority.

In assessing the probative value of historical data on the supply of biodiesel and renewable diesel, we must also consider the extent to which historic supply and growth rates can be seen as representing what is possible with the RFS standards and other incentives in place. The years with the highest historic growth rates (2013 and 2016) were years in which both tax incentives and RFS incentives were in place to incentivize growth through the entire year.[95] While the biodiesel blenders tax credit expired at the end of 2016, we believe it is reasonable to assume the incentives provided by the RFS standards in 2017 and 2018 will be sufficient to enable the supply of biodiesel and renewable diesel to reach 2.9 billion gallons in 2018 despite the current absence of the tax credit. The absence of the tax credit would be expected to have two primary potential impacts on the supply of biodiesel and renewable diesel in 2018; lower imported volumes of biodiesel and renewable diesel and a lesser economic incentive for blenders and retailers to offer fuel blends containing biodiesel and renewable diesel (which could potentially impact both domestic and foreign biodiesel and renewable diesel producers). Imported volumes of these fuels could be impacted if the loss of the economic incentive previously provided by the tax credit results in other markets offering higher value to potential importers of biodiesel and renewable diesel than the United States.[96] Similarly, the loss of the tax credit could impact the ability for blenders and retailers of biodiesel and renewable diesel blends to offer these fuels at prices that are competitive with petroleum diesel. We note, however, that these potential impacts of the loss of the tax credit could be offset, in whole or in part, by rising RIN values associated with biodiesel and renewable diesel. We believe the most likely impact of the absence of the tax credit will be a decrease in the rate of growth of the supply of biodiesel and renewable diesel to the United States in 2017 and 2018, rather than an absolute decrease in the supply of these fuels.[97]

Ultimately, we believe the historic data provides a reasonable guide for assessing the potential growth of advanced biodiesel and renewable diesel in 2018. We recognize that there

[95] While the rule finalizing the 2013 RFS RVOs was not finalized until August 2013, EPA announced the proposed volume requirements for 2013 in January 2013. EPA did not propose to use our waiver authorities to reduce the statutory advanced or total renewable fuel volume requirements. We believe the market anticipated the final RVOs in 2013 and responded accordingly.

[96] While this could also impact domestic producers, leading some to consider exporting the biodiesel or renewable diesel they produce to foreign markets. Domestic producers, however, would have to amend their current distribution systems to enable them to supply fuel to foreign markets, while parties that are currently importing biodiesel and renewable diesel to the United States must simply divert the deliveries to new destinations.

[97] The most recent years in which the biodiesel tax credit was not available during the year in which it applied were 2014 and 2015. The total supply of biodiesel and renewable diesel decreased by 98 million gallons from 2013 to 2014 and then increased by 221 million gallons from 2014 to 2015, averaging an increase of approximately 100 million gallons over these two years. We also note that the RVOs for 2014 and 2015 were not finalized until December 2015. We believe that it is reasonable to project that the supply of biodiesel and renewable diesel could increase by at least this amount (100 million gallons per year) from 2017 to 2018 without the biodiesel tax credit, but with the 2018 RFS requirements in place to incentivize the necessary supply.

are limitations in the probative value of past growth rates to assess what can be done in the future, however we believe there is significant value in considering historical data, especially in cases where the future growth rate is expected to be largely determined by the same variety of complex and interdependent factors that have factored into historical growth, as is the case for 2018.

In the 2017 final rule EPA assessed a number of factors that could potentially constrain the supply of biodiesel and renewable diesel to the United States. The list of factors considered included feedstock availability, the capacity of the market to produce, import, and distribute biodiesel and renewable diesel, the retail infrastructure capacity, the ability for the market to consume biodiesel and renewable diesel in approved engines, and consumer response. We noted that in each of these areas there are challenges that will need to be overcome to enable the continued growth in the supply of biodiesel and renewable diesel in the United States, but nevertheless concluded that the market was capable of supplying 2.9 billion gallons of biodiesel and renewable diesel (including both advanced and conventional biodiesel and renewable diesel) to the United States in 2017.[98] The global supply of feedstocks projected to be available for biodiesel and renewable diesel production significantly exceeds the quantity necessary to produce 2.9 billion gallons of biodiesel and renewable diesel.[99] Similarly, an assessment of the production capacity of registered biodiesel and renewable diesel production facilities conducted for the 2017 final rule demonstrates that there is sufficient production capacity to produce 2.9 billion gallons of biodiesel and renewable diesel in 2018.[100] Finally, we believe that there will be sufficient infrastructure in place to enable the distribution, sale, and use of 2.9 billion gallons of biodiesel and renewable diesel in 2018. Comments received from the National Biodiesel Board, as well as from the National Association of Truck Stop Owners (which represents parties with significant experience and investment in the distribution and sales of biodiesel) on our 2017 proposed rule support this projection, suggesting that parties have already begun making the necessary investments to distribute and sell the volumes of biodiesel and renewable diesel necessary to meet the required volume of total renewable fuel in 2017 (and thus 2018), after exercising the cellulosic waiver authority.[101]

Since finalizing the 2017 rule, EPA has continued to monitor the development of the biodiesel and renewable diesel industry, including the ability for the market to produce/import, distribute, and consume these fuels. Based on the data available to EPA at this time, including data considered in the 2017 final rule, we believe that the market is capable of producing, distributing, and using 2.9 billion gallons of biodiesel and renewable diesel in 2018. EPA is unaware of any information that would lead us to conclude that our assessment that the biodiesel and renewable diesel market is capable of supplying 2.9 billion gallons to the United States in 2017 is no longer reasonable, nor are we aware of any factors (other than the absence of the biodiesel blenders tax credit) that will likely negatively impact the ability for the market to supply biodiesel and renewable diesel in 2018 relative to 2017. We therefore do not see any significant marketplace impediments that are likely to prevent the supply of 2.9 billion gallons of biodiesel and renewable diesel in 2018 and believe that despite the loss of the biodiesel blenders tax credit the 2.9 billion gallon supply of biodiesel and renewable diesel projected to be available in 2017 can also be supplied in 2018.

We recognize that the market may not necessarily respond to the proposed total renewable standard by supplying exactly 2.9 billion gallons of biodiesel and renewable diesel to the transportation fuels market in the United States in 2018, but that the market may instead supply a lower or higher volume of biodiesel and renewable diesel with corresponding changes in the supply of other types of renewable fuel. As a result, we believe there is less uncertainty with respect to the attainability of the total volume requirement of 19.24 billion gallons than there is concerning the projected 2.9 billion gallons of biodiesel and renewable diesel that we have used in determining the adequacy of supply of total renewable fuel for 2018.

3. Total Renewable Fuel Supply

In Section V.A we described how use of the cellulosic waiver authority to provide a volume reduction for total renewable fuel that equals that provided for advanced biofuels yields a volume of 19.24 billion gallons. Based on our assessment of supply of ethanol and biodiesel/renewable diesel, along with smaller amounts of non-ethanol cellulosic biofuel and other non-ethanol renewable fuels, we believe that a total of 19.24 billion gallons of renewable fuel is reasonably attainable in 2018. As a result, we do not propose any further reductions on the basis of an ''inadequate domestic supply'' using the general waiver authority.

Our use of the cellulosic waiver authority alone to set the advanced biofuel and total renewable fuel volume requirements would result in an implied volume for non-advanced (*i.e.,* conventional) renewable fuel of 15.0 billion gallons. This would be equal to the statutory implied volume for 2018. We anticipate that this volume would be comprised primarily of corn-ethanol with lesser amounts of conventional biodiesel and renewable diesel. As shown in Table V.B.1.iii–1, the volume of ethanol that can be consumed as E10 in 2018 is projected to be 14.29 billion gallons. Thus, the implied volume for

[98] 81 FR 89781, December 12, 2016.

[99] A study conducted by LMC International in 2016 projected the global availability of feedstocks for use in advanced biodiesel and renewable diesel production would be sufficient to produce approximately 9.2 billion gallons of these fuels in 2018. The OECD–FAO Agricultural Outlook 2016–2025 estimated global biodiesel production at approximately 8.8 billion gallons in 2016, rising to 9.3 billion gallons in 2018. This suggests that the 2.6 billion gallons of biodiesel and renewable diesel consumed in the U.S. in 2016 (according to EMTS data) was approximately 30% of the global supply of these fuels. 30% of the 9.3 billion gallons of biodiesel and renewable diesel projected to be produced in 2018 (or the 9.2 billion gallons based on projected available feedstocks from the LMC international projection) is approximately 2.8 billion gallons. We believe the RFS program is capable of the marginal increase in U.S. consumption of the global biodiesel supply necessary to supply 2.9 billion gallons of biodiesel to the United States in 2018. While we believe some of the assumptions made by LMC International in this study were overly optimistic and the study did not project the quantity of these feedstocks available to supply the U.S. biodiesel and renewable diesel markets, we nevertheless believe this study, along with other information reviewed in preparing the 2017 final rule, demonstrate that sufficient feedstocks will be available in 2018 to supply 2.9 billion gallons of biodiesel and renewable diesel to the United States (See 81 FR 89767–89769, December 12, 2016, for a further discussion of the availability of biodiesel and renewable diesel feedstocks).

[100] ''Biodiesel and Renewable Diesel Registered Capacity (October 2016)'', Memorandum from Dallas Burkholder to EPA Docket EPA–HQ–OAR–2016–0004. In this assessment we determined that biodiesel and renewable diesel production capacity at registered facilities in the United States was approximately 4.2 billion gallons. Registered production capacity of biodiesel and renewable diesel facilities in the United States that generated RINs in 2015 or 2016 was approximately 3.1 billion gallons, and actual supply of biodiesel and renewable diesel from these facilities in 2016 was approximately 1.72 billion gallons. Significant additional production capacity also exists at registered biodiesel and renewable diesel production facilities outside of the United States.

[101] See testimony of Michael Whitney, Musket Corporation, June 9, 2016 (Chicago Room), comments from NATSO (EPA–HQ–OAR–2016–0004–1830), comments from NBB (EPA–HQ–OAR–2016–0004–2904), and comments from REG (EPA–HQ–OAR–2016–0004–3477). A fuller discussion of these comments is contained in the 2017 final rule (81 FR 89746, December 12, 2016).

conventional renewable fuel would exceed this value by 0.71 billion gallons.[102]

C. Market Responses to the Advanced Biofuel and Total Renewable Fuel Volume Requirements

Because the transportation fuel market is dynamic and complex, and the RFS standards that we set can be satisfied through use of a wide variety of renewable fuels, we cannot precisely predict the mix of different fuel types that will result from the standards we are proposing. In this section we describe a range of possible outcomes, and doing so provides a means of demonstrating that the proposed standards can reasonably be satisfied through multiple possible paths.

We evaluated a number of scenarios with varying levels of E0, E15, E85, imported sugarcane ethanol, advanced biodiesel and renewable diesel, and conventional biodiesel and renewable diesel. In doing so we sought to capture a reasonable range of possibilities for each individual source, based both on levels achieved in the past and how the market might respond to the applicable standards. Each of the rows in Table V.C–1 represents a scenario in which the proposed total renewable fuel and advanced biofuel standards would be satisfied.

TABLE V.C–1—VOLUME SCENARIOS ILLUSTRATING POSSIBLE COMPLIANCE WITH THE PROPOSED 2018 VOLUME REQUIREMENTS

[Million gallons] [a] [b]

E85	E15	E0	Total ethanol [c]	Sugarcane ethanol	Total biodiesel and renewable diesel [d]	Minimum volume of advanced biodiesel and renewable diesel [d]
200	600	200	14,430	0	2,934	2,543
200	600	500	14,399	0	2,954	2,543
200	600	500	14,399	100	2,954	2,479
200	600	500	14,399	300	2,954	2,350
200	600	500	14,399	500	2,954	2,221
200	1,200	200	14,461	300	2,914	2,350
350	600	500	14,498	500	2,890	2,221
350	1,200	200	14,560	0	2,850	2,543
350	1,200	200	14,560	100	2,850	2,479
350	1,200	200	14,560	300	2,850	2,350
350	1,200	200	14,560	500	2,850	2,221
350	1,200	500	14,529	100	2,870	2,479

[a] Assumes for the purposes of these scenarios that supply of other advanced biofuel other than imported sugarcane ethanol, BBD, and renewable diesel (*e.g.,* domestic ethanol, heating oil, naphtha, etc.) is 60 mill gal, and that the cellulosic biofuel proposed volume requirement is 238 mill gal, of which 15 mill gal is ethanol and the remainder is primarily biogas.

[b] Biodiesel + renewable diesel is given in physical gallons, and can be converted into ethanol-equivalent gallons by multiplying by 1.55. Other categories are given as ethanol-equivalent volumes.

[c] For the range of total ethanol shown in this table, the poolwide average ethanol content would range from 10.08% to 10.18%.

[d] Includes supply from both domestic producers as well as imports.

The scenarios in the tables above are not the only ways that the market could choose to meet the total renewable fuel and advanced biofuel volume requirements that we are establishing in this action. Indeed, other combinations are possible, with volumes higher than the highest levels we have shown above or, in some cases, lower than the lowest levels we have shown. The scenarios above cannot be treated as EPA's views on the only, or even most likely, ways that the market may respond to the proposed 2018 volume requirements. Instead, the scenarios are merely illustrative of the various ways that it could play out. Our purpose in generating the list of scenarios above is only to illustrate a range of possibilities which demonstrate that the standards we are establishing in this action can reasonably be met.

We continue to believe, as we stated in previous rulemakings, that it would be inappropriate to construct a new scenario based on the highest or lowest volumes in each category that are shown in the table above. Thus, for instance, while every scenario in Table V.C–1 represents 4.24 billion gallons of advanced biofuel and 19.24 billion gallons of total renewable fuel, combining the lowest volume of E0 shown in the table with the highest volumes of E15, E85, sugarcane ethanol, total biodiesel and renewable diesel, and advanced biodiesel and renewable diesel shown in the table, would result in 4.74 billion gallons of advanced biofuel and 19.40 billion gallons of total renewable fuel. We do not believe that such volumes would be reasonably attainable for 2018. Conversely, combining the highest volume of E0 shown in the table with the lowest volumes of E15, E85, sugarcane ethanol, total biodiesel and renewable diesel, and advanced biodiesel and renewable diesel shown in the table, would result in 3.74 billion gallons of advanced biofuel and 19.08 billion gallons of total renewable fuel. Such volumes would be below the levels that we believe are reasonably attainable to require in 2018. We have more confidence in the ability of the market to attain the proposed volume requirements for advanced biofuel and total renewable fuel than we have in the ability of the market to achieve a specific level of, say, biodiesel, or E85.

With regard to E85, under highly favorable conditions related to growth in the number of E85 retail stations, retail pricing, and consumer response to that pricing, it is possible that E85 volumes as high as 350 million gallons could be reached. For instance, growth

[102] We note, however, that some volume of advanced ethanol is expected to be used in 2018. This additional volume of implied conventional biofuel above the volume of ethanol that can be supplied as E10 (less any advanced ethanol used in 2018) could be met with any combination of E15, E85, biodiesel, and renewable diesel.

in the number of retail stations offering E85 may increase more rapidly than historical rates following the completion of USDA's BIP grant program and the ethanol industry's Prime the Pump program (both of which we have assumed will be fully phased in by the end of 2017). If so, the total number of retail stations offering E85 could perhaps increase from about 3,100 today to more than 5,000 in 2018. Also, it is possible that increases in the price of D6 RINs since the release of the 2017 final rule can help to increase the E85 price discount relative to E10 if producers and marketers of E85 pass on more of the value of the RIN to the prices offered to customers at retail, providing greater incentive to FFV owners to refuel with E85 instead of E10. Under such circumstances, an E85 price discount as high as 30 percent might be possible. Indeed, E85 price discounts this high have been reached in the past in some locales.[103] Efforts to increase the visibility of E85, including expanded marketing and education, can also help to increase E85 sales. Sales volumes of E85 higher than 400 million gallons are very unlikely, but are possible if pump installations increase significantly and the market can overcome constraints associated with E85 pricing at retail and consumer responses to those prices.

Similarly, under favorable conditions, it is possible that E15 volumes as high as 1,200 million gallons could be reached in 2018 as shown in Table V.D–1. This volume could be reached through some combination of different changes such as the following:

- Following the conclusion of the BIP program and Prime the Pump program, it is possible that the growth rate for retail stations offering E15 could be higher than historical rates, potentially reaching as high as 2,700 in 2018 (average for the year).
- Sales of E15 could be as high as 50 percent of all gasoline sales at stations selling both E10 and E15 under favorable pricing conditions rather than the 15 percent we assumed in the 2017 final rule, based on limited data from Iowa.
- Additional terminals could produce E15 in 2018 beyond those that are expected to do so in 2017.[104]

As the table above illustrates, the volume requirements could result in the consumption of 2.95 billion gallons of biodiesel and renewable diesel in 2018. This level is less than our estimate of the production capacity for all registered domestic biodiesel and renewable diesel production facilities, though slightly higher than the 2.9 billion gallons that we used in the context of determining whether a total renewable fuel volume requirement of 19.24 billion gallons in 2018 would be reasonably attainable. Given the necessarily imprecise nature of our estimate of the ability of the market to supply about 2.9 billion gallons of biodiesel and renewable diesel for purposes of meeting a total renewable fuel volume requirement of 19.24 billion gallons in 2018, volumes as high as 2.95 billion gallons and potentially higher are possible.

Finally, out of the maximum of about 2.9 billion gallons of biodiesel and renewable diesel shown in Table V.C–1, 2.54 billion gallons could be advanced biodiesel. While this is slightly higher than the 2.5 billion gallons that we used in determining the advanced biofuel volume requirement, it could be supplied from current biodiesel and renewable diesel domestic production capacity,[105] though this would possibly involve additional feedstock switching as discussed in Section IV.

D. Impacts of 2018 Standards on Costs

1. Illustrative Cost Savings Associated With Reducing Statutory Cellulosic Volumes

To provide an illustrative estimate of the cost of the proposed 2018 RFS volume requirements, EPA has compared the proposed 2018 volume requirements to the statutory volume that would be required absent the exercise of our cellulosic waiver authority under CAA section 211(o)(7)(D)(i) to reduce the applicable volume of cellulosic biofuel.[106] As described in other sections of this proposed rule, we believe that the additional 6.76 billion gallons of cellulosic biofuel envisioned by the statute will not be produced in 2018. Therefore, estimating costs of this volume reduction is inherently challenging. However, we have taken the relatively straightforward methodology of multiplying the per-gallon costs associated with the volumes that would be required under this proposal by the amount of cellulosic renewable fuel proposed to be waived. This comparison results in a cost savings estimated to be at least $6.2–$11.8 billion.

To estimate the overall cost savings from waiving the cellulosic renewable fuel volumes, EPA has taken the following steps. First, EPA determined the magnitude of the volume reduction of cellulosic biofuel we are proposing in this rule, relative to the statutory volume. In this rule we are proposing to reduce the required volume of cellulosic biofuel by approximately 6.76 billion gallons, with corresponding reductions in the advanced biofuel and total renewable fuel standards. Second, we estimated the per gallon costs of producing cellulosic ethanol derived from corn kernel fiber that would be expected in complying with the proposed standards. Third, the per gallon costs of cellulosic biofuel from corn fiber were multiplied by the volume of cellulosic renewable fuels being waived from the statutory levels to the proposed cellulosic renewable fuel volumes.[107]

While there may be growth in other cellulosic sources, for this exercise we believe it is appropriate to use corn kernel fiber as the representative cellulosic renewable fuel since the majority of liquid cellulosic biofuel in 2018 is expected to be produced using this technology. The application of this technology in the future could result in significant incremental volumes of cellulosic biofuel. In addition, as explained in Section III, we believe that production of the major alternative cellulosic biofuel—CNG/LNG derived from biogas—is likely to plateau eventually due to a limitation in the number of vehicles capable of using this form of fuel. To estimate the per gallon costs of corn kernel fiber ethanol, we focus on wholesale level costs. These cost estimates do not consider taxes, retail margins, or other costs or transfers that occur at or after the point of blending (transfers are payments within

[103] For instance, data from the Fuels Institute indicates that 3% of E85 price discounts were above 30% at surveyed retail stations in 2015.

[104] HWRT Oil Company intends to eventually offer E15 from 17 additional terminals in addition to the four announced on July 19, 2016. ''HWRT & RFA Announce First-Ever Offering of Pre-blended E15,'' docket EPA–HQ–OAR–2016–0004.

[105] ''Biodiesel and Renewable Diesel Registered Capacity (October 2016)'', Memorandum from Dallas Burkholder to EPA Docket EPA–HQ–OAR–2016–0004. In this assessment we determined that biodiesel and renewable diesel production capacity at registered facilities in the United States was approximately 4.2 billion gallons. Registered production capacity of biodiesel and renewable diesel facilities in the United States that generated RINs in 2015 or 2016 was approximately 3.1 billion gallons, and actual supply of biodiesel and renewable diesel from these facilities in 2016 was approximately 1.72 billion gallons. Significant additional production capacity also exists at registered biodiesel and renewable diesel production facilities outside of the United States.

[106] EPA is also using its discretion to reduce the advanced biofuel and total renewable fuel requirements using the cellulosic waiver authority. This discretionary action is based partially on the costs of advanced biofuels and provides additional cost savings.

[107] The cost estimates for cellulosic biofuel provided in this section are primarily intended to provide a cost estimate for this rule. The proposed cellulosic biofuel standard is based on EPA's projection of cellulosic biofuel production in 2018.

society and are not additional costs). We do not attempt to estimate potential cost savings related to avoided infrastructure costs (*e.g.,* the cost savings of not having to provide pumps and storage tanks associated with higher-level ethanol blends). When estimating per gallon costs, we consider the costs of ethanol on an energy equivalent basis to gasoline (*i.e.,* per energy equivalent gallon), since more ethanol gallons must be consumed to go the same distance as gasoline due to the ethanol's lower energy content.

Table V.D–1 below presents the cost savings associated with this proposed rule.[108] The statutory cellulosic volume set in EISA for 2018 is seven billion gallons (ethanol equivalent). The proposed cellulosic volume requirement for this annual rule is 238 million gallons (ethanol equivalent). The amount of cellulosic renewable fuels being waived is approximately 6.76 billion gallons (ethanol equivalent), or approximately 4.51 billion gallons on a gasoline equivalent basis. The per-gallon cost difference estimates for cellulosic ethanol ranges $1.37–$2.62 gallon on a gasoline equivalent basis, compared to gasoline.[109] Multiplying those per-gallon cost differences by the amount of cellulosic biofuel waived in this proposed rule, 4,510 million gallons of gasoline equivalent, results in approximately $6.2–$11.8 billion in cost savings.

TABLE V.D–1—IMPACTS OF THE DIFFERENCE BETWEEN EISA VOLUMES FOR THE CELLULOSIC BIOFUEL STANDARD AND PROPOSED CELLULOSIC VOLUME IN 2018

	2018 EISA cellulosic volume standard	2018 Proposed cellulosic volume
Cellulosic Volume Required (Million Ethanol-Equivalent Gallons) [110]	7,000	238
Change in Required Cellulosic Biofuels (Million Gallons as Ethanol)		(6,762)
GGE [111]		*(4,510)*
Cost Difference Between Cellulosic Corn Fiber-Derived Ethanol and Gasoline Per Gallon ($/GGE) [112]		$1.37–$2.62
Estimated Cost Difference in Meeting Cellulosic Biofuel Volume (Billion $) [113]		$(6.2)–$(11.8)

2. Illustrative Cost Analysis Using the 2017 Baseline

We recognize that for the purpose of estimating the cost of the proposed 2018 RFS volume requirements that a number of different scenarios using different ''baselines'' would be of interest to stakeholders. Therefore, in this section we are also providing an illustrative cost analysis that shows the costs as compared to those associated with the preceding year's standard, which as discussed in section IV.C. is a reduction of 40 million gallons of advanced biofuel in comparison to 2017.[114]

It is important to note that these ''illustrative costs'' do not attempt to capture the full impacts of this proposed rule. These estimates are provided solely for the purpose of showing how the cost to produce a gallon of a ''representative'' renewable fuel compares to the cost of petroleum fuel. There are a significant number of caveats that must be considered when interpreting these cost estimates. There are a number of different feedstocks that could be used to produce biofuels, and there is a significant amount of heterogeneity in the costs associated with these different feedstocks and fuels. Some renewable fuels may be cost competitive with the petroleum fuel they replace; however, we do not have cost data on every type of feedstock and every type of fuel. Therefore, we do not attempt to capture this range of potential costs in our illustrative estimates.

The annual standard-setting process encourages consideration of the RFS program on a piecemeal (*i.e.,* year-to-year) basis, which may not reflect the full, long-term costs and benefits of the program. For the purposes of this proposed rule, EPA did not quantitatively assess other direct and indirect costs or benefits of changes in renewable fuel volumes such as infrastructure costs, investment, GHG emissions and air quality impacts, or energy security benefits, which all are to some degree affected by the annual standards. While some of these impacts were analyzed in the 2010 final rulemaking that established the current RFS program, we have not analyzed these impacts for the 2018 volume requirements. We framed the analyses we have performed for this proposed rule as ''illustrative'' so as not to give the impression of comprehensive estimates.

EPA is providing an illustrative cost analysis for the proposed reduction in the overall advanced biofuel volume of 40 million ethanol equivalent gallons using four different scenarios, assuming this reduction in advanced biofuel volumes is comprised of (1) cellulosic biofuel from CNG/LNG, (2) cellulosic biofuel from corn kernel fiber, (3) soybean oil BBD, or (4) sugarcane ethanol from Brazil. Showing the illustrative costs of soybean oil BBD and sugarcane ethanol is consistent with the methodology EPA developed for previous rulemakings. Since EPA has also developed per gallon cost estimates for corn kernel fiber ethanol and cellulosic biofuel from CNG/LNG, we are also including costs for these hypothetical scenarios for informational purposes. However, this discussion should not be interpreted as suggesting that the various renewable fuel types discussed are necessarily available in the marketplace. The availability of different types of renewable fuel is discussed in other sections of this preamble; in this section we assess costs

[108] Details of the data and assumptions used can be found in a Memorandum available in the docket entitled ''Cost Impacts of the Proposed 2018 Annual Renewable Fuel Standards'', Memorandum from Michael Shelby, Dallas Burkholder, and Aaron Sobel to EPA Docket EPA–HQ–OAR–2017–0091.

[109] For the purposes of the cost estimates in this Section EPA has not attempted to adjust the price of the petroleum fuels to account for the impact of the RFS program. Rather, we have simply used the wholesale price projections for gasoline and diesel as reported in EIA's STEO.

[110] Overall fuel volumes may not match due to rounding.

[111] Gasoline gallon equivalent; due to the difference in energy content between ethanol and gasoline, one gallon of ethanol is energy-equivalent to approximately 67% of a gallon of gasoline; 6,762 million gallons of ethanol is energy-equivalent to approximately 4,510 million gallons of gasoline.

[112] Approximate costs are rounded to the cents place.

[113] Approximate costs are rounded to the first decimal place.

[114] There is also a reduction of 40 million gallons in the proposed 2018 applicable volume of total renewable fuel as compared to the 2017 volume. However, in light of the nested standards, that reduction is entirely attributable to the reduction in the advanced volume.

as if the different fuel types are available, without intending to suggest that they are.

In previous annual RFS rules, EPA provided an illustrative cost estimate for the entire change in the total renewable fuel volume standard assuming it was satisfied with conventional (*i.e.,* non-advanced) corn ethanol. As there is no proposed change in the 2018 conventional volume relative to the 2017 volume, all of the changes in both the advanced and total renewable fuel volumes are properly attributed to advanced biofuel.

As described earlier, we are focusing on the wholesale level in our cost scenarios, and do not consider taxes, retail margins, additional infrastructure, or other costs or transfers that occur at or after the point of blending. More background information on this section, including details of the data sources used and assumptions made for each of the scenarios, can be found in a Memorandum available in the docket.[115]

Table V.D–2 below presents estimates of per energy-equivalent gallon costs for producing soybean biodiesel, Brazilian sugarcane ethanol, CNG/LNG derived from landfill biogas, and cellulosic ethanol derived from corn fiber relative to the petroleum fuels they replace at the wholesale level. For each of the four scenarios, these per gallon costs are then multiplied by the 40 million ethanol-equivalent gallon reduction in the proposed 2018 advanced standard relative to the previous 2017 standard to obtain an overall cost estimate.

TABLE V.D–2—ILLUSTRATIVE COSTS OF THE PROPOSED 40 MILLION GALLON REDUCTION TO THE ADVANCED BIOFUEL VOLUME REQUIREMENTS IN 2018 RELATIVE TO THE 2017 VOLUME REQUIREMENTS

Soybean Biodiesel Scenario	
Cost Difference Between Soybean Biodiesel and Petroleum Diesel Per Gallon ($/DGE)[116]	$1.36–$1.85
Annual Change in Overall Costs (Million $)[117]	$(45)–$(33)
Brazilian Sugarcane Ethanol Scenario	
Cost Difference Between Sugarcane Ethanol and Gasoline Per Gallon ($/GGE)[118]	$0.87–$2.29
Annual Change in Overall Costs (Million $)	$(61)–$(23)
CNG/LNG Derived from Landfill Biogas Scenario	
Cost Difference Between CNG/LNG Derived from Biogas and Natural Gas ($/EGE)	$(0.06)–$0.05
Annual Change in Overall Costs (Million $)	$(2)–$2
Corn Fiber-Derived Ethanol Scenario	
Cost Difference Between Cellulosic Corn Fiber-Derived Ethanol and Gasoline Per Gallon ($/GGE)	$1.37–$2.62
Annual Change in Overall Costs (Million $)	$(70)–$(36)

Based on this illustrative analysis of four separate hypothetical scenarios, EPA estimates that the costs for changes in the advanced fuel volumes compared to 2017 could range from $(70)–$2 million in 2018. It is important to note that these illustrative costs do not take into consideration the benefits of the program. For the purpose of this annual rulemaking, we have not quantified benefits for the proposed 2018 standards. We do not have a quantified estimate of the GHG or energy security impacts for a single year (*e.g.,* 2018), and there are a number of benefits that are difficult to quantify, such as rural economic development and employment impacts from more diversified fuel sources.

VI. Biomass-Based Diesel Volume for 2019

In this section we discuss the proposed BBD applicable volume for 2019. We are establishing this volume in advance of those for other renewable fuel categories in light of the statutory requirement in CAA section 211(o)(2)(B)(ii) to establish the applicable volume of BBD for years after 2012 no later than 14 months before the applicable volume will apply. We are not at this time establishing the BBD percentage standards that would apply to obligated parties in 2019 but intend to do so in the Fall of 2018, after receiving EIA's estimate of gasoline and diesel consumption for 2019. Although the BBD applicable volume sets a floor for required BBD use, because the BBD volume requirement is nested within both the advanced biofuel and the total renewable fuel volume requirements, any ''excess'' BBD produced beyond the mandated 2019 BBD volume can be used to satisfy both of these other applicable volume requirements. Therefore, these other standards also influence BBD production and use.

A. Statutory Requirements

The statute establishes applicable volume targets for years through 2022 for cellulosic biofuel, advanced biofuel, and total renewable fuel. For BBD, applicable volume targets are specified in the statute only through 2012. For years after those for which volumes are specified in the statute, EPA is required under CAA section 211(o)(2)(B)(ii) to determine the applicable volume of BBD, in coordination with the Secretary of Energy and the Secretary of Agriculture, based on a review of the implementation of the program during calendar years for which the statute

[115] ''Cost Impacts of the Proposed 2018 Annual Renewable Fuel Standards'', Memorandum from Michael Shelby, Dallas Burkholder, and Aaron Sobel to EPA Docket EPA–HQ–OAR–2017–0091.

[116] 40 million gallons on an ethanol gallon equivalent (EGE) basis is approximately 27 million gallons of biodiesel on an energy equivalent basis, assuming 1.5 RINs per gallon of biodiesel for the purposes of this illustrative costs example. Due to the difference in energy content between biodiesel and diesel, one gallon of biodiesel is energy-equivalent to approximately 91% of a gallon of diesel; 27 million gallons of biodiesel (or 40 million ethanol-equivalent gallons) is energy-equivalent to approximately 24 million gallons of diesel.

[117] Overall costs may not match per gallon costs times volumes due to rounding.

[118] Due to the difference in energy content between ethanol and gasoline, one gallon of ethanol is energy-equivalent to approximately 67% of a gallon of gasoline; 40 million gallons of ethanol is energy-equivalent to approximately 27 million gallons on a gasoline gallon equivalent (GGE) basis.

specifies the volumes and an analysis of the following factors:

1. The impact of the production and use of renewable fuels on the environment, including on air quality, climate change, conversion of wetlands, ecosystems, wildlife habitat, water quality, and water supply;
2. The impact of renewable fuels on the energy security of the United States;
3. The expected annual rate of future commercial production of renewable fuels, including advanced biofuels in each category (cellulosic biofuel and BBD);
4. The impact of renewable fuels on the infrastructure of the United States, including deliverability of materials, goods, and products other than renewable fuel, and the sufficiency of infrastructure to deliver and use renewable fuel;
5. The impact of the use of renewable fuels on the cost to consumers of transportation fuel and on the cost to transport goods; and
6. The impact of the use of renewable fuels on other factors, including job creation, the price and supply of agricultural commodities, rural economic development, and food prices.

The statute also specifies that the volume requirement for BBD cannot be less than the applicable volume specified in the statute for calendar year 2012, which is 1.0 billion gallons. The statute does not, however, establish any other numeric criteria, or provide any guidance on how the EPA should weigh the importance of the often competing factors, and the overarching goals of the statute when the EPA sets the applicable volumes of BBD in years after those for which the statute specifies such volumes. In the period 2013–2022, the statute specifies increasing applicable volumes of cellulosic biofuel, advanced biofuel, and total renewable fuel, but provides no guidance, beyond the 1.0 billion gallon minimum, on the level at which BBD volumes should be set. As shown in Table VI.B.1–1 below, we have raised the BBD standard above the statutory minimum each year beginning in 2013.

B. Determination of Applicable Volume of Biomass-Based Diesel

One of the primary considerations in determining the BBD volume for 2019 is a review of the implementation of the program to date, as it affects BBD. This review is required by the CAA, and also provides insight into the capabilities of the industry to produce, import, export, and distribute BBD. It also helps us to understand what factors, beyond the BBD standard, may incentivize the production and import of BBD. The number of BBD RINs generated, along with the number of RINs retired due to export or for reasons other than compliance with the annual BBD standards from 2011–2018 are shown in Table VI.B.1–1 below.

TABLE VI.B.1–1—BIOMASS-BASED (D4) RIN GENERATION AND STANDARDS IN 2011–2018

[million gallons] [119]

	BBD RINs generated	Exported BBD (RINs)	BBD RINs retired, non-compliance reasons	Available BBD RINs [a]	BBD standard (gallons)	BBD standard (RINs)
2011	1,692	72	98	1,522	800	1,200
2012	1,737	102	90	1,545	1,000	1,500
2013	2,739	124	101	2,514	1,280	1,920
2014	2,710	134	92	2,484	1,630	[b] 2,490
2015	2,796	145	32	2,619	1,730	[b] 2,655
2016	4,008	203	52	3,753	1,900	2,850
2017	N/A	N/A	N/A	N/A	2,000	3,000
2018	N/A	N/A	N/A	N/A	2,100	3,150

[a] Available BBD RINs may not be exactly equal to BBD RINs Generated minus Exported RINs and BBD RINs Retired, Non-Compliance Reasons, due to rounding.

[b] Each gallon of biodiesel qualifies for 1.5 RINs due to its higher energy content per gallon than ethanol. Renewable diesel qualifies for between 1.5 and 1.7 RINs per gallon. In 2014 and 2015 the number of RINs in the BBD Standard column is not exactly equal to 1.5 times the BBD volume standard as these standards were established based on actual RIN generation data for 2014 and a combination of actual data and a projection of RIN generation for the last three months of the year for 2015. Some of the volume used to meet the BBD standard was renewable diesel, which generally has an equivalence value of 1.7.

In reviewing historical BBD RIN generation and use, we see that the number of RINs available for compliance purposes exceeded the volume required to meet the BBD standard in 2011, 2012, 2013, and 2016. Additional production and use of biodiesel was likely driven by a number of factors, including demand to satisfy the advanced biofuel and total renewable fuels standards, the biodiesel tax credit,[120] and favorable blending economics. The number of RINs available in 2014 and 2015 was approximately equal to the number required for compliance in those years, as the standards for these years were finalized at the end of November 2015. In 2016, with RFS standards established prior to the beginning of the year and the blenders tax credit in place, BBD RIN generation exceeded the volume required by the BBD standard by more than one billion RINs. This strongly suggests that there is demand for BBD RINs to satisfy the advanced biofuel and/or total renewable fuel requirements beyond the required volume of BBD.[121]

In establishing the BBD and cellulosic standards as nested within the advanced biofuel standard, Congress clearly intended to support development of BBD and cellulosic biofuels, while also providing an incentive for the growth of other non-specified types of advanced biofuels. That is, the advanced biofuel standard provides an opportunity for other advanced biofuels (advanced

[119] Net BBD RINs Generated, Exported BBD RINs, and BBD RINs Retired for Non-Compliance Reasons information from EMTS.

[120] The biodiesel tax credit was reauthorized in January 2013. It applied retroactively for 2012 and for the remainder of 2013. It was once again extended in December 2014 and applied retroactively to all of 2014 as well as to the remaining weeks of 2014. In December 2015 the biodiesel tax credit was authorized and applied retro-actively for all of 2015 as well as through the end of 2016.

[121] For a further discussion of the ability for the advanced biofuel and total renewable fuel volume requirements to provide a demand for BBD beyond the BBD required volume see ''Memorandum to docket: Draft Statutory Factors Assessment for the 2019 Biomass-Based Diesel (BBD) Applicable Volumes'' and the 2017 final rule (81 FR 89795–89798, December 12, 2016).

biofuels that do not qualify as cellulosic biofuel or BBD) to be used to satisfy the advanced biofuel standard after the cellulosic biofuel and BBD standards have been met. Indeed, since Congress specifically directed growth in BBD only through 2012, leaving development of volume targets for BBD to EPA for later years while also specifying substantial growth in the cellulosic biofuel and advanced biofuel categories, we believe that Congress clearly intended for EPA to evaluate the appropriate rate of participation of BBD within the advanced biofuel standard.

The BBD industry is currently the single largest contributor to the advanced biofuel pool, one that to date has been largely responsible for providing the growth in advanced biofuels envisioned by Congress. We continue to believe that preserving space under the advanced biofuel standard for non-BBD advanced biofuels, as well as BBD volumes in excess of the BBD standard, will help to encourage the development and production of a variety of advanced biofuels over the long term without reducing the incentive for additional volumes of BBD beyond the BBD standard in 2019. A variety of different types of advanced biofuels, rather than a single type such as BBD, would positively impact energy security (*e.g.,* by increasing the diversity of feedstock sources used to make biofuels, thereby reducing the impacts associated with a shortfall in a particular type of feedstock) and increase the likelihood of the development of lower cost advanced biofuels that meet the same GHG reduction threshold as BBD.[122]

With the considerations discussed above and in Section IV.B.2 in mind, as well as our analysis of the factors specified in the statute, we are proposing to maintain the applicable volume of BBD at 2.1 billion gallons for 2019. We believe it is appropriate to continue to support the BBD industry through a guaranteed volume requirement, while allowing room within the advanced biofuel volume requirement for the participation of non-BBD advanced fuels. While in recent years we have annually increased this BBD guarantee, we note that there has been a very substantial cumulative increase since 2012, and that the 2018 guarantee is over twice the minimum BBD volume specified in the statute. While we believe it is important to provide continued support to the BBD industry, we do not believe it is necessary to increase the BBD set-aside in 2019 in order to do so. Our assessment of the required statutory factors, summarized in the next section and in a memorandum to the docket (the ''2019 BBD docket memorandum''), supports our proposal.[123] We request comment on the biomass-based diesel volume requirement for 2019.

We believe this approach strikes the appropriate balance between providing a market environment where the development of other advanced biofuels is incentivized, while also maintaining support for the BBD industry. Based on our review of the data, and the nested nature of the BBD standard within the advanced standard, we conclude that the advance standard continues to drive the ultimate volume of BBD supplied. This means that setting a marginally lower or higher BBD standard would not change the volume of BBD used in 2019. Given the success of the industry in the past few years, as well as the substantial increases in the BBD volume requirement since 2012, we are proposing that a higher volume requirement for BBD in 2019 is not necessary to provide support for the industry, and are proposing to maintain the volume requirement at the level specified for 2018. Setting the BBD standard in this manner would continue to allow a considerable portion of the advanced biofuel volume to be satisfied by either additional gallons of BBD or by other unspecified and potentially less costly types of qualifying advanced biofuels. As discussed in Section I.E., EPA also requests comment on decreasing the required volume of BBD for 2019 in an effort to increase the energy independence impacts of the RFS program.

C. Consideration of Statutory Factors Set Forth in CAA Section 211(o)(2)(B)(ii)(I)–(VI) for 2019

As noted earlier in Section IV.B., the BBD volume requirement is nested within the advanced biofuel requirement and the advanced biofuel requirement is, in turn, nested within the total renewable fuel volume requirement. This means that any BBD produced beyond the mandated BBD volume can be used to satisfy both these other applicable volume requirements. The result is that in considering the statutory factors we must consider the potential impacts of increasing BBD in comparison to other advanced biofuels.[124] For a given advanced biofuel standard, greater or lesser BBD volume requirements do not change the amount of advanced biofuel used to displace petroleum fuels; rather, increasing the BBD requirement may result in the displacement of other types of advanced biofuels that could have been used to meet the advanced biofuels volume requirement.

Consistent with our 2018 approach in setting the final BBD volume requirement, EPA's primary assessment of the statutory factors for the proposed 2019 BBD applicable volume is that because the BBD requirement is nested within the advanced biofuel volume requirement, we expect that the 2019 advanced volume requirement, when set next year, will determine the level of BBD production and imports that occur in 2019.[125] Therefore, EPA continues to believe that the same overall volume of BBD would likely be supplied in 2019 regardless of the BBD volume we mandate for 2019 in this proposed rule. This assessment is based, in part, on our review of the RFS program implementation to date, as discussed above in Section VI.B. and in the 2019 BBD docket memorandum. Thus, we do not expect our proposed 2019 BBD volume requirement to result in a difference in the factors we consider pursuant to CAA section 211(o)(2)(B)(ii)(I)–(VI).

As an additional supplementary assessment, we have considered the potential impacts of selecting an applicable volume of BBD other than 2.1 billion gallons in 2019 based on the assumption that in guaranteeing the BBD volume at any given level there could be greater use of BBD and a corresponding decrease in the use of other types of advanced biofuels. However, setting a BBD volume requirement higher or lower than 2.1 billion gallons in 2019 would only be expected to impact BBD volumes on the margin, protecting to a lesser or greater degree BBD from being outcompeted by

[122] All types of advanced biofuel, including BBD, must achieve lifecycle GHG reductions of at least 50%.

[123] ''Memorandum to docket: Draft Statutory Factors Assessment for the 2019 Biomass-Based Diesel (BBD) Applicable Volumes.'' See Docket EPA–HQ–OAR–2017–0091.

[124] While excess BBD production could also displace conventional renewable fuel under the total renewable standard, as long as the BBD applicable volume is significantly lower than the advanced biofuel applicable volume our action in setting the BBD applicable volume is not expected to displace conventional renewable fuel under the total renewable standard, but rather other advanced biofuels.

[125] Even though we are not proposing to set the 2019 advanced biofuel volume requirement as part of this rulemaking, we expect that the 2019 advanced volume requirement will be considerably higher than the 2019 BBD requirement, consistent with past practice and, therefore, that the BBD volume requirement for 2019 would not be expected to impact the volume of BBD that is actually produced and imported during the 2019-time period.

other advanced biofuels. In this supplementary assessment we have considered all of the statutory factors found in CAA section 211(2)(B)(ii), and as described in the 2019 BBD docket memorandum, our assessment does not appear, based on available information, to provide a reasonable basis for setting a higher or lower volume requirement for BBD than 2.1 billion gallons for 2018.

Overall and as described in the 2019 BBD docket memorandum, we have determined that both the primary assessment and the supplemental assessment of the statutory factors specified in CAA section 211(o)(2)(B)(ii)(I)–(VI) for the year 2019 does not provide significant support for setting the BBD standard at a level higher or lower than 2.1 billion gallons in 2019.

VII. Percentage Standards for 2018

The renewable fuel standards are expressed as volume percentages and are used by each obligated party to determine their Renewable Volume Obligations (RVOs). Since there are four separate standards under the RFS program, there are likewise four separate RVOs applicable to each obligated party. Each standard applies to the sum of all non-renewable gasoline and diesel produced or imported. The percentage standards are set so that if every obligated party meets the percentages by acquiring and retiring an appropriate number of RINs, then the amount of renewable fuel, cellulosic biofuel, BBD, and advanced biofuel used will meet the applicable volume requirements on a nationwide basis.

Sections III through V provide our rationale and basis for the proposed volume requirements for 2018.[126] The volumes used to determine the proposed percentage standards are shown in Table VII–1.

TABLE VII–1—VOLUMES FOR USE IN SETTING THE 2018 APPLICABLE PERCENTAGE STANDARDS

[Billion gallons]

Cellulosic biofuel	0.238
Biomass-based diesel [a]	2.10
Advanced biofuel	4.24
Renewable fuel	19.24

[a] Represents physical volume.

For the purposes of converting these volumes into percentage standards, we generally use two decimal places to be consistent with the volume targets as given in the statute, and similarly two decimal places in the percentage standards. However, for cellulosic biofuel we use three decimal places in both the volume requirement and percentage standards to more precisely capture the smaller volume projections and the unique methodology that in some cases results in estimates of only a few million gallons for a single producer.

A. Calculation of Percentage Standards

To calculate the proposed percentage standards, we are following the same methodology for 2018 as we have in all prior years. The formulas used to calculate the percentage standards applicable to producers and importers of gasoline and diesel are provided in § 80.1405. The formulas rely on estimates of the volumes of gasoline and diesel fuel, for both highway and nonroad uses, which are projected to be used in the year in which the standards will apply. The projected gasoline and diesel volumes are provided by EIA, and include projections of ethanol and biodiesel used in transportation fuel. Since the percentage standards apply only to the non-renewable gasoline and diesel produced or imported, the volumes of ethanol and biodiesel are subtracted out of the EIA projections of gasoline and diesel.

Transportation fuels other than gasoline or diesel, such as natural gas, propane, and electricity from fossil fuels, are not currently subject to the standards, and volumes of such fuels are not used in calculating the annual percentage standards. Since under the regulations the standards apply only to producers and importers of gasoline and diesel, these are the transportation fuels used to set the percentage standards, as well as to determine the annual volume obligations of an individual gasoline or diesel producer or importer.

As specified in the March 26, 2010 RFS2 final rule,[127] the percentage standards are based on energy-equivalent gallons of renewable fuel, with the cellulosic biofuel, advanced biofuel, and total renewable fuel standards based on ethanol equivalence and the BBD standard based on biodiesel equivalence. However, all RIN generation is based on ethanol-equivalence. For example, the RFS regulations provide that production or import of a gallon of qualifying biodiesel will lead to the generation of 1.5 RINs. The formula specified in the regulations for calculation of the BBD percentage standard is based on biodiesel-equivalence, and thus assumes that all BBD used to satisfy the BBD standard is biodiesel and requires that the applicable volume requirement be multiplied by 1.5. However, BBD often contains some renewable diesel, and a gallon of renewable diesel typically generates 1.7 RINs.[128] In addition, there is often some renewable diesel in the conventional renewable fuel pool. As a result, the actual number of RINs generated by biodiesel and renewable diesel is used in the context of our assessing reasonably attainable volumes for purposes of deriving the applicable volume requirements and associated percentage standards for advanced biofuel and total renewable fuel, and likewise in obligated parties' determination of compliance with any of the applicable standards. While there is a difference in the treatment of biodiesel + renewable diesel in the context of determining the percentage standard for BBD versus determining the percentage standard for advanced biofuel and total renewable fuel, it is not a significant one given our approach to determining the BBD volume requirement. Our intent in setting the BBD applicable volume is to provide a level of guaranteed volume for BBD, but as described in Section VI.B, we do not expect the BBD standard to be binding. That is, we expect that actual supply of BBD, as well as supply of conventional biodiesel + renewable diesel, will be driven by the advanced biofuel and total renewable fuel standards.

B. Small Refineries and Small Refiners

In CAA section 211(o)(9), enacted as part of the Energy Policy Act of 2005, and amended by the Energy Independence and Security Act of 2007, Congress provided a temporary exemption to small refineries [129] through December 31, 2010. Congress provided that small refineries could receive a temporary extension of the exemption beyond 2010 based either on the results of a required DOE study, or based on an EPA determination of ''disproportionate economic hardship'' on a case-by-case basis in response to small refinery petitions. In reviewing petitions, EPA, in consultation with the Department of Energy, evaluates the impacts petitioning refineries would likely face in achieving compliance with the RFS requirements and how compliance would affect their ability to remain competitive and profitable.

EPA has granted exemptions pursuant to this process in the past. In the Consolidated Appropriations Act of

[126] The 2018 volume requirement for BBD was established in the 2017 final rule.

[127] 75 FR 14670, March 26, 2010.

[128] Although in some cases a gallon of renewable diesel generates either 1.5 or 1.6 RINs.

[129] A small refiner that meets the requirements of 40 CFR 80.1442 may also be eligible for an exemption.

2017, an explanatory statement directed EPA ''to follow DOE's recommendations which are based on the original 2011 Small Refinery Exemption study prepared for Congress and the conference report to division D of the Consolidated Appropriations Act of 2016.'' [130] This directive could impact how EPA evaluates small refinery hardship petitions and the number and magnitude of exemptions granted. As a result, EPA seeks comment on how we should account for exemptions in setting the annual percentage standards for 2018 under CAA section 211(o)(3) and 40 CFR 80.1405.

C. Proposed Standards

The formulas in § 80.1405 for the calculation of the percentage standards require the specification of a total of 14 variables covering factors such as the renewable fuel volume requirements, projected gasoline and diesel demand for all states and territories where the RFS program applies, renewable fuels projected by EIA to be included in the gasoline and diesel demand, and exemptions for small refineries. The values of all the variables used for this proposed rule are shown in Table VII.C–1.[131]

TABLE VII.C–1—VALUES FOR TERMS IN CALCULATION OF THE 2018 STANDARDS [132]

[Billion gallons]

Term	Description	Value
RFV_{CB}	Required volume of cellulosic biofuel	0.238
RFV_{BBD}	Required volume of biomass-based diesel	2.10
RFV_{AB}	Required volume of advanced biofuel	4.24
RFV_{RF}	Required volume of renewable fuel	19.24
G	Projected volume of gasoline	142.90
D	Projected volume of diesel	55.23
RG	Projected volume of renewables in gasoline	14.38
RD	Projected volume of renewables in diesel	2.58
GS	Projected volume of gasoline for opt-in areas	0.00
RGS	Projected volume of renewables in gasoline for opt-in areas	0.00
DS	Projected volume of diesel for opt-in areas	0.00
RDS	Projected volume of renewables in diesel for opt-in areas	0.00
GE	Projected volume of gasoline for exempt small refineries	0.00
DE	Projected volume of diesel for exempt small refineries	0.00

Projected volumes of gasoline and diesel, and the renewable fuels contained within them, were taken from the April, 2017 version of EIA's STEO. For the final rule, we intend to use volume projections provided by EIA as required in the statute at CAA section 211(o)(3)(A), which are typically consistent with those available in the STEO.

Using the volumes shown in Table VII.C–1, we have calculated the percentage standards for 2018 as shown in Table VII.C–2.

TABLE VII.C–2—PROPOSED PERCENTAGE STANDARDS FOR 2018

Cellulosic biofuel	0.131
Biomass-based diesel	1.74
Advanced biofuel	2.34
Renewable fuel	10.62

VIII. Public Participation

We request comment on all aspects of this proposal. This section describes how you can participate in this process.

A. How do I submit comments?

We are opening a formal comment period by publishing this document. We will accept comments during the period indicated under the **DATES** section above. If you have an interest in the proposed standards, we encourage you to comment on any aspect of this rulemaking. We also request comment on specific topics identified throughout this proposal.

Your comments will be most useful if you include appropriate and detailed supporting rationale, data, and analysis. Commenters are especially encouraged to provide specific suggestions for any changes that they believe need to be made. You should send all comments, except those containing proprietary information, to our Docket (see **ADDRESSES** section above) by the end of the comment period.

You may submit comments electronically through the electronic public docket, *www.regulations.gov,* by mail to the address shown in **ADDRESSES**, or through hand delivery/courier. To ensure proper receipt by EPA, identify the appropriate docket identification number in the subject line on the first page of your comment. 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 wish to submit Confidential Business Information (CBI) or information that is otherwise protected by statute, please follow the instructions in Section VIII.B below.

EPA will also hold a public hearing on this proposed rule. We will announce the public hearing date and location for this proposal in a supplemental **Federal Register** document.

B. How should I submit CBI to the agency?

Do not submit information that you consider to be CBI electronically through the electronic public docket, *www.regulations.gov,* or by email. Send or deliver information identified as CBI only to the following address: U.S. Environmental Protection Agency,

[130] Consolidated Appropriations Act, 2017, Public Law 115–31. The Explanatory Statement is available at: *https://rules.house.gov/sites/republicans.rules.house.gov/files/115/OMNI/DIVISION%20G%20-%20INT%20SOM%20FY17%20OCR.pdf,* and reads ''The agreement includes the directive contained in Senate Report 114–281 related to small refinery relief.'' Senate Report 114–281 includes the quoted language above directing EPA to follow DOE's recommendation and is available at: *https://www.congress.gov/114/crpt/srpt281/CRPT-114srpt281.pdf.*

[131] To determine the 49-state values for gasoline and diesel, the amounts of these fuels used in Alaska is subtracted from the totals provided by DOE because petroleum based fuels used in Alaska do not incur RFS obligations. The Alaska fractions are determined from the June 29, 2016 EIA State Energy Data System (SEDS), Energy Consumption Estimates.

[132] See ''Calculation of proposed % standards for 2018'' in docket EPA–HQ–OAR–2017–0091.

Assessment and Standards Division, 2000 Traverwood Drive, Ann Arbor, MI 48105, Attention Docket ID EPA–HQ–OAR–2017–0091. You may claim information that you submit to EPA as CBI by marking any part or all of that information as CBI (if you submit CBI on disk or CD ROM, 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 CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

In addition to one complete version of the comments that include any information claimed as CBI, a copy of the comments that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. This non-CBI version of your comments may be submitted electronically, by mail, or through hand delivery/courier. If you submit the copy that does not contain CBI on disk or CD ROM, mark the outside of the disk or CD ROM clearly that it does not contain CBI. Information not marked as CBI will be included in the public docket without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person identified in the **FOR FURTHER INFORMATION CONTACT** section.

IX. Statutory and Executive Order Reviews

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

This action is an economically significant regulatory action that was submitted to the Office of Management and Budget (OMB) for review. Any changes made in response to OMB recommendations have been documented in the docket. The EPA prepared an analysis of illustrative costs associated with this action. This analysis is presented in Section V.D of this preamble.

B. Paperwork Reduction Act (PRA)

This action does not impose any new information collection burden under the PRA. OMB has previously approved the information collection activities contained in the existing regulations and has assigned OMB control numbers 2060–0637 and 2060–0640. The proposed standards would not impose new or different reporting requirements on regulated parties than already exist for the RFS program.

C. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. In making this determination, the impact of concern is any significant adverse economic impact on small entities. An agency may certify that a rule will not have a significant economic impact on a substantial number of small entities if the rule relieves regulatory burden, has no net burden, or otherwise has a positive economic effect on the small entities subject to the rule.

The small entities directly regulated by the RFS program are small refiners, which are defined at 13 CFR 121.201. We have evaluated the impacts of this proposed rule on small entities from two perspectives: as if the 2018 standards were a standalone action or if they are a part of the overall impacts of the RFS program as a whole.

When evaluating the standards as if they were a standalone action separate and apart from the original rulemaking which established the RFS2 program, then the standards could be viewed as decreasing the advanced and total renewable fuel volumes required of obligated parties by 40 million gallons between 2017 and 2018. To evaluate the impacts of the proposed volumes on small entities relative to 2017, EPA has conducted a screening analysis [133] to assess whether it should make a finding that this action would not have a significant economic impact on a substantial number of small entities. Currently available information shows that the impact on small entities from implementation of this rule would not be significant. EPA has reviewed and assessed the available information, which shows that obligated parties, including small entities, are generally able to recover the cost of acquiring the RINs necessary for compliance with the RFS standards through higher sales prices of the petroleum products they sell than would be expected in the absence of the RFS program.[134] [135] This is true whether they acquire RINs by purchasing renewable fuels with attached RINs or purchase separated RINs. The costs of the RFS program are thus generally being passed on to consumers in the highly competitive marketplace. Even if we were to assume that the cost of acquiring RINs were not recovered by obligated parties, and we used the maximum values of the illustrative costs discussed in Section V.D of this preamble and the gasoline and diesel fuel volume projections and wholesale prices from the April 2017 version of EIA's Short-Term Energy Outlook, and current wholesale fuel prices, a cost-to-sales ratio test shows that the costs to small entities of the RFS standards are far less than 1 percent of the value of their sales.

While the screening analysis described above supports a certification that this rule would not have a significant economic impact on small refiners, we continue to believe that it is more appropriate to consider the standards as a part of ongoing implementation of the overall RFS program. When considered this way, the impacts of the RFS program as a whole on small entities were addressed in the RFS2 final rule (75 FR 14670, March 26, 2010), which was the rule that implemented the entire program required by the Energy Independence and Security Act of 2007 (EISA 2007). As such, the Small Business Regulatory Enforcement Fairness Act (SBREFA) panel process that took place prior to the 2010 rule was also for the entire RFS program and looked at impacts on small refiners through 2022.

For the SBREFA process for the RFS2 final rule, EPA conducted outreach, fact-finding, and analysis of the potential impacts of the program on small refiners, which are all described in the Final Regulatory Flexibility Analysis, located in the rulemaking docket (EPA–HQ–OAR–2005–0161). This analysis looked at impacts to all refiners, including small refiners, through the year 2022 and found that the program would not have a significant economic impact on a substantial number of small entities, and that this impact was expected to decrease over time, even as the standards increased. For gasoline and/or diesel small refiners subject to the standards, the analysis included a cost-to-sales ratio test, a ratio of the estimated annualized compliance costs to the value of sales per company. From this test, it was estimated that all directly regulated small entities would have compliance costs that are less than one percent of their sales over the life

[133] "Draft Screening Analysis for the Proposed Renewable Fuel Standard Program Renewable Volume Obligations for 2018", memorandum from Dallas Burkholder, Nick Parsons, and Tia Sutton to EPA Air Docket EPA–HQ–OAR–2017–0091.

[134] For a further discussion of the ability of obligated parties to recover the cost of RINs see "A Preliminary Assessment of RIN Market Dynamics, RIN Prices, and Their Effects," Dallas Burkholder, Office of Transportation and Air Quality, US EPA. May 14, 2015, EPA Air Docket EPA–HQ–OAR–2015–0111.

[135] Knittel, Christopher R., Ben S. Meiselman, and James H. Stock. "The Pass-Through of RIN Prices to Wholesale and Retail Fuels under the Renewable Fuel Standard." Working Paper 21343. NBER Working Paper Series. Available online *http://www.nber.org/papers/w21343.pdf.*

of the program (75 FR 14862, March 26, 2010).

We have determined that this proposed rule would not impose any additional requirements on small entities beyond those already analyzed, since the impacts of this proposed rule are not greater or fundamentally different than those already considered in the analysis for the RFS2 final rule assuming full implementation of the RFS program. This rule proposes the 2018 advanced and total renewable fuel volume requirements at levels 40 million gallons lower than the 2017 volume requirements, and significantly below the statutory volume targets. This exercise of EPA's waiver authority reduces burdens on small entities, as compared to the burdens that would be imposed under the volumes specified in the Clean Air Act in the absence of waivers—which are the volumes that we assessed in the screening analysis that we prepared for implementation of the full program. Regarding the BBD standard, we are proposing to maintain the volume requirement for 2019 at the same level as 2018. While this volume is an increase over the statutory minimum value of 1 billion gallons, the BBD standard is a nested standard within the advanced biofuel category, which we are significantly reducing from the statutory volume targets. As discussed in Section VI, we are proposing to set the 2019 BBD volume requirement at a level below what is anticipated will be produced and used to satisfy the reduced advanced biofuel requirement. The net result of the standards being proposed in this action is a reduction in burden as compared to implementation of the statutory volume targets, as was assumed in the RFS2 final rule analysis.

While the rule will not have a significant economic impact on a substantial number of small entities, there are compliance flexibilities in the program that can help to reduce impacts on small entities. These flexibilities include being able to comply through RIN trading rather than renewable fuel blending, 20 percent RIN rollover allowance (up to 20 percent of an obligated party's RVO can be met using previous-year RINs), and deficit carry-forward (the ability to carry over a deficit from a given year into the following year, providing that the deficit is satisfied together with the next year's RVO). In the RFS2 final rule, we discussed other potential small entity flexibilities that had been suggested by the SBREFA panel or through comments, but we did not adopt them, in part because we had serious concerns regarding our authority to do so.

Additionally, as we realize that there may be cases in which a small entity may be in a difficult financial situation and the level of assistance afforded by the program flexibilities is insufficient. For such circumstances, the program provides hardship relief provisions for small entities (small refiners), as well as for small refineries.[136] As required by the statute, the RFS regulations include a hardship relief provision (at 40 CFR 80.1441(e)(2)) that allows for a small refinery to petition for an extension of its small refinery exemption at any time based on a showing that compliance with the requirements of the RFS program would result in the refinery experiencing a ''disproportionate economic hardship.'' EPA regulations provide similar relief to small refiners that are not eligible for small refinery relief (see 40 CFR 80.1442(h)). EPA evaluates these petitions on a case-by-case basis and may approve such petitions if it finds that a disproportionate economic hardship exists. In evaluating such petitions, EPA consults with the U.S. Department of Energy, and takes the findings of DOE's 2011 Small Refinery Study and other economic factors into consideration. EPA successfully implemented these provisions by evaluating petitions for exemption from 12 small refineries for the 2016 RFS standards.

Given that this proposed rule would not impose additional requirements on small entities, would decrease burden via a reduction in required volumes as compared to statutory volume targets and as compared to the 2017 volume requirements, would not change the compliance flexibilities currently offered to small entities under the RFS program (including the small refinery hardship provisions we continue to successfully implement), and available information shows that the impact on small entities from implementation of this rule would not be significant viewed either from the perspective of it being a standalone action or a part of the overall RFS program, we have therefore concluded that this action would have no net regulatory burden for directly regulated small entities.

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain an unfunded mandate of $100 million or more as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. This action implements mandates specifically and explicitly set forth in CAA section 211(o) and we believe that this action represents the least costly, most cost-effective approach to achieve the statutory requirements of the rule.

E. Executive Order 13132: Federalism

This 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: Consultation and Coordination With Indian Tribal Governments

This action does not have tribal implications as specified in Executive Order 13175. This proposed rule would be implemented at the Federal level and affects transportation fuel refiners, blenders, marketers, distributors, importers, exporters, and renewable fuel producers and importers. Tribal governments would be affected only to the extent they produce, purchase, and use regulated fuels. 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 action is not subject to Executive Order 13045 because it implements specific standards established by Congress in statutes (CAA section 211(o)) and does not concern an environmental health risk or safety risk.

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

This action is not a ''significant energy action'' because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy. This action proposes to establish the required renewable fuel content of the transportation fuel supply for 2018, consistent with the CAA and waiver authorities provided therein. The RFS program and this rule are designed to achieve positive effects on the nation's transportation fuel supply, by increasing energy independence and lowering lifecycle GHG emissions of transportation fuel.

[136] See CAA section 211(o)(9)(B).

I. National Technology Transfer and Advancement Act (NTTAA)

This rulemaking does not involve technical standards.

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

The EPA believes that this action does not have disproportionately high and adverse human health or environmental effects on minority populations, low-income populations, and/or indigenous peoples, as specified in Executive Order 12898 (59 FR 7629, February 16, 1994). This proposed rule does not affect the level of protection provided to human health or the environment by applicable air quality standards. This action does not relax the control measures on sources regulated by the RFS regulations and therefore would not cause emissions increases from these sources.

X. Statutory Authority

Statutory authority for this action comes from section 211 of the Clean Air Act, 42 U.S.C. 7545. Additional support for the procedural and compliance related aspects of this proposed rule come from sections 114, 208, and 301(a) of the Clean Air Act, 42 U.S.C. 7414, 7542, and 7601(a).

List of Subjects in 40 CFR Part 80

Environmental protection, Administrative practice and procedure, Air pollution control, Diesel fuel, Fuel additives, Gasoline, Imports, Oil imports, Petroleum, Renewable fuel.

Dated: July 5, 2017.

E. Scott Pruitt,

Administrator.

For the reasons set forth in the preamble, EPA proposes to amend 40 CFR part 80 as follows:

PART 80—REGULATION OF FUELS AND FUEL ADDITIVES

■ 1. The authority citation for part 80 continues to read as follows:

Authority: 42 U.S.C. 7414, 7521, 7542, 7545, and 7601(a).

Subpart M—Renewable Fuel Standard

■ 2. Section 80.1405 is amended by adding new paragraph (a)(9) to read as follows:

§ 80.1405 What are the Renewable Fuel Standards?

(a) * * *

(9) *Renewable Fuel Standards for 2018.*

(i) The value of the cellulosic biofuel standard for 2018 shall be 0.131 percent.

(ii) The value of the biomass-based diesel standard for 2018 shall be 1.74 percent.

(iii) The value of the advanced biofuel standard for 2018 shall be 2.34 percent.

(iv) The value of the renewable fuel standard for 2018 shall be 10.62 percent.

* * * * *

[FR Doc. 2017–14632 Filed 7–20–17; 8:45 am]

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FEDERAL REGISTER

Vol. 82 Friday,

No. 139 July 21, 2017

Part IV

The President

Notice of July 20, 2017—Continuation of the National Emergency With Respect to Transnational Criminal Organizations

Federal Register
Vol. 82, No. 139
Friday, July 21, 2017

Presidential Documents

Title 3—

The President

Notice of July 20, 2017

Continuation of the National Emergency With Respect to Transnational Criminal Organizations

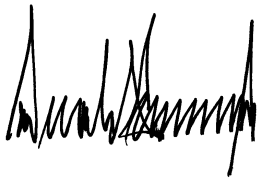
I hereby withdraw the notice ''Continuation of the National Emergency with Respect to Transnational Criminal Organizations,'' submitted on July 19, 2017, and submit in lieu thereof the following:

On July 24, 2011, by Executive Order 13581, the President declared a national emergency with respect to transnational criminal organizations pursuant to the International Emergency Economic Powers Act (50 U.S.C. 1701–1706) to deal with the unusual and extraordinary threat to the national security, foreign policy, and economy of the United States constituted by the activities of the significant transnational criminal organizations.

The activities of significant transnational criminal organizations have reached such scope and gravity that they threaten the stability of international political and economic systems. Such organizations are increasingly sophisticated and dangerous to the United States; they are increasingly entrenched in the operations of foreign governments and the international financial system, thereby weakening democratic institutions, degrading the rule of law, and undermining economic markets. These organizations facilitate and aggravate violent civil conflicts and increasingly facilitate the activities of other dangerous persons.

The activities of significant transnational criminal organizations continue to pose an unusual and extraordinary threat to the national security, foreign policy, and economy of the United States. For this reason, the national emergency declared in Executive Order 13581 of July 24, 2011, and the measures adopted on that date to deal with that emergency, must continue in effect beyond July 24, 2017. Therefore, in accordance with section 202(d) of the National Emergencies Act (50 U.S.C. 1622(d)), I am continuing for 1 year the national emergency with respect to transnational criminal organizations declared in Executive Order 13581.

This notice shall be published in the *Federal Register* and transmitted to the Congress.



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July 20, 2017.

[FR Doc. 2017–15592
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